

Autonomy, the Law, and Ante-Mortem Interventions to Facilitate Organ Donation

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Abstract

Over the last few years, policies have been introduced in the UK which aim to improve organ transplantation rates by changing the way that potential organ donors are treated before death. Patients incapacitated due to catastrophic brain injury may now undergo ante-mortem donor optimisation procedures to facilitate deceased organ donation. As I identify in this thesis, the most significant ethical and legal problem with these policies is that they are not based on what the patient would have chosen for themselves in the specific circumstances. The policies identify and treat patients meeting certain clinical criteria as a group rather than the individuals, with their own viewpoints, that the law on best interests requires. They equate registration on the Organ Donation Register with ante-mortem donor optimisation procedures being in their best interests, despite registrants having neither been informed about nor given consent to ante-mortem interventions.

The overarching claim I make in this thesis is that a system of specific advance consent is needed to provide a clear and unequivocal legal justification for ante-mortem donor optimisation procedures. The ethical foundation for this claim is autonomy, and this is the central theme running through all six chapters. I argue that autonomy should be incorporated into donor optimisation policy to promote the dignity and integrity of potential organ donors and to safeguard trust in the organ donation programme. I argue that a system of specific advance consent is needed as part of the duty of care owed to registrants on the Organ Donor Register and to facilitate the determination of the best interests of the potential organ donor. I argue that the state has not established the necessity of the current policy of non-consensual donor optimisation procedures and that they are under an ethical and legal obligation to introduce an autonomy-based framework for ante-mortem interventions to facilitate organ donation.

Declaration

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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Dedication

I dedicate this thesis to my mother Valerie Leonard, who instilled in me an appreciation of the value of education and a determination to work hard to achieve my goals.

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Parts of this thesis, particularly Chapter 4, have been published in S-J. Brown, 'The Legal Justification for Donor Optimisation Procedures' (2016) 11(4) *Clinical Ethics* 122-129.

Preface

My background is in hospital medicine and not in law. However, over the last few years I have established a specialist interest in healthcare ethics and law through study, independent research, and teaching law undergraduates. After ten years working as a hospital doctor in dermatology and the acute medical specialties, I developed my interest in healthcare ethics and law by completing a Masters in Law at the University of Liverpool. To pursue this interest further, I then joined the PhD programme in law at the Centre for Social Ethics and Policy at the University of Manchester.

I aim in this thesis to use an interdisciplinary approach, encompassing medicine, ethics, and law, to address my concerns relating to the legal justification for ante-mortem donor optimisation procedures.

1. The Legal and Policy Framework for Donor Optimisation Procedures

Introduction

Organ transplantation is one of the great success stories of modern medicine and demand is high. It is the primary treatment for patients with end-stage organ failure, and often the only means of preventing their deaths, yet transplantable organs are in short supply both nationally and globally.¹ In the United Kingdom (UK), this gap between demand and supply resulted in 457 patients dying in 2016-2017 whilst on the active waiting list for a transplant, with a further 875 patients being removed from the transplant list, mostly due to deteriorating health, many of whom would have died shortly afterwards.² These preventable deaths have provided the impetus for a “paradigm shift” in the end-of-life care received by potential organ donors³ - a shift that presents significant ethical and legal challenges surrounding the autonomy interests and rights of the potential donor.

The mainstay of the law on medical interventions in general, and on deceased organ donation in particular, is widely upheld at a national, regional and international level to be the principle of patient autonomy or self-determination. This principle is promulgated by the torts of negligence and trespass to the person,⁴ by the statutes that regulate the treatment of the

¹ The International Registry in Organ Donation and Transplantation (IRODaT) maintains a database of donation and transplantation figures, see <http://www.irodat.org/?p=database>. As of 11/09/17, the most recent figures are given in IRODaT, ‘Preliminary Numbers 2016’ (IRODaT, August 2017), available at http://www.irodat.org/img/database/pdf/NEWSLETTER2017_firstedition.pdf. International figures for preventable deaths are less easily obtainable.

² NHS Blood and Transplant, *Organ Donation and Transplantation Activity Report 2016/2017*, available at <https://www.organdonation.nhs.uk/supporting-my-decision/statistics-about-organ-donation/transplant-activity-report/>, p.2 (last accessed 11/09/17) [‘Activity Report’].

³ D. Price, ‘End-of-life Treatment of Potential Organ Donors: Paradigm Shifts in Intensive and Emergency Care’ (2011) 19 *Med Law Rev* 86 [‘Paradigm Shifts’]

⁴ These torts are evaluated in Chapter 3.

dead and the dying,⁵ by the “opt-in” system for organ donation that exists throughout most of the UK, and allegedly even by the “opt-out” system that has recently been introduced in Wales.⁶ It is championed by the judgements of the European Court of Human Rights,⁷ and law- and policy-makers in the UK are required under the Human Rights Act 1998 to take its pronouncements into account.⁸ It is emphasised in the World Medical Association’s Statement on Human Tissue for Transplantation and in the World Health Organisation Guiding Principles on Human Cell, Tissue and Organ Transplantation.⁹ However, the status of autonomy as the ethical and legal foundation for organ donation is threatened by new policies that aim to improve organ transplantation rates by changing the way that potential donors are treated at the end of life,¹⁰ but that are not accompanied by any changes to the information and consent procedures available to potential registrants on the National Health Service (NHS) Organ Donor Register (ODR).¹¹

⁵ The provisions of the Human Tissue Act 2004 and the Mental Capacity Act 2005 will be discussed later in this chapter.

⁶ See eg. H. Welbourn, ‘A Principlist Approach to Presumed Consent for Organ Donation’ (2014) 9(1) *Clin Ethics* 10-16; also M.B. Gill, ‘Presumed Consent, Autonomy and Organ Donation’ (2004) 29 *J Med Philos* 37-59.

⁷ Eg. *Tysiac v Poland* (App no. 5410/03) (2007) 45 EHRR 947; *Pretty v UK* (App no. 2346/02) (2002) 35 EHRR 1.

⁸ S. 2, 3 & 6.

⁹ *World Medical Association Statement on Human Tissue for Transplantation*, Adopted by the WMA Assembly, Copenhagen, Denmark, October 2007, [3]; *WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation*, as endorsed by the 63rd World Health Assembly in May 2010, in Resolution WHA63.22 available at http://www.who.int/transplantation/Guiding_PrinciplesTransplantation_WHA63.22en.pdf (last accessed 11/09/17).

¹⁰ National Institute for Health and Care Excellence (NICE), *Organ Donation for Transplantation: Improving Donor Identification and Consent Rates for Deceased Organ Donation* (Clinical Guidance 135, 2011, updated 2016) [‘*Improving Donor Identification*’]; Organ Donation Taskforce (ODT), *Organs for Transplants: A Report from the Organ Donation Taskforce* (2008) [‘*Organs for Transplants*’]; Department of Health (DOH), *Legal Issues Relevant to Non-heartbeating Organ Donation* (2009) [‘*Legal Issues*’]; UK Donation Ethics Committee (UKDEC), *An Ethical Framework for Controlled Donation after Circulatory Death* (2011) [‘*Ethical Framework*’]; see also BMA Medical Ethics Committee, *Building on Progress: Where Next for Organ Donation Policy in the UK?* (2012) [‘*Building on Progress*’].

¹¹ I highlight this problem in S-J. Brown, ‘The Legal Justification for Donor Optimisation Procedures’ (2016) 11(4) *Clin Ethics* 122-129, [‘*Legal Justification*’]: this article is based on my doctoral research and some of the discussion contained within it is repeated in this and later chapters (particularly chapter 4) of this thesis.

This chapter lays the groundwork for this thesis by providing a thorough examination of the current legal and policy framework for ante-mortem interventions to facilitate organ donation, which I also refer to as donor optimisation procedures. I use both of these terms interchangeably to cover any changes to end-of-life care that are solely aimed at increasing the chances of successful organ donation. These changes to end-of-life care are not well-detailed in current donor optimisation policy, which does not seek to limit the interventions that could be used to facilitate organ donation.¹² However, academics and clinicians alike have interpreted current donor optimisation policy as encompassing intensive interventions including non-therapeutic ventilation.¹³ The overarching questions I seek to answer in this chapter are, first, whether a clear and unequivocal legal justification exists for non-therapeutic ventilation and other ante-mortem donor optimisation procedures within the current framework, and second, what the challenges are in terms of patient autonomy.

I begin the chapter with an evaluation of how the organ donation system is set up across the UK, and the limitations this set-up places on autonomous decision-making. I then review the law with a view to determining whether a clear legal justification exists for ante-mortem interventions to facilitate organ donation. First, I evaluate the Human Tissue Act 2004, the Human Transplantation (Wales) Act 2013, and the Human Tissue (Scotland) Act 2006, with an emphasis on their potential role in providing a legal justification for ante-mortem donor optimisation procedures. Having excluded this as a possibility, I consider the role of common law principles and the Mental Capacity Act 2005, or the Adults with Incapacity (Scotland) Act 2000, in providing a clear legal justification for these procedures. I begin to

¹² See particularly NICE, *Improving Donor Identification* as above, p.7 [1.1.6-1.1.7]. N.B. this guidance was originally published in 2011 by the National Institute for Health and Clinical Excellence (as NICE were then known). It was updated in 2016, but the recommendations remain unchanged. The page and paragraph citations provided in this thesis refer to the 2016 updated version, unless otherwise stated.

¹³ P. Watkinson, S. McKechnie, D. Wilkinson *et al.* 'Actively Delaying Death to Increase Organ Donation' (2012) 344(7846) *BMJ* 1179-1180 ['Actively Delaying Death']; J. Coggon, 'Elective Ventilation for Organ Donation: Law, Policy and Public Ethics' (2013) 39 *J Med Ethics* 130-134, ['Elective Ventilation'].

elucidate the relationship between the patient's wishes and their individual best interests, as well as the challenges the current system places on determining those best interests. Having explicated the mental capacity legislation that applies before death and the human tissue legislation that applies after death, I then evaluate the law on death itself.

In the second half of the chapter, I focus on evaluating recent policies that advocate ante-mortem donor optimisation procedures and the problems in encompassing these policies within the current law. I evaluate the challenges to patient autonomy that are generated by policies that identify and refer the potential organ donor on the basis of clinical criteria only. I examine the difficulties presented by policies that require the assessment of best interests before the assessment of the patient's wishes. I conclude my evaluation of donor optimisation policies with a section in which I attempt to read between the lines of the policies and identify what specific interventions might be included within these policies.

The domestic legal and policy framework examined within this chapter exists within the regional and international human rights framework. The key human rights challenges presented by donor optimisation policies revolve around patient autonomy. I briefly introduce these challenges within the penultimate section of this chapter, and will return to them further in Chapter 5 of this thesis. I conclude this first chapter by identifying patient autonomy as the significant ethical and legal challenge presented by donor optimisation procedures, and by setting out how I aim to address this challenge throughout the remaining chapters of this thesis.

The Organ Donation System in the UK

The responsibility for “facilitating, providing and securing the provision of services to assist tissue and organ transplantation”¹⁴ across the UK lies with NHS Blood and Transplant (NHSBT), a Special Health Authority in England and Wales which works in partnership with all 4 UK health departments to coordinate organ donation and transplantation across the UK.¹⁵ NHSBT’s responsibilities extend to both the promotion of organ donation, including via its management of the UK-wide Organ Donor Register (ODR), and to increasing organ retrieval and transplantation.¹⁶ To reach its strategic objective of “match[ing] world class performance in organ donation and transplantation”, it seeks to “promote a shift in behaviour and increase consent” for organ donation.¹⁷ This refers not only to registration on the ODR but also to the consent/authorisation of the family to deceased organ donation.¹⁸

NHSBT’s strategy for increasing consent to organ donation includes making sure it is “easy to pledge support for organ donation”.¹⁹ There are now several means of registering a pledge or willingness to donate organs after death, which together fulfil the aim of making pledging easy but do not facilitate understanding of the organ donation process or of how that pledge may be interpreted in the future. Over half of all registrations (58%) are now done either by ticking a box on a driving licence application form or via a reminder from the Driver

¹⁴ The NHS Blood and Transplant (Establishment and Constitution) Order 2005 S. 3 (1)(c).

¹⁵ NHS Blood and Transplant, ‘Taking Organ Transplantation to 2020: A Detailed Strategy’ (2013) p.5-8 available at <http://www.nhsbt.nhs.uk/to2020/the-strategy/> (last accessed 11/09/17) [‘Detailed Strategy’]; The Scottish Government, ‘A Donation and Transplantation Plan For Scotland 2013-2020’ (2013) [1.11], available at <http://www.gov.scot/Resource/0042/00427357.pdf> (last accessed 11/09/17).

¹⁶ NHS Blood and Transplant, ‘Saving and Improving Lives: Strategic Plan 2016-2021’ (2016) available at https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/1499/strategic_plan_2016_21.pdf (last accessed 15/01/18) p.11-12, [‘Strategic Plan’].

¹⁷ NHSBT, ‘Strategic Plan’ as above p.11.

¹⁸ The requirements of the Human Tissue Act (2004) for “appropriate consent” and the Human Tissue (Scotland) Act 2006 for “authorisation” will be discussed later in this chapter.

¹⁹ NHSBT, ‘Strategic Plan’ as above, p.11.

and Vehicle Licensing Agency (DVLA).²⁰ The next two most common routes are by directly registering on the ODR website (30%) or when registering as a patient with a general practitioner (9%).²¹ The majority of pledges, including those made via the DVLA or when applying for a Boots store card (2%),²² are made whilst the registrant is filling out a form for another purpose. They are certainly quick and easy, requiring the least possible effort on the part of the registrant. However, the downside is that the individual making the pledge may not necessarily have the information and understanding needed for their pledge to constitute informed consent.²³

Individuals registering on the ODR website are assured that registration will take them no more than 2 minutes.²⁴ Registration is not limited to competent adults, and may include young children²⁵ and even mentally incapacitated adults. Only limited information is provided about deceased organ donation itself and none about ante-mortem interventions to facilitate organ donation.²⁶ Specifically, there is no mention of donor optimisation procedures, their timing, their nature, or their risks. No information is provided that suggests that the registrant is agreeing to anything other than the donation of their organs after death. However, their registration is interpreted by NHSBT not only as constituting “express consent” for deceased organ donation but as authorising or even requiring changes to their end-of-life care to facilitate organ donation.²⁷ Their quick and easy registration may result in them receiving

²⁰ Statistics from NHSBT, *Activity Report* as earlier, p.118-119. See also Department of Health, *Driving up Organ Donations* (News Story, 01/08/11) available at <https://www.gov.uk/government/news/driving-up-organ-donations> (last accessed 11/09/17).

²¹ NHSBT, *Activity Report* as above, p.118-119. NB. These figures do not include a “back-log” of gp registrations (see footnote to figure 12.3, p.119).

²² *Ibid*, p.118-119.

²³ The extent to which these pledges meet the legal standards of informed consent is considered in Chapter 3.

²⁴ <https://www.organdonation.nhs.uk/register-to-donate/register-your-details/> (last accessed 11/09/17).

²⁵ See NHSBT, *Activity Report* as earlier, p.120-121 for demographics.

²⁶ See <https://www.organdonation.nhs.uk/about-donation/> (last accessed 11/09/17).

²⁷ NHS Blood and Transplant, ‘Taking Organ Transplantation to 2020: A UK Strategy’ (2013) p.7. available at <http://www.nhsbt.nhs.uk/to2020/the-strategy/> (last accessed 15/01/18).

intensive instead of palliative end-of-life care, even though they had neither been informed of nor understood this consequence at the time of registration.

Although the ODR is UK-wide, the “opt-in” or “express consent” system only now exists in England, Scotland²⁸ and Northern Ireland. As of December 2015, the Human Transplantation (Wales) Act 2013 came into effect moving Wales to a “soft opt-out” or “deemed consent” system. Under this system, Welsh residents who die in Wales and have not registered a decision to opt out of organ donation will be deemed to have given consent for organ donation, unless a relative is able to provide evidence to the contrary.²⁹ To accommodate Welsh residents who wanted to retain the option to register a wish to become an organ donor, the Welsh arm of the ODR provides registrants with a choice between opting in and opting out.³⁰ Since the introduction of the Welsh legislation, individuals registering on the UK-wide, Scottish, and Northern Irish ODR websites are now also afforded the option to register a refusal to donate.³¹ All 4 arms of the ODR restrict the choice to deceased organ donation itself, with none extending to ante-mortem donor optimisation procedures.

NHSBT’s target is for an overall consent/authorisation rate for deceased organ donation of in excess of 80%,³² a significant increase from the actual rate in 2015/2016 of 62%.³³ However, this does not refer to registration on the ODR but to the relative’s consent to

²⁸ N.B. The Scottish Government announced in June 2017 that they will be introducing legislation moving them to a soft opt-out system. See ‘Increasing Organ and Tissue Donation’ (News release, 28/06/17) <https://news.gov.scot/news/increasing-organ-and-tissue-donation> (accessed 27/09/17) [‘Increasing Organ Donation’]. This followed a public consultation, the responses of which are analysed in *Organ Donation and Transplantation: Analysis of Responses* (Scottish Government, June 2017) [‘Analysis of Responses’]. It also followed the earlier failure of the Transplantation (Authorisation of Removal of Organs etc.)(Scotland) Bill.

²⁹ Human Transplantation (Wales) Act S. 4(4)

³⁰ See <http://organdonationwales.org/FAQs/Organ-donation-from-december-2015/?lang=en> (last accessed 11/09/17).

³¹ See <https://www.organdonation.nhs.uk/register-to-donate/refuse-to-donate/>; <https://www.organdonationscotland.org/more-information-your-choices-explained>; <https://organdonationni.info/optout/online> (all accessed 11/09/17).

³² NHSBT, ‘Strategic Plan’ as earlier, p.12.

³³ Ibid, p.14.

deceased organ donation. NHSBT view registration on the ODR as a “barometer of society’s support for donation”³⁴ rather than as an essential element of consent to organ donation. Only 36% of the UK population is registered on the opt-in ODR, and only 44% of deceased organ “donors” are registered as opting in to organ donation.³⁵ Registration is viewed as a way of “help[ing]...families”³⁶ to consent to deceased organ donation, and in most cases there is no consent from the individual identified as a potential organ donor. This might not necessarily be a problem if consent to deceased organ donation only means the removal of organs after death. However, if the relatives’ consent is also interpreted as extending to that part of the organ donation process that begins before death, then treating registration on the ODR as non-essential creates significant problems. The patient identified as a potential organ donor may now be subject to non-consensual interventions at the end-of-life to facilitate an objective they never had.

The National Clinical Lead on Organ Donation recognised 5 years ago that registration on the ODR “falls well short of the standard of informed consent” and that there are particular concerns when registration is used to justify ante-mortem interventions to facilitate organ donation.³⁷ The NHSBT’s reluctance to address this problem and introduce informed consent procedures for the organ donation process,³⁸ when viewed as part of a legal and policy framework that is mostly concerned with the relatives’ consent rather than the potential organ donor’s,³⁹ leaves the autonomy of the potential organ donor out of current organ procurement policies. There is no opportunity to give advance consent or refusal to donor optimisation procedures and it is not deemed necessary anyway. This exclusion of the

³⁴ NHSBT, ‘Detailed Strategy’ as earlier, p.15.

³⁵ NHSBT, *Activity Report* as earlier, p.114 & table 12.1, p. 116.

³⁶ NHSBT, ‘Detailed Strategy’ as earlier, p.15.

³⁷ P. Murphy, ‘Optimizing Donor Potential in the UK’ (2011) 6 *Clin Ethics* 127-133 [‘Optimizing Donor Potential’] 128.

³⁸ *Ibid*, 128; see also UKDEC, ‘Ethical Framework’, as earlier, p.55 [3.1.1].

³⁹ Including the Human Tissue Act 2004, as discussed in the next section.

autonomy of the individual who is to be subject to these interventions is not only concerning in terms of the ethics of such non-consensual treatment.⁴⁰ It also presents significant challenges to determining what, if any, the legal justification for ante-mortem donor optimisation procedures might be within the current legal framework.

Human Tissue Legislation

The Human Tissue Authority, the statutory body in England, Wales and Northern Ireland whose role is to “promote and safeguard the interests of the public”⁴¹ in activities surrounding human tissues and organs, emphasises the role of “proper consent” and “public confidence” in activities including organ transplantation.⁴² The role of consent in safeguarding the interests of the public and in maintaining public trust and confidence was established following the public furore regarding the practice of organ retention.⁴³ It was the non-consensual nature of the practice which generated such widespread distrust in the system and which laid the foundation for consent’s central role in the regulation of other activities involving human tissues and organs.⁴⁴ However, the regulation of these activities by the Human Tissue Authority does not extend to ante-mortem interventions to facilitate organ donation.

⁴⁰ Autonomy as an ethical concept will be evaluated in Chapter 2.

⁴¹ Human Tissue Authority, ‘Regulating for the Public Good: Human Tissue Authority Annual Review 2013/14’ (2014) https://www.hta.gov.uk/sites/default/files/Annual_Review_2013-14_Low_Res_-_Final.pdf p. 3 (last accessed 11/09/17).

⁴² Ibid, 3.

⁴³ The Bristol Royal Infirmary Inquiry, *Learning from Bristol: The Report of the Public Inquiry into Children’s Heart Surgery at the Bristol Royal Infirmary (1984-1995)* Cm 5207(1)(2001); The Stationery Office, *The Royal Liverpool Children’s Inquiry Report* (2001) HC 12-11; DoH, *Report of a Census of Organs and Tissue Retained by Pathology Services in England* (2001).

⁴⁴ M.Brazier & E.Cave, *Medicine, Patients and the Law* (6th edition, Manchester University Press, 2016) 517 & 546-548; M.Brazier & S.Fovargue, ‘A Brief Guide to the Human Tissue Act 2004’ (2006) 1(1) *Clin Ethics* 26; M.Brazier, ‘Organ Retention and Return: Problems of Consent’ (2003) 29 *J Med Ethics* 30-33.

The Human Tissue Act (2004) (HTA) was drafted primarily as a response to concerns surrounding consent.⁴⁵ The Act relies on the principle of “appropriate consent” to authorise the removal, storage and use of human tissues and organs.⁴⁶ Appropriate consent is defined only in terms of who may give the consent.⁴⁷ This may be the deceased, if a decision of theirs was “in force immediately before he died”,⁴⁸ although in practice relatives are usually permitted to override the consent of the deceased or soon-to-be deceased.⁴⁹ If the deceased patient has not given appropriate consent, it may be given by a person with parental responsibility;⁵⁰ a nominated representative;⁵¹ or a person in a qualifying relationship.⁵² The emphasis on the relatives’ consent was intended to “prevent a recurrence of the distress”⁵³ triggered by the practice of non-consensual organ retention.

Although the Act does not define appropriate consent in terms of information or understanding, the Code of Practice clarifies that for consent to be valid the person giving it must be appropriately informed and understand the nature of the activity and any reasonable alternatives, as well as any material risks.⁵⁴ Those seeking consent are advised that it is essential to tailor information to each specific situation, in line with the judgement in *Montgomery v Lanarkshire Health Board*.⁵⁵ However, the specific activities authorised by the Act do not include ante-mortem donor optimisation procedures. Neither can the notion of generic consent be relied upon to encompass ante-mortem interventions within the Act’s

⁴⁵ See eg. *Brazier & Cave* as above, 517.

⁴⁶ See particularly Sections 1-3.

⁴⁷ HTA Code of Practice A: Guiding Principles and the Fundamental Principle of Consent (Human Tissue Authority, April 2017) p.7[18] & p.9[30].

⁴⁸ S.2(7)(a) & S.3(6)(a).

⁴⁹ See eg. W.Hulme, J. Allen, A. Manara *et al*, ‘Factors Influencing the Family Consent Rate for Organ Donation in the UK’ (2016) 71 *Anaesthesia* 1053-1063, particularly p.1056, table 3.

⁵⁰ Applies to children only, S.2 (7)(b)(i).

⁵¹ S.3(6)(b)(ii); S.4.

⁵² S.2(7)(b)(ii); S.3(6)(c); S.54(9).

⁵³ House of Commons Research Paper 04/04: The Human Tissue Bill, Bill 9 of 2003- 04, p.4.

⁵⁴ HTA Code of Practice A as earlier, p11 [40]; the test for materiality under the common law on informed consent will be discussed in Chapter 3.

⁵⁵ [2015] UKSC 11. This will be evaluated in detail in Chapter 3; HTA Code of Practice as above, p.21[96].

provisions on the removal, storage, and use of organs after death.⁵⁶ Although the Code refers to the notion of generic consent, it only references it in relation to research activities.⁵⁷ This, together with the recognition that consent must be tailored to the specific circumstances, implies that generic consent is not a notion that the Human Tissue Authority envisage being extended to ante-mortem donor optimisation procedures. The Act's provisions that are of relevance to deceased organ donation are only concerned with interventions after death⁵⁸ and there are no specific consent provisions for ante-mortem donor optimisation procedures contained within the Act.

During the process of drafting the HTA, a clause was proposed authorising the ante-mortem ventilation of dying comatose patients for the sole purpose of protecting their organs for transplantation.⁵⁹ The proposed clause would have provided legal authority for a healthcare professional who "reasonably believe[d]"⁶⁰ that consent for post-mortem removal of organs would be forthcoming to administer this so-called elective ventilation before any consent had actually been given.⁶¹ The clause was rejected on the grounds that the practice was "ethically unacceptable and unlawful" as well as unnecessary.⁶² However, the ethical problem with the clause was not deemed to be due to the lack of consent but due to the risks of prolonging the dying process and of inducing a permanent vegetative state.⁶³ The legal problem appears to have been that these outcomes would be against the best interests of the potential organ donor⁶⁴ and hence in conflict with the central principle governing the treatment of the incapacitated. The "unnecessary" argument was based on promising results

⁵⁶ Notions of specific and generic consent are considered in more detail in Chapter 3.

⁵⁷ HTA Code of Practice A as above, p.9[41-42].

⁵⁸ See particularly S.43, as discussed later in this section.

⁵⁹ Clause 5, S.6 as detailed in Human Tissue Bill Third Reading HC Deb (28th June 2004) vol. 423 col. 43.

⁶⁰ Clause 5 as above, S.1(b)

⁶¹ Clause 5 as above, S.1(b) & 2.

⁶² Human Tissue Bill third Reading HC Deb (28th June 2004) vol. 423 col. 88 (Ms Winterton).

⁶³ Ibid (Ms Winterton).

⁶⁴ Ibid (Ms Winterton).

from “non-heart beating” donors.⁶⁵ However, this group of donors may now be subject to other ante-mortem procedures to facilitate organ donation, such as femoral cannulation, inotropic support to maintain blood pressure, and measures to optimise oxygenation.⁶⁶ All of these procedures, and others, have been left with no statutory foundation in the Act.

The comprehensive dismissal of the elective ventilation clause, and the lack of any other provisions authorising ante-mortem interventions to facilitate organ donation, has excluded ante-mortem donor optimisation procedures from the Act’s provisions. A similarly-worded clause was accepted in the final draft, but it only applies to “the body of a deceased person”.⁶⁷ Section 43 of the Act provides authority for non-consensual steps to be taken to preserve body parts from a deceased person for transplantation,⁶⁸ until or unless it is established that consent has not and will not be given.⁶⁹ The ethical problem of moving away from consent remains, but it is clear from the wording that this move away from consent does not encompass interventions performed on live patients. This was the intention of the parliamentary committee charged with drafting the HTA, who asserted that section 43 “will not involve elective ventilation, which is and will remain unlawful”.⁷⁰ Their determination to restrict the HTA provisions on preservation activities to post-mortem interventions has resulted in the Act providing no authority for either consensual or non-consensual ante-mortem donor optimisation procedures.

⁶⁵ Ibid (Ms Winterton). N.B. “Non-heart beating” donation is usually now referred to as Donation after Circulatory (or Cardiac) Death (DCD). Deceased organ donation is usually classified as either DCD or Donation after Brain Death (DBD).

⁶⁶ See DoH, *Legal Issues* as earlier, p.9-10; UKDEC, *Ethical Framework* as earlier, p.19 & 43; S. Patel, J. Martin, P. Marino, ‘Donation after Circulatory Death: A National Survey of Current Practice in England 2012’, (2014) 42 *Crit Care Med* 2219- 2224, [‘Survey of Current Practice’].

⁶⁷ S.43(6); see also C. Sangster, ‘Cooling Corpses: Section 43 of the Human Tissue Act 2004 and Organ Donation’ (2007) 2 *Clin Ethics* 23–27; C. Sangster, ‘A Legal Assessment of the Impact of the Human Tissue Act 2004 upon Unplanned Non-Heart Beating Donation and Elective Ventilation’ (PhD thesis, University of Liverpool 2007) 256-7.

⁶⁸ S.43(1)(a) & S.43(6).

⁶⁹ S.43(3).

⁷⁰ Standing Committee G, Human Tissue Bill col 238 (5th February 2004) per Ms Winterton.

The Human Transplantation (Wales) Act 2013 (HTW) amends the HTA so that the provisions on appropriate consent in relation to transplantation activities no longer apply in Wales.⁷¹ The HTW authorises deceased organ donation on the basis of “deemed consent”,⁷² with express consent only being required in limited circumstances.⁷³ Deemed consent is not defined in relation to any consent actually being given, but in relation to the circumstances in which it applies. Unless the deceased was a child,⁷⁴ an incapacitated adult,⁷⁵ or not ordinarily resident in Wales,⁷⁶ these circumstances are those in which there is no record of the deceased having made a decision on organ donation,⁷⁷ they have not appointed a representative to deal with the issue of consent,⁷⁸ and no evidence has been provided by a relative or friend establishing that the deceased did not want to be an organ donor.⁷⁹ The notion of deemed consent is extended by Section 13 of the Act to post-mortem steps to preserve body parts for transplantation,⁸⁰ but no provision of the Act extends the notion of deemed consent to ante-mortem donor optimisation procedures.

There is separate legislation in Scotland, the Human Tissue (Scotland) Act 2006 (HTS), providing legal authority for transplantation activities.⁸¹ The HTS is drafted around the central tenet of “authorisation”,⁸² a principle which both the Scottish Health department and the

⁷¹ HTW S.16(2) amends HTA S.1.

⁷² S.3 & 4-9

⁷³ S.3 & 4-7.

⁷⁴ S.4(1) & 6.

⁷⁵ S.4(1) & S.5(3)(b).

⁷⁶ S.4(1) & S.3(3)(a)

⁷⁷ S.2(3); HTA Code of Practice 10 (2014) on the Human Transplantation (Wales) Act (2013)p.9 [11].

⁷⁸ S.8.

⁷⁹ S.4(4); HTA Code of Practice 10 (2014) on the Human Transplantation (Wales) Act (2013)p.9 [11].

⁸⁰ S.13(3).

⁸¹ Note also the recent announcement of the Scottish Government that they intend to introduce presumed consent legislation. See Scottish Government, ‘Increasing Organ Donation’ and *Analysis of Responses* as earlier.

⁸² S.6-10.

Human Tissue Authority consider equivalent to the notion of appropriate consent.⁸³

Authorisation, like appropriate consent, relates not to ante-mortem procedures but to “the removal and use of a part of the... body afterdeath”,⁸⁴ for purposes including transplantation.⁸⁵ Section 13 of the HTS, in common with section 43 of the HTA, only provides a legal defence for steps to preserve the body or body parts for transplantation where that body is a “deceased person”.⁸⁶ Although the legislation in Scotland is separate and distinct from the HTA as it applies in England and Northern Ireland, and the amended HTA applied in conjunction with the HTW in Wales, the exclusion of ante-mortem donor optimisation procedures from transplantation legislation is uniform across the UK.

Legal Framework Governing Ante-Mortem Donor Optimisation Procedures

The legislation governing transplantation across the UK does not extend to ante-mortem interventions to facilitate organ donation. No specific statutory justification has been introduced to provide a clear legal defence for ante-mortem donor optimisation procedures. The regulation of such procedures, which are being implemented under new organ procurement policies,⁸⁷ has been left to common law principles and the Mental Capacity legislation. The overarching question I seek to answer in this thesis is whether the common law principles of consent, informed consent, and best interests, interpreted alongside the

⁸³ Scottish Health Department (2006) ‘Human Tissue Act (Scotland) 2006 : A Guide to its Implications for NHS Scotland’ [8] available at [https://www.hta.gov.uk/sites/default/files/Information_about_HT_\(Scotland\)_Act.pdf](https://www.hta.gov.uk/sites/default/files/Information_about_HT_(Scotland)_Act.pdf) (last accessed 11/09/17); HTA Code of Practice 1: Consent (2009; updated 2014) [19], although note this is not specified in the 2017 Code of Practice.

⁸⁴ S.6(1); also S.7(1); S.8(1); S.9(1); & S.10(1).

⁸⁵ S.3(1).

⁸⁶ S.13(1).

⁸⁷ See particularly NICE, *Improving Donor Identification* as earlier.

legislation governing the treatment of the incapacitated, are specific enough, protective enough, and facilitative enough to regulate the treatment of the potential organ donor.⁸⁸

The common law principles of consent and informed consent stem from the criminal and civil law on battery and from the civil law on negligence respectively.⁸⁹ Although they are related to the protection and achievement of patient autonomy, they are principles to correct legal wrongs and their application does not necessarily protect and facilitate patient rights. Whilst recent cases, notably *Montgomery v Lanarkshire Health Board*,⁹⁰ recognise self-determination as the ethical and legal justification for obtaining informed consent, the patient can only give informed consent to a treatment that they have been informed about whilst competent to make a decision. The fall-back position of organ procurement policy-makers seems to be that they cannot obtain informed consent as the potential organ donor is already incapacitated. Although, as I will argue in Chapter 3, this position is untenable, it does allow them to shift the focus of attention to the rather nebulous concept of best interests.

Best interests is a common law principle that originated out of a need to fill a gap in consent provisions for mentally incapacitated individuals.⁹¹ The principle received a firm statutory grounding when it was adopted as a defining principle of the Mental Capacity Act (MCA) 2005.⁹² It appears in a slightly different form as “benefit” in the Adults with Incapacity (Scotland) Act (AISA) 2000.⁹³ Both benefit and best interests refer to an overall benefit, when

⁸⁸ This question will be addressed first in relation to common law principles of consent and informed consent in Chapter 3; and second in relation to best interests and the Mental Capacity Act 2005 in Chapter 4.

⁸⁹ These principles are evaluated in Chapter 3.

⁹⁰ [2015] UKSC 11.

⁹¹ *In re F (Mental Patient: Sterilisation)* [1990] 2 AC 1; See J. Munby, ‘Protecting the Rights of Vulnerable and Incapacitous Adults - the Role of the Courts: An Example of Judicial Law Making’ (2014) 26(1) *CFLQ* 64-77, 64-66.

⁹² S.1(5); it has also recently been incorporated into the Mental Capacity Act (Northern Ireland) 2016.

⁹³ S.1(2).

weighed against potential harms, of medical interventions.⁹⁴ At the time of the original elective ventilation protocol,⁹⁵ published in 1990 by a group of physicians,⁹⁶ it was accepted as “fact that [non-therapeutic] interventions are not in the patient’s best interests”.⁹⁷ This acceptance that the “patient’s own benefit”⁹⁸ categorically excluded “ensur[ing] his or her organs can be retrieved for transplantation”⁹⁹ is readily apparent in the phraseology of a 1994 health service guideline declaring the practice “unlawful”.¹⁰⁰ The viewpoint that “intubation and ventilation of patients where this is not in their best clinical interests is unlawful” also permeates a 2010 Intensive Care Society Report, written in collaboration with the Department of Health (DoH).¹⁰¹ A key question I seek to address in this thesis is whether this viewpoint is correct with the current understanding of best interests which, as the DoH recognise, is “wider than simply treating a person’s medical condition and includes a person’s social, emotional, cultural and religious interests”.¹⁰²

The wider interests of any incapacitated patient, including any individual identified as a potential organ donor, require - as emphasised in section 4(6) of the MCA - the healthcare professional to consider “so far as reasonably ascertainable” -

- (a) the person’s past and present wishes and feelings (and, in particular, any relevant written statement made by him when he had capacity),

⁹⁴ Best interests, the considerations that may be included within it, and the balancing of these considerations, is evaluated in detail in Chapter 4.

⁹⁵ Often referred to as the Exeter protocol after the hospital at which it was promulgated and trialled.

⁹⁶ T. Feest, H. Riad, C. Collins, M. Golby *et al*, ‘Protocol for Increasing Organ Donation after Cerebrovascular Deaths in a District General Hospital’ (1990) 335 *Lancet* 1133-5, [‘Protocol for Increasing Organ Donation’].

⁹⁷ M. Booth & P. Wallace, ‘Ventilating Patients for Organ Donation’, Chapter 10 in N.A.Pace & S.A.M.Mclean, *Ethics and the Law in Intensive Care* (OUP, 1996) 142- 157, 143, [‘Ventilating Patients’].

⁹⁸ DoH Health Service Guideline (94) 41, *Identification of Potential Donors of Organs for Transplantation* (1994) [HSG(94)41].

⁹⁹ HSG(94)41.

¹⁰⁰ HSG(94)41.

¹⁰¹ Intensive Care Society, British Transplantation Society, Department of Health, and NHS Blood and Transplant, *Donation after Circulatory Death: Report of a Consensus Meeting* (2010) p.19 [3.1]. Quote modified for clarity.

¹⁰² DoH, *Legal Issues* as earlier, [1.5]; this question will be addressed in detail in Chapter 4.

- (b) the beliefs and values that would be likely to influence his decision if he had capacity, and
- (c) the other factors that he would be likely to consider if he were able to do so.¹⁰³

The individual's wishes, beliefs and values are the key factors that could potentially encompass donor optimisation procedures within the best interests of a patient identified as a potential organ donor.¹⁰⁴ However, problems remain and they mostly revolve around patient self-determination. A wide interpretation of best interests is not a corrective for the lack of information provided to and the lack of consent given by ODR registrants to donor optimisation procedures. Despite recommendations in the 1990s that a new donor card be introduced to allow individuals to provide advance consent to "interventional ventilation",¹⁰⁵ no such system has been introduced and the public remain uninformed about ante-mortem donor optimisation procedures. The "patient's willingness to donate his or her organs post-mortem"¹⁰⁶ cannot be equated with "his or her ante-mortem treatment"¹⁰⁷ because their interests before death include factors other than organ donation.¹⁰⁸ The patient remains an individual, and cannot be treated on the basis of a "good enough chance"¹⁰⁹ that they would wish to undergo ante-mortem interventions to facilitate organ donation. Knowledge of their wishes regarding donor optimisation procedures, before and not after the initiation of treatment, is needed to avoid the risk of getting their best interests wrong.

The principle of best interests applies not only to incapacitated adults identified as potential organ donors but also to children. These may include older children who have

¹⁰³ MCA S.4(6).

¹⁰⁴ See J. Coggon, M. Brazier, P. Murphy & M. Quigley, 'Best Interests and Potential Organ Donors' (2008) 336 (7567) *BMJ* 1346-1347.

¹⁰⁵ Booth & Wallace, 'Ventilating Patients', as earlier, 153; see also A. Browne, G. Gillett & M. Tweeddale, 'The Ethics of Elective (Non-Therapeutic) Ventilation' (2000) 14 *Bioethics* 2000 42-57, 46 & S. Mclean, 'Making Advance Medical Decisions' (1995) 11 *J Med Dent Defence Union* 28-29.

¹⁰⁶ Booth & Wallace, 'Ventilating Patients' 150.

¹⁰⁷ Ibid.

¹⁰⁸ These factors will be identified and evaluated in Chapter 4.

¹⁰⁹ Coggon's claim that they can be treated on the basis of probable benefit is evaluated in Chapter 4. See Coggon, 'Elective Ventilation' as earlier, 132.

themselves registered on the ODR and children of any age who have never considered organ donation and/or issues surrounding their end-of-life care. The statutory test provided by the Children Act 1989 is that “the child’s welfare shall be the court’s paramount consideration”:¹¹⁰ a test that is usually equated to best interests or benefit. In determining the child’s welfare, the court places particular importance on “the ascertainable wishes and feelings of the child concerned (considered in the light of his age and understanding)”¹¹¹ as well as other factors including “any harm which he has suffered or is at risk of suffering”.¹¹² As with incapacitated adults, the best interests of the child encompasses their medical, social and psychological interests.¹¹³ These are the key factors to be taken into account in any best interests determination and the law requires that they are included in the balancing exercise to determine overall benefit.¹¹⁴

In relation to incapacitated adults, the MCA provisions on advance decision-making, Lasting Powers of Attorney (LPAs), and Court-appointed Deputies may also be applicable to the circumstances of ante-mortem donor optimisation procedures.¹¹⁵ However, LPAs and Deputies - if they have been appointed - are also legally obliged to make decisions in the patient’s best interests.¹¹⁶ Welfare attorneys under the Scottish legislation are also guided by the general principle of benefit.¹¹⁷ The legal principle remains the same: it is the decision-maker that changes. If that attorney or deputy is a close relative or friend they may have more knowledge of the patient’s wishes than a healthcare professional. However, as the public has not been widely informed about ante-mortem interventions to facilitate organ donation, it is likely that even a close relative would only be able to speculate on the patient’s wishes in the

¹¹⁰ S.1(1)(b).

¹¹¹ S.1(3)(a).

¹¹² S.1(3)(e).

¹¹³ See eg. *Re A (A Child)* [2016] EWCA Civ 759, Lady Justice King at [31] & [57] citing Lady Hale in *Aintree University Hospitals NHS Trust v James* [2013] UKSC 67 at [39].

¹¹⁴ *An NHS Trust v MB* [2006] EWHC 507 (Fam) 58-62.

¹¹⁵ S.9-11, S.16 & 20, S.24-26; the provisions on advance decision-making will be evaluated in Chapter 3.

¹¹⁶ S.1(5); S.9(4)(a); S.16(3).

¹¹⁷ AISA 2000 S.1(2); S.16.

circumstances.¹¹⁸ This speculative aspect to decision-making on behalf of the incapacitated can only be removed with the provision of specific information that allows individuals to formulate and express their wishes whilst still competent to do so.

The MCA provisions on advance decision-making are limited to advance refusals of medical treatment by adults who have reached the age of 18.¹¹⁹ There is no statutory basis for advance directives in Scotland.¹²⁰ There, as in the rest of the UK, advance consent to treatment is just one factor - albeit a significant one - in the determination of benefit or best interests.¹²¹ It could potentially be overridden by factors such as the risk of harm from donor optimisation procedures.¹²² Advance refusal by a competent adult, on the other hand, is supposed to be legally binding throughout most of the UK. However, it too can be overridden if the treating doctor is not “satisfied that an advance decision exists which is valid and applicable to the treatment”.¹²³ An advance refusal that otherwise fulfils the MCA provisions can be declared inapplicable if “there are reasonable grounds for believing that circumstances exist which P did not anticipate at the time of the advance decision and which would have affected his decision had he anticipated them”.¹²⁴ This presents a risk that an advance refusal of medical interventions at the end of life could be declared inapplicable to donor optimisation procedures because the lack of information provided to ODR registrants and members of the public means that they cannot have anticipated them in advance.

The existing common law and statutory principles that could potentially regulate ante-mortem donor optimisation procedures are all hampered by the lack of information, and

¹¹⁸ P. Lewis, ‘Procedures that are Against the Medical Interests of Incompetent Adults’ (2002) 22 (4) *Ox J Leg Stud* 575-618, 586.

¹¹⁹ S.24(1) in particular, S.24-26 in general.

¹²⁰ With the exception of mental health advance directives under the Mental Health (Care and Treatment) (Scotland) Act 2003 S. 275-276 which mental health tribunals are required to “have regard to” (see S. 276(1)).

¹²¹ MCA S.4(6)(a); AISA S.1(4)(a).

¹²² The balancing of autonomy against harm is evaluated in Chapter 4.

¹²³ S.26(2).

¹²⁴ S.25(4)(c).

consequent lack of decision-making opportunity, provided to ODR registrants and the wider public. Chapters 3 and 4 of this thesis will evaluate their application in more depth and the changes that would need to be made to policy and practice for these existing principles to provide a clear and unambiguous framework in which to regulate ante-mortem donor optimisation procedures.

The Legal Regulation of Death

The law on informed consent applies to medical decisions made by competent individuals. The MCA provisions on best interests, or in Scotland the AIAS provisions on benefit, apply to medical interventions performed on incapacitated individuals. The HTA provisions on appropriate consent, the HTW provisions on deemed consent, and the HTS provisions on authorisation, apply to medical interventions performed on deceased individuals. Death has no statutory definition. The time when the individual's treatment moves from being regulated by mental capacity legislation to human tissue legislation is not statutorily regulated.

The Human Tissue Authority has been afforded the power to develop a Code of Practice on the definition of death for the purposes of the HTA 2004,¹²⁵ a power that they have not yet utilised. Death is not easily defined in the era of intensive care treatments that make it possible for brain-injured patients to show some signs that seem to indicate life, including a heartbeat and a chest that rises and falls with mechanical ventilation, yet be cognitively or brain dead.¹²⁶ Since the first published report of “coma dépassé” in 1959,¹²⁷ there has been a continued debate on when exactly death occurs and how it should be diagnosed.¹²⁸ When and how death is legally diagnosed is critical to the treatment of the

¹²⁵ S.26(2)

¹²⁶ For a history of brain death diagnosis see B. Jennett, ‘Brain Death and the Persistent Vegetative State’, Chapter 2 in N.A. Pace & S.A.M. Mclean, *Ethics and the Law in Intensive Care* (OUP, 1996) 13-28.

¹²⁷ P. Mollaret & M. Goulon, ‘Le Coma Dépassé’ (1959) 101 (1) *Revue Neurologique* 3-15.

¹²⁸ See eg. S Shah, R. Truog, and F. Miller, ‘Death and Legal Fictions’ (2011) 37 *J Med Ethics* 719-722.

patient identified as a potential organ donor. Before death, the medical and legal treatment of an incapacitated patient is as an individual with their own interests, whose past (and, if any, present) wishes are – or at least should be – given weight in decisions about their care.¹²⁹ After death, those past wishes may retain some weight in decision-making but the interests,¹³⁰ if any, of the deceased person in medical interventions are largely superseded by other concerns, including those relating to maintaining the trust of relatives in post-mortem interventions and to securing the supply of organs for transplantation.¹³¹

The sudden legal switch from the mental capacity legislation to the human tissue legislation is not reflective of the view that death is a process. As McGuinness and Brazier recognise, “death is not akin to a switch”.¹³² However, legally a switch does occur at the time when death is clinically diagnosed and confirmed. As death itself is not statutorily regulated, healthcare professionals rely on a Code of Practice published by the Academy of Medical Royal Colleges (AMRC).¹³³ This Code of Practice begins with the qualification that it has been approved “as a statement of current practice in the diagnosis and confirmation of death” and does not “seek to provide guidance in every single clinical situation where a doctor is required to diagnose death”.¹³⁴ It is a series of “practical recommendations” that allow the diagnosis and confirmation of death “to be carried out in a variety of circumstances where further intervention aimed at sustaining life can be of no further benefit to patients”.¹³⁵ These

¹²⁹ MCA S.4(6)(a); AIA S.1(4)(a).

¹³⁰ See S. McGuinness & M. Brazier, ‘Respecting the Living Means Respecting the Dead too’ (2008) 28(2) *Ox J Leg Stud* 297-316, [‘Respecting the Living’];

¹³¹ HTA S.43 and HTS S.13 both allow a move away from consent to secure organs for transplantation; the concept of trust will be evaluated in Chapter 2; see also J. Harris, ‘Organ Procurement: Dead Interests, Living Needs’ (2003) 29 *J Med Ethics* 130-134.

¹³² McGuinness & Brazier, ‘Respecting the Living’ as above, 305.

¹³³ Academy of Medical Royal Colleges, ‘A Code of Practice for the Diagnosis and Confirmation of Death’ (2008), [‘AMRC Code of Practice’].

¹³⁴ AMRC Code of Practice, p.6.

¹³⁵ AMRC Code of Practice, p.9; these recommendations are grounded in a number of earlier reports, including H. Beecher, ‘A Definition of Irreversible Coma. Report of the Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Brain Death’ (1968) 205(6) *JAMA* 337-340; Conference of Medical Royal Colleges and their Faculties in the United Kingdom, ‘Diagnosis of Brain

practical recommendations attempt to pinpoint death, whilst the reluctance of the AMRC to extend them to all clinical situations suggests that it is something that is not always easily pinpointed.

The diagnosis and confirmation of death is alleged to be entirely separate from anything to do with organ donation and transplantation.¹³⁶ However, the AMRC do intend that the Code on the diagnosis of death should be used in conjunction with Intensive Care Society guidelines on organ donation and transplantation and with Human Tissue Authority Codes of Practice.¹³⁷ Separating out the three stages of the organ donation process – end of life care, diagnosis of death, and organ donation itself – is increasingly difficult to maintain in practice. Death no longer “marks the transition from patient to donor.”¹³⁸ The reality is that this transition often now occurs before death has been diagnosed and confirmed.¹³⁹ As Price recognises, this does not necessarily mean that patients are treated only in their capacity of donors, but that any altruistic wishes they may have are being permitted to influence treatment decisions.¹⁴⁰ However, ensuring that an individual patient actually had an altruistic wish to donate and that this wish extended to interventions before death can be problematic.

One definition of death but two alternative means of diagnosis are given by the AMRC. Death is defined as “the irreversible loss of the capacity for consciousness, combined with the irreversible loss of the capacity to breathe”.¹⁴¹ This definition clarifies that a patient can retain a heartbeat yet still be legally dead. Death can be diagnosed either on the basis of

Death’ (1976) 2(11) *BMJ* 1187-8; Health Departments of Great Britain and Northern Ireland, ‘Cadaveric Organs For Transplantation: A Code of Practice including the Diagnosis of Brain Death’ (1983); Royal Colleges of Physicians Working Party, ‘Criteria for the Diagnosis of Brain Stem Death’ (1995) 29 *J R Coll Physicians Lond* 381-2.

¹³⁶ AMRC Code of Practice, p.9.

¹³⁷ AMRC Code of Practice, p.9; Intensive Care Society, *Guidelines for Adult Organ and Tissue Donation* (2005); HTA Codes of Practice A-G available at <https://www.hta.gov.uk/hta-codes-practice-and-standards-0> (last accessed 11/09/17).

¹³⁸ Intensive Care Society, *Guidelines for Adult Organ and Tissue Donation* (2005) p.25.

¹³⁹ Price, ‘Paradigm Shifts’ as earlier, p.115.

¹⁴⁰ *Ibid.*

¹⁴¹ AMRC Code of Practice, p.11.

irreversible cessation of brainstem function or on the basis of irreversible cessation of cardiorespiratory function.¹⁴² Noting the range of practice for the confirmation of cardiorespiratory death, and the focusing of attention brought by the practice of non-heartbeating organ donation (i.e. donation after circulatory death),¹⁴³ the AMRC recommend standardised criteria for confirming death following cardiorespiratory arrest.¹⁴⁴ The time of cardiorespiratory death is the time at which these clinical criteria are fulfilled.¹⁴⁵ Diagnosis and confirmation of brain-stem death requires a different set of standardised criteria to be fulfilled, and the fulfilment of these criteria is also equated with the death of the individual.¹⁴⁶ Although some residual brain and spinal cord activity may persist after a diagnosis of irreversible cessation of brain-stem function, these patients are thought to be no longer able to benefit from treatment and can be legally certified as dead.¹⁴⁷

The AMRC recommendations on the diagnosis and confirmation of brain-stem death include the absence of several reflexes, including pupillary, corneal, oculo-vestibular, and cough reflexes, followed by an apnoea test.¹⁴⁸ Two complete sets of brain-stem tests must be performed before the patient can be confirmed dead.¹⁴⁹ Although the patient cannot be treated as legally dead until the second set of tests has been completed, the legal time of

¹⁴² AMRC Code of Practice, p.11.

¹⁴³ Deceased organ donation is usually categorised as either Donation after Cardiac or Circulatory Death (DCD) or Donation after Brain Death (DBD).

¹⁴⁴ AMRC Code of Practice, p.12.

¹⁴⁵ AMRC Code of Practice, p.12.

¹⁴⁶ AMRC Code of Practice, P.11.

¹⁴⁷ AMRC Code of Practice p.11; some authors claim that this legal certification of death is misleading and that brain-stem dead organ donors are not really dead: see eg. A. Joffe, 'The Ethics of Donation and Transplantation: Are Definitions of Death being Distorted for Organ Transplantation?' (2007) 2(1) *Philos Ethics Humanit Med* 28; J. Bleich, 'Establishing Criteria of Death' & T. Beauchamp & R. Veatch, 'The Definition of Death' in T. Beauchamp & R. Veatch, *Ethical Issues in Death and Dying* (2nd edition, Prentice Hall, USA, 1996) 28 & 1 respectively; M. Nair-Collins & F. Miller, 'Do the "Brain Dead" Merely Appear to be Dead?' (2017) *J Med Ethics* Published Online First 28/08/2017; see also C. Machado, J. Korein, Y. Ferrer *et al*, 'The Concept of Brain death did not Evolve to Benefit Organ Transplants' (2007) 33 *J Med Ethics* 197-200.

¹⁴⁸ AMRC Code of Practice p.17-18, [6.1.1-6.1.6]; these diagnostic tests are described in more detail in M. McLaughlin & B. Miles, 'Brain Stem Death' (2015) 16(7) *Anaesthesia and Intensive Care Medicine* 311-314.

¹⁴⁹ AMRC Code of Practice p.19, [6.3].

death is given retrospectively as when the first set of tests indicate brain-stem death.¹⁵⁰ The guidelines make it clear that, unless death has been conclusively established, the patient should be treated according to their best interests in line with the MCA 2005.¹⁵¹ Under the heading “Elective Ventilation”, the guidelines advise that in the circumstances of a patient being withdrawn from ventilatory support due to the inevitably fatal nature of their condition, that they should only be reintubated and ventilated “to further [their] benefit and not as a means of preserving organ function”.¹⁵² Although this statement does appear to exclude the preservation of organ function from the patient’s best interests, it also exemplifies just how important it is perceived to be not to risk treating a patient who may still be alive against their best interests.

Although the clinical recommendations of the Medical Royal Colleges are a Code of Practice rather than hard law, the judiciary has accepted the brain-stem criteria advocated as constituting the legal basis for the diagnosis and confirmation of death.¹⁵³ In a recent case involving a child who had been declared dead on the basis of two sets of brain stem tests,¹⁵⁴ the father of the child challenged the viewpoint that brain stem death is the same as clinical and/or legal death.¹⁵⁵ Applying the AMRC’s recommendations on brain-stem death,¹⁵⁶ Mr Justice Hayden concluded that the criteria for death had been established,¹⁵⁷ and permission

¹⁵⁰ Ibid [6.3]; this is the legal time of death as accepted by clinicians, see eg. J. Dinsmore & A. Garner, ‘Brain Stem Death’ (2009) 27(5) *Critical Illness and Intensive Care* 216-220, 219.

¹⁵¹ AMRC Code of Practice p.21.

¹⁵² AMRC Code of Practice p.21, [7.3]; this statement may in part reflect an understanding of benefit as being restricted to clinical benefit. The development of the law on best interests towards a more expansive understanding will be evaluated in Chapter 4.

¹⁵³ The original common law ruling is *Re A (A Minor)* [1992] 3 Med LR 303: see discussion by J. Brierley, ‘UK Court Accepts Neurological Determination of Death’ (2015) 385(9984) *Lancet* 2254 [‘UK Court Accepts’], also B. Jennett, ‘Brain Stem Death Defines Death in Law’ (1999) 318 *BMJ* 1755, [‘Death in Law’].

¹⁵⁴ *Re A (A Child)* [2015] EWHC 443 (Fam) [1].

¹⁵⁵ Ibid [10]; see also Brierley, ‘UK Court Accepts’ as above.

¹⁵⁶ AMRC Code of Practice as earlier, p.11 [2.1] & p.17, as cited in *Re A (A Child)* [2015] as above [12-13].

¹⁵⁷ *Re A (A Child)* as above [15].

was granted for the child's ventilator to be turned off.¹⁵⁸ This ruling, when viewed together with previous case-law equating brain-stem death with legal death,¹⁵⁹ elevates the AMRC Code of Practice to the status of law.

Crucially for the management of potential organ donors, the legal time of death is the time at which either brain-stem death or cardiorespiratory death is established.¹⁶⁰ It is neither an earlier time when respiratory arrest occurs¹⁶¹ nor a later time after the withdrawal of artificial ventilation.¹⁶² This legal time of death marks the transition from being treated according to best interests to being treated as a deceased person under the human tissue legislation.¹⁶³ This may include the deceased person having their vital organs removed, stored, and used for the purpose of transplantation.¹⁶⁴ Although death may not necessarily be a bright line clinically, it is a bright line legally.

The legal switch from mental capacity to human tissue legislation that occurs at the legal time of death reflects the ethical and legal rule that is known as the dead donor rule.¹⁶⁵ This rule requires that "organ donation must not kill the donor"¹⁶⁶ and that vital organs should only be removed from individuals who have been diagnosed as dead.¹⁶⁷ It is an extension of the law on homicide that protects patients from "be[ing] killed in order to obtain their

¹⁵⁸ Ibid [26].

¹⁵⁹ Notably *Re A (a minor)* [1992] 3 Med LR 303.

¹⁶⁰ Jennett, 'Death in Law' as earlier.

¹⁶¹ In contrast to claims made by authors of Exeter Protocol – see H. Riad & A. Nicholls, 'An Ethical Debate: Elective Ventilation of Potential Organ Donors' (1995) 310(6981) *BMJ* 714-715.

¹⁶² Jennett, 'Death in Law' as earlier, 1755.

¹⁶³ HTA 2004 S.43; HTS 2006 S.13.

¹⁶⁴ HTA 2004 S.1 & Schedule 1 Part 1(7); HTS 2006 S.3.

¹⁶⁵ See particularly J. Robertson, 'The Dead Donor Rule' (1999) 29(6) *Hastings Cent Rep* 6-14, ['Dead Donor'].

¹⁶⁶ J. Bernat, 'Life or Death for the Dead-Donor Rule?' (2013) 369(14) *NEJM* 1289-1291, 1289['Life or Death'].

¹⁶⁷ It has recently been criticised by R. Truog, F. Miller, & S. Halpern, 'The Dead-donor Rule and the Future of Organ Donation' (2013) 369(14) *NEJM* 1287-1289 & defended by S. Birch, 'The Dead Donor Rule: A Defense' (2013) 38 *J Med Philos* 426-440 & by J. Bernat, 'Life or Death' as above.

organs”.¹⁶⁸ The continued application of this ethical and legal standard has a central role in the maintenance of public trust in the organ donation programme and the willingness of individuals to consent for deceased organ donation.¹⁶⁹ It permits a clinically appropriate, legally supported, and ethically well-grounded judgement on the time of death to be followed in order to facilitate organ donation.¹⁷⁰ However, in the context of donor optimisation procedures, the standard may also be interpreted as requiring that changes to end-of-life care do not inadvertently kill the donor. Although the dying patient is on a trajectory towards death, they are not dead and the law requires that any potential harms are outweighed by benefit to the donor themselves.

Identification and Referral of the Potential Organ Donor

Over the last few years, several policies have been published which move the time at which patients are identified and treated as potential deceased organ donors to before death.¹⁷¹ Death is no longer a bright line between being treated as a patient only and being treated as an organ donor. Since the recommendation of the Organ Donation Taskforce (ODT) in 2008 that organ donation be viewed as a usual part of end-of-life care,¹⁷² policy and practice have changed to allow an earlier identification of potential organ donors with the aim of improving organ donation rates.¹⁷³ This earlier identification is accompanied by a range of ante-mortem interventions to facilitate organ donation.¹⁷⁴ In practice, this may include invasive interventions such as the cannulation of major blood vessels and endotracheal intubation for

¹⁶⁸ Robertson, ‘Dead Donor’ as earlier, 6.

¹⁶⁹ See Bernat, ‘Life or Death’ as earlier, 1290-1291; the concept of trust and its relationship to autonomy will be evaluated in Chapter 2.

¹⁷⁰ Bernat, ‘Life or Death’ 1291.

¹⁷¹ NICE, *Improving Donor Identification* as earlier; ODT, *Organs for Transplants* as earlier; DOH, *Legal Issues* as earlier; UKDEC, *Ethical Framework* as earlier; see also BMA Medical Ethics Committee, *Building on Progress* as earlier.

¹⁷² ODT, *Organs for Transplants* as above, p.9 [1.23] and recommendation 4.

¹⁷³ See particularly NICE, *Improving Donor Identification* as above.

¹⁷⁴ See DoH, ‘Legal Issues’ as earlier, p. 9-10 & UKDEC, ‘Ethical Framework’ as earlier, p.19 & 43.

mechanical ventilation, and pharmacological interventions such as inotropic support to maintain blood pressure.¹⁷⁵

The ODT's 2008 recommendations on encompassing organ donation within end-of-life care are one part of their overall strategy, now achieved,¹⁷⁶ aimed at increasing organ donation by 50% within 5 years.¹⁷⁷ Each hospital trust is held accountable for their performance in implementing the ODT recommendations and is required to ensure that data on the size of the potential donor pool, collected from all areas where critical care is provided – including accident and emergency departments – are made available to healthcare regulators.¹⁷⁸ Information about every patient who dies in either intensive care or the emergency department is gathered by Specialist Nurses in Organ donation (SNODs) and input into the UK Potential Donor Audit.¹⁷⁹ This includes information on whether brain-stem death was suspected or imminent cardiac death was anticipated, whether the patient was referred to the Organ Donation Services team, and what the main reason was if not referred.¹⁸⁰ The referral rate is now 97.4% for those patients meeting the organ donation referral criteria for Donation after Brain Death (DBD) and 85.6% for those meeting the referral criteria for Donation after Cardiac Death (DCD).¹⁸¹ These referral criteria are clinical criteria and are not based on the individual's wishes regarding their end-of-life care or organ donation. Interestingly, in only two cases in 2015-2016 (0.2% of those not referred to the Organ

¹⁷⁵ Patel et al, 'Survey of Current Practice' as earlier; Wilkinson et al, 'Actively Delaying Death' as earlier, 1179.

¹⁷⁶ NHSBT News Release, 'NHS Achieves Ground Breaking 50% Increase in Deceased Organ Donors' (NHSBT 11 April 2013).

¹⁷⁷ ODT, *Organs for Transplants* [1.1] & Chair's Introduction, p.2.

¹⁷⁸ ODT, *Organs for Transplants* p.10 [1.25].

¹⁷⁹ Annual reports available at <http://www.odt.nhs.uk/statistics-and-reports/potential-donor-audit/> (last accessed 11/09/17).

¹⁸⁰ NHS Blood and Transplant (NHSBT), *Potential Donor Audit Record* (FRM4361/3, July 2015) p.4, Sections 3 & 4; information has also been collected from a number of European countries and recommendations made by Achieving Comprehensive Coordination in Organ Donation (ACCORD) *Work Package 5 – Increasing the Collaboration Between Donor Transplant Coordinators and Intensive Care Professionals* (European Commission, Final Report, April 2015).

¹⁸¹ Summary data from the National Potential Donor Audit provided in NHSBT, 'Activity Report' as earlier, p.126 Table 13.1.

Donation team) was the reason for non-referral given as the patient's previously expressed wishes not to become an organ donor.¹⁸²

Patients are identified, referred, and treated as potential organ donors on the basis of clinical criteria, which are termed "clinical triggers"¹⁸³ for referral. The clinical triggers model was first introduced in the UK following the ODT's endorsement of a national protocol for comprehensive donor identification and notification.¹⁸⁴ These clinical triggers, which the ODT recognise represent a "radical change of practice",¹⁸⁵ are described by the ODT as a "minimum description of what is necessary" and "should be implemented in all acute Trusts".¹⁸⁶ They include "no further treatment options [being] available or appropriate" and either "a plan to confirm death by neurological criteria" or "a decision...by a consultant to withdraw active treatment".¹⁸⁷ The fulfilment of these clinical triggers requires the clinical staff to refer to the Donor Transplant Coordinator even if they believe "that donation...might be contraindicated or inappropriate".¹⁸⁸ The staff's knowledge of the patient's wishes, the relative's knowledge, and the patient's viewpoint, are entirely removed from the decision regarding whether or not to refer to the Organ Donation team.

The National Institute for Health and Care Excellence (NICE), which at the time was known as the National Institute for Health and Clinical Excellence,¹⁸⁹ was asked by the

¹⁸² NHSBT, *Potential Donor Audit Summary Report* (1 April 2015 - 31 March 2016) p.4 table 3; reasons for non-referral are not detailed in the NHSBT 'Activity Report' for 2016-2017, as earlier, and the full Potential Donor Audit Report for 2016-2017 is not (as of 11/09/2017) as yet available.

¹⁸³ This term is used by both ODT in *Organs for Transplants*, p.10 [1.26 -1.30] & NICE in *Improving Donor Identification*, p.6 [1.1.2].

¹⁸⁴ ODT *Organs for Transplants* p.11 [1.27-1.28].

¹⁸⁵ ODT *Organs for Transplants* p.11-12 [1.30].

¹⁸⁶ ODT *Organs for Transplants* p.11 [1.29].

¹⁸⁷ ODT *Organs for Transplants* p.11 [1.28].

¹⁸⁸ Ibid.

¹⁸⁹ The Health and Social Care Act 2012, S. 232 established the National Institute for Health and Care Excellence. This took over from the National Institute for Health and Clinical Excellence, which had been established by the National Institute for Clinical Excellence (Establishment and Constitution) Order 1999.

Department of Health (DoH) to produce a clinical guideline specifically aimed at improving donor identification and consent rates for deceased organ donation.¹⁹⁰ NICE is an independent organisation whose statutory functions include “giving advice or guidance, providing information or making recommendations” to healthcare professionals.¹⁹¹ NICE defines its clinical guidelines as “recommendations about the treatment or care of people with specific diseases and conditions”.¹⁹² NICE produced recommendations that change the treatment and care of one group of patients to improve the treatment and care of third parties with organ failure. This not only moves NICE away from its usual remit but also introduces concerns surrounding a conflict of interests. The current law holds the best interests of the patient who will be subject to medical interventions to be the paramount concern, yet the NICE guidelines are aimed at promoting the interests of third parties. In this thesis, I argue that the conflict that could ensue between the aim of improving organ donation rates and the interests of the potential organ donor can only legally – and ethically - be resolved in favour of the potential organ donor.¹⁹³

NICE recognises that its clinical guideline on organ donation is dependent on qualitative evidence: indeed, it modified its conventional assessment tool to fit the available evidence.¹⁹⁴ It carries this approach to evidence through to its recommendations on the identification of potential donors on the basis of clinical triggers. The evidence profile for its recommendations on the timing and clinical criteria for referral is prefaced with the proviso that “the characteristic of imprecision was not assessed for this question as the type of

¹⁹⁰ NICE *Improving Donor Identification* as earlier.

¹⁹¹ National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013, pursuant to the Health and Social Care Act 2012, S. 237(1); see also NICE Charter (April 2013) [1].

¹⁹² NICE *Improving Donor Identification* as earlier, p.4. N.B this definition appears in the 2011 guidance although no definition is provided in the 2016 updated version.

¹⁹³ This is particularly argued in Chapters 4-6.

¹⁹⁴ NICE *Improving Donor Identification* (2011 guidance) p.5.

evidence included often did not allow any assessment of the preciseness of any summary estimate”.¹⁹⁵ The quality of all of the evidence relied upon for the early identification and referral of potential organ donors, including the use of clinical triggers, was rated as low or very low.¹⁹⁶ The patient’s wishes are not considered relevant, and the clinical evidence is acknowledged to be poor, but despite this NICE recommends that patients should be identified as potential donors and referred to the specialist nurse for organ donation on the basis of either of the following criteria:

- defined clinical trigger factors in patients who have had a catastrophic brain injury, namely:
 - the absence of one or more cranial nerve reflexes **and**
 - a Glasgow Coma Scale (GCS) score of 4 or less that is not explained by sedation
 unless there is a clear reason why the above clinical triggers are not met (for example because of sedation) and/or a decision has been made to perform brainstem death tests, whichever is the earlier
- the intention to withdraw life-sustaining treatment in patients with a life-threatening or life-limiting condition which will, or is expected to, result in circulatory death.¹⁹⁷

NICE qualifies these recommendations with the recognition that “a proportion of the patients identified by these clinical triggers will survive”.¹⁹⁸ They are criteria that suggest that a patient is likely to die but are not definite indicators of death. A recent study, to which NICE refers in its 2014 evidence update,¹⁹⁹ aims to determine which clinical assessment tool provides the most reliable “risk estimate” of a patient progressing to death and subsequent organ donation.²⁰⁰ The outcome of donor optimisation procedures may include surviving, and it may

¹⁹⁵ NICE Clinical Guideline 135 Appendices: Appendix C Full GRADE evidence profiles, Review Question 1, p.69-76 (N.B. Appendices to 2011 guidance).

¹⁹⁶ Ibid.

¹⁹⁷ NICE, *Improving Donor Identification* (2016 updated version) p.6 [1.1.2-1.1.3].

¹⁹⁸ NICE, *Improving Donor Identification* as earlier p. 7, footnote 4 in original 2011 guidance or endnote 2 in 2016 update.

¹⁹⁹ NICE, *Organ donation for transplantation: Evidence Update* (2014).

²⁰⁰ Y.De Groot, E.Wijdicks, M.van der Jagt, J.Bakker *et al*, ‘Donor Conversion Rates Depend on the Assessment Tools used in the Evaluation of Potential Organ Donors’ (2011) 37 *Intensive Care Med* 665-670, 669, [‘Donor Conversion’].

include surviving with serious complications,²⁰¹ so assessment tools should ideally be specific for imminent death. Three assessment tools are evaluated in the study, including one based on the Glasgow Coma Scale and one based on the Full Outline of UnResponsiveness (FOUR) score.²⁰² The authors conclude that “the FOUR score appears to be the more neurologically practical tool for identifying patients with a realistic chance of becoming brain dead”.²⁰³ Currently, patients are being identified as potential organ donors on the basis of clinical assessment tools with an unquantified chance of misdiagnosing imminent death.²⁰⁴ It is not known what proportion of these patients might survive with severe neurological impairment as a consequence of their management as potential organ donors.²⁰⁵

Some potential organ donors who are identified by the second clinical trigger, i.e. the intention to withdraw life-sustaining treatment, may retain decision-making capacity. Under these circumstances, doctors are advised to “obtain their views on, and consent to, organ donation”,²⁰⁶ but they are not specifically advised to obtain their views on and consent to ante-mortem interventions to facilitate organ donation. All patients identified by the first clinical trigger, i.e. on the basis of their GCS score, and some patients identified by the second clinical trigger, will be unable to express decisions about their end-of-life care and about organ donation. It is possible that some of this group of patients may have the cognitive function

²⁰¹ See eg. B. New, M. Solomon & R. Dingwall *et al*, ‘A Question of Give and Take: Improving the Supply of Donor Organs for Transplantation’ (Research Report 18, King’s Fund Institute, UK, 1994) 64 [‘King’s Fund Report’] which identified surviving in a permanent vegetative state (PVS) as the major ethical problem of elective ventilation.

²⁰² *Groot et al*, ‘Donor Conversion’ as earlier, 666.

²⁰³ *Ibid*, 669.

²⁰⁴ Misdiagnosis of imminent death is not as far-fetched as might be thought. In 2009, a US patient was misdiagnosed with irreversible anoxic brain damage and taken to the operating theatre for donation after circulatory death (DCD), where she “opened her eyes and looked at the lights. Pursuit of DCD was subsequently halted”. See Department of Health and Human Services report 19/08/2010, available at <https://www.scribd.com/document/148583905/U-S-Centers-for-Medicare-and-Medicaid-Services-report-on-St-Joe-s> (accessed 02/10/17). Also H. Whiteman, ‘Patient Presumed Dead Wakes up Moments Before Organ Donation Surgery’ (Medical News Today, 11 July 2013).

²⁰⁵ There do not appear to be any published clinical trials on the risks of elective ventilation inducing a permanent vegetative state and none are referred to in the NICE guidelines.

²⁰⁶ NICE *Improving donor Identification* as earlier p.6 [1.1.4].

needed to make a decision, yet be unable to express a decision due to damage to the language and/or motor parts of their brain.²⁰⁷ However, legally a lack of ability to communicate a decision by any means encompasses the patient identified as a potential organ donor within the definition of mental incapacity.²⁰⁸ Their treatment is therefore guided by the legal principle of best interests.

The Assessment of Best Interests

Healthcare professionals now have several policy documents that claim to guide them on the assessment of the best interests of the potential organ donor.²⁰⁹ The 2009 DoH guidance followed closely on from the ODT report's recommendations on making donation a usual part of end-of-life care and represents a significant move from their earlier 1994 guidance, which reflecting the law at the time, had entirely excluded organ donation from the "patient's own benefit".²¹⁰ The 2009 guidance is specifically aimed at donation after cardiac death,²¹¹ yet the interpretation of best interests contained within might also be applied by healthcare professionals to donation after brain death (DBD). The guidelines begin with an important proviso, and one that is not so readily apparent in the NICE guidelines,²¹² which is that as "best interests depend on their individual circumstances, it is not possible to say categorically whether a specific action will always be in every patient's best interests".²¹³ The individual nature of best interests means that potential organ donors cannot be simply treated as a group or as a resource from which to obtain organs.

²⁰⁷ This is considered in more detail in Chapter 4.

²⁰⁸ MCA 2005 3(1)(d).

²⁰⁹ Most notably NICE, *Improving Donor Identification* as earlier; DoH, *Legal Issues* as earlier; UKDEC *Ethical Framework* as earlier; see review article by P. Matthews, 'Organ Donation: Development and Practicalities' (2012) 7 *Clin Ethics* 122-127.

²¹⁰ DoH, HSG(94)41 as earlier.

²¹¹ DoH, *Legal Issues* as earlier, p.4 [1.1-1.3].

²¹² NICE, *Improving Donor Identification* as earlier, p.7 [1.1.6-1.1.7].

²¹³ DoH, *Legal Issues* as earlier, p.4 [1.5]. Quote modified for clarity.

Although the 2009 DoH guidance requires that “individual decisions are made in that person’s best interests”,²¹⁴ they only appear to extend the individual nature of the decision to the “person’s wishes...to be a donor”²¹⁵ and not to the person’s wishes regarding their end-of-life care. However, they also protect prospective donors from harm by limiting “actions to facilitate donation” to those that “do not cause the person harm or distress or place them at a material risk of experiencing harm or distress”.²¹⁶ They require clinicians to consider the risks of physical harm and the patient’s interests in personal dignity, and to balance these risks against the patient’s wish to donate, as part of the best interests decision and before actions to facilitate organ donation are carried out.²¹⁷ All of these safeguards are lacking from the 2011 NICE guidance. NICE place no limits on life-sustaining treatments “provided that delay is in the patient’s best interests”;²¹⁸ there is no specific requirement to assess the risk of harm; and actions to facilitate organ donation are initiated “while assessing the patient’s best interests”²¹⁹ and not after the best interests determination.

The NICE recommendations on assessing best interests are problematic in a number of ways, not least because of the timing of the best interests determination and the transfer of the patient to intensive care for unlimited life-sustaining treatments, “until the patient’s wishes around organ donation and the clinical potential for the patient to donate has been assessed”²²⁰. As McGee and White recognise,

²¹⁴ Ibid, p.5 [1.7].

²¹⁵ Ibid, p.5 [1.6].

²¹⁶ Ibid, p.5 [1.6].

²¹⁷ Ibid, p.8 [5.2-5.4].

²¹⁸ NICE, *Improving Donor Identification* as earlier, p.7 [1.1.7].

²¹⁹ Ibid, p.7 [1.1.6].

²²⁰ Ibid, p.7 [1.1.7].

we need to know how to determine this question on a case by case basis, without falling into the trap of erecting a presumption that it is always in the patient's best interests to be placed on ventilation [and/or other interventions] pending discovery of their wishes.²²¹

Such a presumption would be inconsistent with recent judicial interpretation of the MCA provisions on best interests.²²² As Justice Munby emphasises, "it all depends, it must depend, upon the individual circumstances of the particular case".²²³ His use of the word "must" precludes the reliance on a "good enough chance"²²⁴ that authors such as Coggon consider sufficient. It is not good enough for any dying patient to be treated in a way that subsequently proves to be against their best interests, and such treatment does not reflect the individualistic nature of the law.²²⁵

Policy-writers aiming to improve organ donation and transplantation rates, and academics arguing in favour of encompassing those policies within the current law, are motivated by the interests of the many patients who die whilst awaiting organ transplants. My thesis holds those interests to be important, but not at the expense of the individual interests of patients identified as potential organ donors. The law as it stands reflects the principle of precedence of individual interests, which states that the interests of the individual should always prevail over societal and/or scientific interests.²²⁶ The MCA provisions are clear: interventions for the benefit of potential organ recipients can only be carried out if they are in the individual best interests of the potential organ donor. Moving

²²¹ A. McGee & B. White, 'Is Providing Elective Ventilation in the Best Interests of Potential Donors' (2013) 39(3) *J Med Ethics* 135-138, 136, ['Providing Elective Ventilation'].

²²² McGee & White, 'Providing Elective Ventilation' as above, 137.

²²³ *In Re M* [2009] EWHC 2525 (Fam) [35]

²²⁴ Coggon, 'Elective Ventilation' as earlier, 132.

²²⁵ This is evaluated in more detail in Chapter 4.

²²⁶ This principle appears in a number of ethical guidelines, including the Universal Declaration on Bioethics and Human Rights (2005) (Article 3, para. 2); see table 1 in J. Piasecki, M. Waligora, V. Dranseika, 'Non-beneficial Pediatric Research: Individual and Social Interests' (2015) 18(1) *Med Health Care and Philos*, 103-112, 105 ['Non-beneficial Research']; the principle is considered in more depth in Chapter 4; see also Brown, 'Legal Justification' as earlier, p. 125.

away from the principle of precedence of individual interests poses significant risks to both public trust and to the supply of organs.²²⁷ To protect against these risks, I aim in this thesis to demonstrate that it is possible to make changes to policy and practice that remove any perceived need to treat a patient in a way that may transpire to be against their individual best interests.²²⁸

The NICE guidelines do consider the patient's wishes, but only after they have been transferred to a critical care setting for unlimited life-sustaining treatments, and even then there are problems meeting the requirements of the mental capacity legislation. NICE only specify the need to consider the patient's wishes regarding deceased organ donation and make no mention of their wishes regarding end-of-life care.²²⁹ NICE equates the patient's "prior consent" to organ donation, including any views expressed to relatives,²³⁰ with donation being an integral part of their end-of-life care.²³¹ The guidance does not require any inquiry into the patient's wishes regarding their end -of-life care, or the input of relatives with knowledge of these, but instead " a clear explanation of.....what interventions may be required between consent and organ retrieval " and "what end of life care involves and where it takes place".²³² This puts the patient's wishes regarding their own end-of-life care into a position of lower importance than their wishes (or those of their relatives) regarding deceased organ donation itself. However, a potential organ donor's wishes regarding their end-of-life care may, for some individuals and in some circumstances, be the deciding factor in the determination of their best interests. As I will argue in Chapter 4, these wishes, together with

²²⁷ I evaluate the relationship between individual autonomy, trust, and the supply of organs in Chapter 2.

²²⁸ I outline my proposed policy changes in Chapter 3-4 and consider their impact on the supply of organs in Chapter 6.

²²⁹ NICE, *Improving Donor Identification* p.7 [1.1.8]

²³⁰ *Ibid*, p.7 [1.1.9].

²³¹ *Ibid*, p.8-9 [1.1.15 & 1.1.21].

²³² *Ibid*, p.10-11 [1.1.22 & 1.1.25]

the individual's risk-benefit preferences, should be included within the best interests determination of the potential organ donor to meet the requirements of section 4(6) of the MCA.²³³

Ante-Mortem Interventions to Facilitate Organ Donation

Organ procurement policies do not always specify which interventions may be required to encompass organ donation within the end-of-life care of the potential organ donor. The 2009 DoH report, for example, states that the “guidance cannot cover in detail all possible interventions but in each case the general principles....will apply”.²³⁴ The NICE guidance does not attempt to delineate what specific interventions might be included within best interests, but instead uses the capacious terminology of “clinical stabilis[ation]”²³⁵ to encompass unlimited life-sustaining treatments²³⁶ and to leave any further interpretation to healthcare professionals.

In common with the original Exeter protocol on elective ventilation, in which “the degree of intensive treatment” is purely a matter for discussion between the hospital consultants,²³⁷ there is little transparency within the NICE clinical guidance as to what intensive treatments the potential organ donor might be subject to in practice. Hospital consultants themselves have interpreted the interventions required by the NICE guidance along the lines that:

²³³ See also *Brown*, ‘Legal Justification’ as earlier, p.124-125.

²³⁴ DoH, *Legal Issues* as earlier p.10 [6.12].

²³⁵ NICE, *Improving Donor Identification* p.7 [1.1.6].

²³⁶ *Ibid*, p.7 [1.1.7] see also *Brown*, ‘Legal Justification’ as earlier, 123.

²³⁷ *Feest et al*, ‘Protocol for Increasing Organ Donation’ as earlier, 1133.

[i]n practice, stabilisation of such patients would probably involve the insertion of multiple cannulae for drug and fluid infusions to maintain circulation, tracheal intubation for mechanical ventilation, and sedation to allow the patient to tolerate these interventions.²³⁸

Academics have also interpreted the NICE recommendations as requiring some form of non-therapeutic or “elective” ventilation.²³⁹ The requirements that the patient is stabilised in a critical care setting, such as the intensive care unit, and that life-sustaining treatments should not be limited, seem difficult to meet without recourse to non-therapeutic ventilation.

However, the guidelines avoid referring to mechanical ventilation, and the recent UK Donation Ethics Committee discussion paper on elective ventilation claims that it has not been practised in the UK since 1994,²⁴⁰ when it was abandoned following the publication of DoH guidance declaring it unlawful.²⁴¹ The lack of transparency means it is unclear what interventions are being practised and could potentially be practised as part of the end-of-life care of the potential organ donor.

The UK Donation Ethics Committee (UKDEC) was established in 2010 following the recommendations of the Organ Donation Taskforce (ODT) in their 2008 report.²⁴² In contrast to NICE’s brief to produce a guideline specifically aimed at increasing donor identification and consent rates, UKDEC was asked to advise on and provide resolution to the ethical complexities surrounding organ donation and transplantation.²⁴³ Before being disbanded in 2016, UKDEC published several reports including generic guidance on balancing the best

²³⁸ *Wilkinson et al*, ‘Actively Delaying Death’ as earlier, 1179.

²³⁹ *McGee and White*, ‘Providing Elective Ventilation’ as earlier; *Coggon*, ‘Elective Ventilation’ as earlier.

²⁴⁰ UKDEC, *Non-Therapeutic Elective Ventilation* (Discussion Paper, April 2016).

²⁴¹ HSG (94) 41 as earlier.

²⁴² ODT, *Organs for Transplants*’ as earlier, p.9 recommendation 3; UKDEC, *Ethical Framework* as earlier, p.5 [iv].

²⁴³ UKDEC, *Ethical Framework* as earlier, p.5 [iv].

interests of the potential organ donor,²⁴⁴ one specific application of that guidance to extubation,²⁴⁵ and a discussion paper on elective ventilation.²⁴⁶ UKDEC recognised, in contrast to NICE, both the need to make a specific best interests determination for each intervention and the need to take a balanced view of the risk of both physical harm and the ethical wrong of not acting in accordance with the patient's wishes.²⁴⁷ However, although it recognised the ethical wrong of acting against an individual's wishes for their end-of-life care,²⁴⁸ UKDEC focused most of their attention on not "frustrating" the patient's wishes to become an organ donor.²⁴⁹

The particular interventions that may fall within the best interests of a potential organ donor are justified by UKDEC in terms of their potential to optimise that patient's chances of successful organ donation, and are recommended to be the minimum level of intervention consistent with this justification.²⁵⁰ This is important in terms of achieving benefit through organ donation and keeping harms to a minimum, but it does not encompass the benefit gained through following the patient's own risk-benefit preferences in end-of-life care,²⁵¹ which are afforded relatively low priority in the UKDEC guidance. Although UKDEC state that "consent to a particular intervention in advance of the loss of capacity should be regarded as compelling evidence"²⁵² that that intervention would be a benefit to the patient, they do not address the problem that no information on or opportunity to provide consent to any ante-mortem donor optimisation procedures is widely available to the general public. This appears

²⁴⁴ UKDEC, *Interventions before Death to Optimise Donor Organ Quality and Improve Transplant Outcomes: Guidance from the UK Donation Ethics Committee* (September 2014), ['Interventions Before Death'].

²⁴⁵ UKDEC, *Extubation: An Application of UKDEC's Generic Guidance on Interventions Before Death to Optimise Donor Organ Quality and Improve Transplant Outcomes* (October 2014) ['Extubation'].

²⁴⁶ UKDEC *Non-therapeutic Elective Ventilation* as earlier.

²⁴⁷ UKDEC, *Ethical Framework* as earlier, p.17.

²⁴⁸ *Ibid*, p.16 [1.4.3].

²⁴⁹ *Ibid*, p.16, [1.4.4].

²⁵⁰ UKDEC, *Interventions Before Death*, [4].

²⁵¹ This is evaluated in Chapter 4.

²⁵² UKDEC, *Interventions Before Death*, [15]. Quote modified for clarity.

to be out of concern that providing this information and opportunity to consent could “put people off” signing up to the ODR.²⁵³

UKDEC’s work has now been discontinued, after the English DoH declared its work “largely complete”.²⁵⁴ This is despite UKDEC not having completed its guidance on specific interventions, this being limited to one report on extubation,²⁵⁵ and the recommended work in its discussion paper on non-therapeutic ventilation remaining undone.²⁵⁶ As recognised by one of its members, it is indeed troubling that healthcare professionals now have no independent body to consult with specific expertise in the law and ethics surrounding organ donation.²⁵⁷ This may lead them to turn more to the medical literature for ethical and legal advice on what interventions might be encompassed within best interests. One of the most recent of the articles they could turn to emphasises the use of “goal directed” donor management to “reflect current best practice in intensive care with invasive monitoring, lung protective ventilation, fluid optimisation and inotropic support”.²⁵⁸ The article uncritically states “in the UK, the law allows for changes in treatment, such as administration of intravenous fluids, increase in oxygen and adjustments to vasopressor stability until retrieval can take place”.²⁵⁹ In view of the legal and ethical complexities in this area, healthcare professionals need more detailed guidance from an independent body on how to determine whether a specific intervention is within the individual best interests of a patient identified as a potential organ donor. Perhaps even more importantly, the general public needs guidance

²⁵³ UKDEC, *Ethical Framework* as earlier, p.55 [3.1.1]. Quote adapted for clarity.

²⁵⁴ D. Shaw, ‘The Untimely Death of the UK Donation Ethics Committee’ (2017) 43(1) *J Med Ethics* 63-64, 63 [‘Untimely Death’].

²⁵⁵ UKDEC, *Extubation* as earlier.

²⁵⁶ UKDEC, *Non-therapeutic Elective Ventilation* as earlier.

²⁵⁷ D. Shaw, ‘Untimely Death’ as above, p.64.

²⁵⁸ C. Findlater & E. Thomson, ‘Organ Donation and Management of the Potential Organ Donor’ (2015) 16(7) *Anaesthesia and Intensive Care Medicine* 315-320, 317. [‘Organ Donation’].

²⁵⁹ Findlater & Thomson, ‘Organ Donation’ p.319.

on what specific interventions might be included within their best interests and how to make a decision in advance regarding these changes to their end of life care.

A survey of English NHS trusts in 2012 found that on referral of a patient for consideration of donation after circulatory death (DCD), 92 out of 119 responding trusts used vasoactive agents to maintain blood pressure and 89 used at least one method to optimise oxygenation, including a ventilatory strategy known as positive end-expiratory pressure.²⁶⁰ At least 8 centres used heparin pre-mortem to thin the blood, at least 5 centres cannulated femoral vessels pre-mortem, and at least 2 centres gave phentolamine (a vasodilator) pre-mortem to optimise the perfusion of organs for transplantation.²⁶¹ However, a further 25, 14 and 21 respondents respectively did not know whether or not these interventions were used in their institutions.²⁶² This suggests that the lack of knowledge surrounding what interventions are being used in practice extends to the healthcare professionals implementing donor optimisation policy.

Although the NICE guidelines are intended to facilitate DCD,²⁶³ they do not stipulate how death should be diagnosed and some potential organ donors identified under the guidelines will go on to have their death diagnosed in accordance with brain-stem death criteria.²⁶⁴ There is no clear distinction between the ante-mortem interventions that may be performed in either scenario, although mechanical ventilation is necessary for the diagnosis of

²⁶⁰ Patel *et al*, 'Survey of Current Practice' as earlier, p.2220-2221, data given in table 1; see also C. Towe, F. Zafar, J. Johnson, J. Tweddell *et al*, 'Impact of Donor Positive End Expiratory Pressure on Lung Utilization Rates and Short and Long Term Outcomes' (2016) 35(4) Supplement *J Heart Lung Transplant* S135-S136.

²⁶¹ Patel *et al*, 'Survey of Current Practice' as above, p. 2221 table 1 & 2222.

²⁶² Ibid.

²⁶³ NICE, *Improving Donor Identification* as earlier, p.6 [1.1.2].

²⁶⁴ Ibid, p.11 [1.1.25- 1.1.26].

brain-stem death.²⁶⁵ Interventions to achieve haemodynamic and ventilatory stability are undertaken both before and after a diagnosis of brainstem death,²⁶⁶ and the NICE guidelines extend these interventions to an even earlier stage before brainstem death is suspected.²⁶⁷ Measures to achieve the physiological stability necessary to undertake brainstem testing are driven, at least in part, by the need to improve organ transplantation rates.²⁶⁸ The extension of clinical stabilisation to an earlier stage is not done for the clinical benefit of the patient and, as is also the case with ante-mortem interventions to facilitate DCD, may cause the patient physical harm.

NICE gives no guidance on the physical harm that could result from ante-mortem interventions to facilitate organ donation. UKDEC gives only limited guidance, with examples of physical harm given including “pain, discomfort, shortening the patient’s life and worsening the patient’s medical condition”.²⁶⁹ However, each ante-mortem donor optimisation procedure has a specific risk profile and the law requires that these risks are included in the determination of the best interests of the potential organ donor. Heparin administration, for example, is known to carry significant risks, including haemorrhage – which could potentially lead to a more immediate death.²⁷⁰ The risks of mechanical ventilation include tracheal rupture, cervical spine injury, arrhythmias, aspiration pneumonia, pneumothorax, ventilator-

²⁶⁵ AMRC Code of Practice as earlier, p. 18 [6.1.6]

²⁶⁶ *Donor Optimisation Guideline for Management of the Brain-Stem Dead Donor*, as accessed on 11/09/2017 from http://odt.nhs.uk/pdf/donor_optimisation_guideline.pdf, p.2; see also D. McKeown, R. Bonser, & J. Kellum, ‘Management of the Heart-Beating Brain-Dead Organ Donor’ (2012) 108 (S1) *BJA* i96–i107, [‘Brain-Dead Organ Donor’]

²⁶⁷ NICE, *Improving Donor Identification*, p.6 [1.1.2].

²⁶⁸ See ODT, *Organs for Transplants* as earlier, p.13 Recommendation 7 p.36 [4.20].

²⁶⁹ UK Donation Ethics Committee, *Generic Interventions Guidance: Interventions Before Death to Optimise Donor Organ Quality and Improve Transplant Outcomes* (2014), [9].

²⁷⁰ E. Motta, ‘The Ethics of Heparin Administration to the Potential Non-Heart-Beating Organ Donor’ (2005) 21(2) *J Prof Nurs* 97-102, 99-100.

associated pneumonia,²⁷¹ and inducing a permanent vegetative state.²⁷² Femoral cannulation is associated with vascular complications including bleeding, haematomas, and perforation or dissection of the common femoral artery.²⁷³ The existence of these risks, in the absence of knowledge of the patient's own risk-benefit preferences in the circumstances, present significant problems in encompassing ante-mortem donor optimisation procedures within the best interests of the potential organ donor.²⁷⁴

The Human Rights of the Potential Organ Donor

Donor optimisation policies that do not include the consent of the potential donor and that may be against the best interests of the potential donor are open to challenge both in relation to their lawfulness and to their compatibility with the European Convention on Human Rights (ECHR). I will evaluate the policies in terms of ECHR compatibility in Chapter 5, in which I particularly evaluate the potential for a challenge under Article 8. This ECHR compatibility is important within domestic law as policy-makers, law-makers, the healthcare system, and the organ donation programme all have obligations under the Human Rights Act 1998 (HRA) to avoid acting in a manner incompatible with Convention rights.²⁷⁵ All UK legislation, including the MCA 2005, must "so far as it is possible to do so...be read and given effect in a way which is compatible with the Convention rights".²⁷⁶ Organ procurement policy-makers are obliged to

²⁷¹ A. Hasan, *The Complications of Mechanical Ventilation*, Chapter 10 in A. Hasan, *Understanding Mechanical Ventilation: A Practical Handbook* (2nd edition, Springer, Dordrecht Heidelberg London New York, 2010) 305-341.

²⁷² *New et al*, 'King's Fund Report' as earlier, 64; A. Browne, G. Gillett, & M. Tweeddale, 'The Ethics of Elective (Non-therapeutic) Ventilation' (2000) 14(1) *Bioethics* 42-57, 46; G. Gillett, 'Brain Death, Vegetative State and the RUB' (1999) V11(2) *Issues Med Ethics*, 54-55.

²⁷³ See eg. A. Seto, M. Abu-Fadel, J. Sparling *et al*, 'Realtime Ultrasound Guidance Facilitates Femoral Arterial Access and Reduces Vascular Complications: FAUST Femoral Arterial Access with Ultrasound Trial' (2010) 3(7) *JACC: Cardiovascular Interventions* 751-758, 755; T. Bisdas, G. Beutel, G. Warnecke *et al*, 'Vascular Complications in Patients Undergoing Femoral Cannulation for Extracorporeal Membrane Oxygenation Support' (2011) 92(2) *Ann Thorac Surg* 626-631, 628.

²⁷⁴ This is considered in more detail in Chapter 4.

²⁷⁵ S. 6.

²⁷⁶ HRA S. 3.

take into account the interpretation of Convention rights, as developed in the judgements of the European Court of Human Rights (ECtHR), and produce a ECHR-compatible model.

Non-consensual medical treatment, including treatment for the benefit of others, falls within the scope of the Article 8 right to respect for private life.²⁷⁷ Non-consensual donor optimisation procedures interfere with the individual's autonomy and their bodily integrity, both of which the ECtHR have interpreted as being central to the achievement of the right to private life.²⁷⁸ Article 8(2) clarifies that "[t]here shall be no interference by a public authority with the exercise of this right except such as in accordance with the law and is necessary in a democratic society" for a number of legitimate aims, including "for the protection of the rights and freedoms of others". Non-consensual donor optimisation procedures must therefore both have a clear legal basis and be necessary to protect the rights of potential organ recipients. This clear legal basis does not currently exist and, as I will argue in Chapter 5, the rights of potential organ recipients are not best protected by inflicting non-consensual and non-therapeutic interventions on incapacitated patients.

A lack of consent for donor optimisation procedures could have as its consequence a lack of dignity in death.²⁷⁹ Undignified treatment at the end of life falls within the scope of the Article 3 right not to be subjected to inhuman or degrading treatment.²⁸⁰ This is an absolute right and it applies to all, including incapacitated patients identified as potential organ donors. Although the threshold for coming within the scope of Article 3 is high, the prospective for ante-mortem donor optimisation procedures to violate the Article 3 rights of an individual remains. Dignity, bodily integrity, and autonomy are all central to human rights law, which as I

²⁷⁷ *Pretty v United Kingdom* (App no. 2346/02) (2002) 35 EHRR 1 [63]; *Herczegfalvy v Austria* (App no. 10533/83) (1992) 15 EHRR 437

²⁷⁸ *Tysiac v Poland* (App no. 5410/03) (2007) 45 EHRR 947; *Pretty v UK* as above [61].

²⁷⁹ The relationship between autonomy and dignity is explored in Chapter 2.

²⁸⁰ See eg. *M.S. v United Kingdom* (App no. 24527/08) (2012) 55 EHRR 23, particularly [38-46].

will argue in chapter 5, requires that these ethical concepts are respected, protected, and promoted for all individuals who are or could be identified and treated as potential organ donors.

Autonomy and Specific Advance Consent

A clear and unequivocal legal justification for ante-mortem donor optimisation procedures, as promulgated in recent UK organ procurement policies, does not exist within current UK law. Patient autonomy presents the key ethical and legal challenge in encompassing current policy and practice within the law. This challenge stems from the limited information and involvement of ODR registrants and the wider public in decisions about that part of the organ donation process which begins before death. The limited opportunity for advance decision-making generates problems in determining the best interests of the incapacitated organ donor. The policies themselves generate problems by requiring the introduction of donor optimisation procedures before the patient's wishes have been determined and by focusing on the patient's wishes regarding organ donation rather than on their wishes regarding their end-of-life care.

The overarching claim I make in this thesis is that the specific advance consent of the potential organ donor is required to provide ante-mortem donor optimisation procedures with a clear and unequivocal legal justification within the current legal framework. The thread running throughout all six chapters is autonomy. The ethical foundation for the thesis is provided in Chapter 2, in which I evaluate autonomy as an ethical concept and explore the value of incorporating autonomy into donor optimisation policy. This exploration includes the value of autonomy in maintaining long-term trust in the organ donation programme. In Chapter 3, I evaluate autonomy as a legal concept, its relationship to informed consent, and the law on advance decision-making. In Chapter 4, I analyse the problems encompassing donor optimisation procedures within the best interests of the potential organ donor. I

identify that these problems mostly revolve around patient autonomy and suggest a system of specific advance consent as a way of resolving these problems.

I aim to demonstrate in this thesis that my proposed system of specific advance consent is not in conflict with the interests of potential organ recipients. Two chapters look at the relationship between the autonomy of potential organ donors and the interests of others in society. These chapters look at this relationship from different angles and both conclude that these factors are not in opposition. In Chapter 2, I identify that the organ donation programme's reliance on blind trust presents significant risks to achieving its aim of an adequate supply of organs. I argue that the incorporation of autonomy into donor optimisation policy is needed to safeguard against these risks. In Chapter 5, I evaluate what the public interest in donor optimisation procedures requires, what its relationship is to the individual interests of the potential organ donor, and how this relationship is perceived under human rights law. I argue that incorporating autonomy into donor optimisation policy is needed to meet the public interest and to fulfil the requirements of human rights law. In the final chapter of my thesis, I consider what the impact on the supply of organs of my proposed system is likely to be and present arguments as to why it should be introduced even though, as with any other changes to healthcare policy, the impact cannot be definitively determined in advance.

2. Autonomy, Trust, and the Supply of Organs

Introduction

As identified in Chapter 1, autonomy is at the centre of the legal problems presented by policies that change the end-of-life care of one group of patients to facilitate the donation of their organs to others.¹ Patients undergoing ante-mortem donor optimisation procedures have not been informed about these procedures nor given an opportunity to formulate their own autonomous decision. Before analysing the legal problems presented by the exclusion of autonomy from donor optimisation policy,² I attempt to set out in this chapter why it matters ethically that this is redressed. I consider this question both in relation to potential organ donors and in relation to others in society. To address the importance of autonomy to potential organ donors, I examine its intrinsic and instrumental value, before explicating its relationship with dignity and integrity. I argue that, because of autonomy's relationship with dignity and integrity, the value of autonomy remains even when autonomy is gone. In the latter half of the chapter, I focus on why the inclusion of autonomy in donor optimisation policy is of value for potential organ recipients, by evaluating the relationship between autonomy, trust, and the supply of organs.

I begin the chapter by looking at the basic principle underlying most philosophical accounts of autonomy. I identify this principle as self-determination and argue that this provides autonomy with a vital core. This core reflects the origin of the word "autonomy" -

¹ See particularly National Institute for Health and Care Excellence (NICE), *Organ Donation for Transplantation: Improving Donor Identification and Consent Rates for Deceased Organ Donation* (Clinical Guidance 135, 2011, updated 2016) [*Improving Donor Identification*].

² This legal analysis will be performed in Chapters 3-5.

from the Greek *autos* (“self”) and *nomos* (“rule” or “law”)³ - and captures the essence of what autonomy is about. It is about individual choice, about being free and able to formulate and act on one’s own wishes, and ultimately about having control of one’s own life. Incorporating this core of self-determination into donor optimisation policy is, I argue, of both intrinsic and instrumental value to the individuals who may be subject to these procedures.

Although many patients will have lost the ability to make an autonomous choice by the time they are identified as potential organ donors, future-orientated self-determination in relation to donor optimisation procedures remains of value. I argue that this is because self-determination has an important role in protecting the related considerations of dignity and integrity, which are not diminished by a loss of capacity at the end of life. Dignity, like self-determination, recognises the individual’s critical interests and requires that dying patients are not treated in a way that denies the personal values by which they have lived their lives.⁴ Integrity allows the narrative by which an individual has lived their life, including the ethical commitments they have made, to continue even when they have lost capacity to express a choice.⁵ These considerations recognise the moral status of the dying incapacitated potential organ donor as equal to that of competent individuals.

While the first half of this chapter focuses on what autonomy is and why it is of value to potential organ donors, in the second half of the chapter I address why it is of importance to potential organ recipients. I do this by examining the relationship between autonomy, trust, and the supply of organs. Trust is the “confidence in one’s expectations”⁶ that enables people to cooperate with healthcare practices and it can be crucial to delivering the aims of

³ G. Dworkin, ‘Autonomy and Behaviour Control’ (February 1976) 6 *Hastings Cent Rep* 23-28, 23; T. Beauchamp & J. Childress, *Principles of Biomedical Ethics*, (6th edition, OUP, New York and Oxford, 2009) 99.

⁴ R. Dworkin, *Life’s Dominion* (Harper Collins, London, 1993) 236-7 [*Life’s Dominion*].

⁵ *Ibid*, 205.

⁶ N. Luhmann in *Trust and Power* (John Wiley and Sons, Chichester 7 New York, 1979) [*Trust and Power*] p.4.

healthcare policy. The interaction of autonomy with trust in decision-making seems to be critically important to securing the supply of organs for transplantation, yet the nature of the interaction is disputable.⁷ I present arguments in this chapter as to why, in the specific circumstances of ante-mortem donor optimisation procedures, the long-term maintenance of trust is dependent on the inclusion of autonomy.

I argue in the chapter that the type of trust conferred has serious consequences for the supply of organs. I distinguish between two types of trust, each of which fulfils trust's role of enabling individuals to cooperate with healthcare practices. The first, blind or uninformed trust, based on ignorance of the facts, is currently relied upon by the organ donation programme. However, it is a precarious form of trust that can readily be replaced by distrust should the true nature, timing, and risks of the organ donation process be revealed. The second type of trust, informed trust, is based on accurate information regarding the possible future consequences of the decision and is a sense of security that only those consequences could ensue from agreeing to the healthcare practice. I argue that this is a more stable form of trust that would avoid the risk of being replaced by distrust and have a safeguarding effect on the supply of organs.

I begin the chapter by looking at some of the different philosophical accounts of autonomy and explicating the basic principle of self-determination. This principle will provide an ethical grounding for my subsequent legal chapter on autonomy as a legal concept and its role in informed consent and advance decision-making. It will also provide a foundation for the arguments made within the current chapter. In summary, these arguments are that self-determination in relation to donor optimisation procedures is of pivotal importance to both the individuals who could be subject to these procedures and to those individuals whose lives depend on the supply of organs.

⁷ See particularly O. O'Neill, *Autonomy and Trust in Bioethics* (CUP, 2002), ['Autonomy, Trust, Bioethics']

Autonomy as Self-determination

Most accounts, certainly most liberal accounts, of autonomy recognise the individual as having authority over their own life. They base this on a belief in the importance of the individual “leading [their life] from the inside, according to [their own] beliefs about value”.⁸ Most of these different accounts are founded on the notion of self-determination. Self-determination requires that the individual is capable of ruling themselves and that they have the freedom to do so. These requirements of self-determination are central to autonomy as generally understood. I explore some of the different understandings of autonomy in this section and conclude that self-determination provides autonomy with a vital core.

Although autonomy is said to be a “polysemous” concept,⁹ the notion of self-determination is indispensable to most of the different philosophical accounts of autonomy. The majority of modern accounts are informed by the work of Kant on autonomy of the will¹⁰ and/or the work of Mill in *On Liberty*.¹¹ These foundational works are both interpreted in this chapter as referring to some form of self-determination, yet can be distinguished on several grounds, including the precedence to be afforded to autonomy. They both contribute to the way that autonomy is perceived in healthcare law and policy and to how important it is deemed to be in relation to other considerations. The way that Kant’s and Mill’s work are interpreted and the degree to which each account informs healthcare law and policy may change the course of medico-legal decision-making. However, in some respects, most notably the basic principle on which they are based, these accounts are not as divergent as they may at first appear.

⁸ W. Kymlicka, *Liberalism, Community and Culture* (OUP, 1989) 12.

⁹ D. Garcia, ‘The Many Faces of Autonomy’ (2012) 33(1) *Theor Med Bioeth* 57-64, 58; Introduction in E. F. Paul, F. Miller, Jr., J. Paul, *Autonomy* (CUP, 2003) vii.

¹⁰ I. Kant, *Groundwork of the Metaphysics of Morals* (translated and edited by M. Gregor & J. Timmermann, revised edition, CUP, 2012) p.51-55 [4.439-4.445] [‘Groundwork’]

¹¹ J.S. Mill, *On Liberty and Other Writings* (CUP, 1989).

Kant's interpretation of morality is dominated by autonomy of the will,¹² which commits moral agents to the principles they have generated for themselves based on their own rational volition.¹³ All genuine moral requirements stem from these commitments, and not from values, principles, or ends that are externally imposed on the moral agent's will.¹⁴ The "idea of the will of every rational being as a universally legislating will" is fixed as the Categorical Imperative.¹⁵ This is upheld as one supreme law of morality and can also be expressed as a requirement to "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".¹⁶ This requirement includes promoting others' rationally chosen ends and avoiding coercion, deception, and oppression.¹⁷ Humanity commands respect because of autonomy of the will and, for Kant, neither autonomy, humanity, nor dignity can be qualified by external circumstances.

Mill's famous harm principle, that "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",¹⁸ does allow autonomy to be constrained by external circumstances. Mill prefers the term liberty, which he describes in several ways,¹⁹ including the freedom to act on one's own opinions.²⁰ However, he acknowledges in a letter to a friend that the central theme of his work is the principle of individual autonomy.²¹ He advocates this principle as a utilitarian, and

¹² Kant, *Groundwork*, see particularly p.51-52 [4:440]; A. Reath, *Agency and Autonomy in Kant's Moral Theory: Selected Essays* (OUP, 2006) 121-122 ['Agency and Autonomy'].

¹³ Kant, *Groundwork*, p.51-55 [4:440- 4:445]. T. Hill, 'Autonomy and Benevolent Lies', Chapter 3 in T. Hill, *Autonomy and Self-Respect* (CUP, 1991) 25-42, 29-30.

¹⁴ Kant, *Groundwork*, p.51-55 [4:440- 4:445]; Reath, *Agency and Autonomy* as earlier, 122.

¹⁵ Kant, *Groundwork*, p.43-44 [4:431- 4:432].

¹⁶ Ibid, p.41 [4:429].

¹⁷ See Introduction by C. Korsgaard in revised CUP edition of *Groundwork*, as above, xxv.

¹⁸ Mill, *On Liberty* as earlier, p.13 .

¹⁹ Ibid, particularly 15-16.

²⁰ Ibid, 56-74; C. Gauthier, 'Philosophical Foundations of Respect for Autonomy' (1993) 3(1) *Kennedy Inst Ethics J* 21-37, 25.

²¹ J. S. Mill, 'Letter to Emile Acolas' in J. S. Mill, H. Elliot, & M. Taylor, *The Letters of John Stuart Mill* (Vol. 2, Longman, Green and Company, 1910) 308-9.

his harm principle is intended to be applied in the way that best advances overall welfare.²² However, determining whether or not overall welfare will be advanced by exercising power over an individual can be problematic. The prevention of harm to others is the only purpose where overall welfare might be considered a justifiable reason for compelling an individual to undergo medical interventions. However, in the circumstances of donor optimisation procedures, non-consensual medical interventions may not necessarily result in an increase in overall welfare. The aim of preventing harm to others could be thwarted by the withdrawal of trust from healthcare practices and its replacement by the more pernicious concept of distrust. As I will argue in the second half of this chapter, in the context of an organ donation programme that includes some element of individual choice, this has serious consequences for the supply of organs.

Modern liberal conceptions of personal or individual autonomy view self-determination as positive in nature, and include the opportunity “to form, to revise, and rationally to pursue a conception of the good”.²³ This conception of the good refers to a plan for living that an individual uses as a basis for making and reflecting on their decisions and for “scheduling his enjoyments and setbacks”.²⁴ Each individual’s conception of a good life defines what is to be regarded as a setback or a benefit to that individual, and it defines the concerns that are of significance to that individual.²⁵ The individual is afforded control of their own lives, following plans and ideals that they themselves have chosen.²⁶ To lead an autonomous

²² See commentary by R. Gillon, ‘Autonomy and the Principle of Respect for Autonomy’ (1985) 290 (6484) *BMJ (Clinical Research edition)* 1806-1808; also D. Molyneux, ‘Should Healthcare Professionals Respect Autonomy Just Because it Promotes Welfare?’ (2009) 35(4) *J Med Ethics* 245-250, 246.

²³ P. Roberts, ‘Privacy, Autonomy, and Criminal Justice Rights’ in P. Alldridge & C. Brants, *Personal Autonomy, the Private Sphere and the Criminal Law* (Hart Publishing, Oxford and Portland Oregon, 2001) 59 [‘Privacy and Autonomy’]; J. Rawls, ‘Kantian Constructivism in Moral Theory’ (1980) 77(9) *J Philos* 515-572, 517 [‘Kantian Constructivism’].

²⁴ J. Waldron, ‘Legislation and Moral Neutrality’ in J. Waldron, *Liberal Rights: Collected Papers 1981-1991* (CUP, 1993) 143, 161 [‘Legislation’]; Roberts, ‘Privacy and Autonomy’ as above, 59.

²⁵ Waldron, ‘Legislation’ as above 161; Roberts, ‘Privacy and Autonomy’, 59.

²⁶ J. Waldron, ‘Moral Autonomy and Personal Autonomy’ in J. Christman, J. & J. Anderson, *Autonomy and the Challenges to Liberalism* (CUP 2005) 307; Roberts, ‘Privacy and Autonomy’, 59.

life, the individual needs to be free to consider, reflect on, and choose the projects they will pursue in life.²⁷ This requires that individuals are able to make a choice that accords with their own values, interests, and specific viewpoint in the circumstances.²⁸ To achieve this positive conception of self-determination, individuals not only need to be free from unwanted interference but also to be afforded the opportunity to formulate and pursue their own conception of a good life. This conception requires far more in terms of the choices available than either Kant or Mill. Whilst Kant is concerned with moral agents and rational volition, and Mill with the prevention of harm and the maximisation of overall welfare, positive liberal conceptions are concerned with the individual being free and able to make a decision based on what is of personal importance to them.

The full realisation of the individual autonomy of potential organ donors is reliant on the presence of favourable social, cultural and political conditions.²⁹ These include living in a society that views personal choice as important; a culture of transparency relating to healthcare practices; and the presence of a policy and legal framework that enables their choices to be realised.³⁰ In relation to donor optimisation procedures, only the first condition is currently met. The latter conditions could be achieved by a policy and legal framework that facilitates a culture of transparency in the organ donation process and the achievement of the personal autonomy of ODR registrants. However, the full realisation of personal autonomy also requires the absence of coercive conditions that may negate the voluntariness of the individual's choice. These conditions are not limited to those presented by wider social, cultural and political circumstances. They may include other factors influencing an individual's decision that may be closer to home. For example, an individual might be conditioned throughout their life by their familial or religious beliefs to the extent that their choice is not

²⁷ Roberts, 'Privacy and Autonomy', 59.

²⁸ Ibid.

²⁹ Roberts, 'Privacy and Autonomy', 60.

³⁰ Ibid.

really their own.³¹ Although no individual's choices can be fully isolated from their personal development and social conditions,³² to be an autonomous choice each individual should be afforded an opportunity to formulate views and wishes of their own. For ODR registrants, this is only possible with the provision of information regarding donor optimisation procedures and the opportunity to reflect on this information free from coercive influences.

Relational accounts of autonomy may enable an evaluation of the options available within society and the social values and processes behind these options.³³ Relational autonomy does not repudiate the notion of autonomy as self-determination but attempts to refigure it to emphasise the social embeddedness of autonomous agents.³⁴ Relational approaches recognise that the development of autonomy occurs within the context of social relationships, practices, and institutions, and is shaped by a mesh of social determinants.³⁵ Some relational conceptions focus on the social constitution of the agent whereas others focus on the ways in which social relationships can either impede or enhance the capacity for autonomy.³⁶ Together, these relational accounts enrich and deepen understanding of the nature and conditions of autonomy and act as a counterbalance to claims that autonomy is an "obsessively individualistic, atomistic or even selfish" notion.³⁷ However, as Christman recognises, being autonomous does not mean having to "stand in proper social relations" to

³¹ J. Christman, 'Autonomy and Personal History' (1991) 21(1) *Can J Philos* 1-24, 6-10.

³² See, eg. M. Friedman, 'Autonomy and the Split-level Self' (1986) 24(1) *South J Philos* 19-35.

³³ S. Sherwin, 'Whither Bioethics? How Feminism Can Help Reorient Bioethics' (2008) 1(1) *Int J Fem Approaches Bioeth* 7-27, 12-13.

³⁴ C. Mackenzie & N. Stoljar, *Introduction: Autonomy Refigured* in *Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self* (OUP, 2000) 3-34, 4-5 & 12 ['*Relational Autonomy*'].

³⁵ *Ibid*, 4 & 17, citing D. Meyer, 'Personal Autonomy and the Paradox of Feminine Socialization' (1987) 84(11) *Journal of Philosophy* 619-628 & D. Meyer, *Self, Society and Personal Choice* (Columbia University Press, New York, 1989).

³⁶ Mackenzie & Stoljar, *Relational Autonomy*, 22.

³⁷ Roberts, 'Privacy and Autonomy', 61-62; A. Westlund, 'Rethinking Relational Autonomy' (2009) 24(4) *Hypatia* 26-27.

others in society and within social practices and institutions.³⁸ Socially embedded individuals are autonomous only when their position within social relationships permits them to act as a free agent according to their own principles, values, and preferences.³⁹ This freedom of self-determination is a defining feature of autonomy.

Dworkin considers that just about the only constant features between the various conceptions of autonomy are that it is a feature of persons and a desirable attribute to have.⁴⁰ However, these features do not help in defining what autonomy is and are of little practical use in medico-legal decision-making. Although there are differences between the various philosophical accounts, this does not mean that they represent “intrinsically different concepts”.⁴¹ There is a central theme running through the philosophical accounts I have explored in this section and this is self-determination. This core of self-determination reflects the way that autonomy is generally understood and informs the way it is generally used in medico-legal practice.⁴²

Christman recognises “the notions of self-government that autonomy is meant to express” as amounting to an “inner citadel”.⁴³ This recognition is based on a survey of some of the philosophical viewpoints towards the notions of self-government and autonomy.⁴⁴ Reviewing the concept of individual autonomy, he identifies self-government as “underl[y]ing at least the central use of the concept”.⁴⁵ In response to Feinberg’s work delineating the

³⁸ J. Christman, ‘Relational Autonomy, Liberal Individualism, and the Social Constitution of Selves’ (2004) 117(1) *Philos Stud* 143-164, 158. Quote adapted for clarity.

³⁹ *Ibid*, 158.

⁴⁰ Dworkin, G. *The Theory and Practice of Autonomy* (CUP, 1988) 6.

⁴¹ In contrast to Aveyard’s claims in H. Aveyard, ‘Is There a Concept of Autonomy That Can Usefully Inform Nursing Practice?’ (2000) 32(2) *J Adv Nurs* 356-357.

⁴² Autonomy as a legal concept will be evaluated in Chapter 3.

⁴³ J. Christman, ‘Constructing the Inner Citadel: Recent Work on the Concept of Autonomy’ (1988) 99(1) *Ethics* 109-121, 110& 121 [‘Inner Citadel’]; Also Introduction in J. Christman, *The Inner Citadel: Essays on Individual Autonomy* (Echo Point Books & Media, Vermont, 2014 edition) 3- 26.

⁴⁴ *Ibid*, 116-121.

⁴⁵ Christman, ‘Inner Citadel’, 109.

relationship between the different meanings of autonomy,⁴⁶ Christman identifies a connecting idea between all of the meanings proposed by Feinberg.⁴⁷ The meanings put forward by Feinberg - the capacity to govern oneself, the actual condition of self-government, an ideal of character derived from that conception, and the sovereign authority to govern oneself⁴⁸ - all centre on “the actual condition of autonomy defined as a psychological ability to be self-governing”.⁴⁹ They are all developments of the core concept of self-determination. Of Feinberg’s related ideas, the actual condition of self-government captures what has been referred to as the “connotative contours” of autonomy.⁵⁰ Self-government or self-determination encapsulates what autonomy is about and how it is generally construed.

Self-determination provides autonomy with its vital core and it is this self-determination that is of value to patients in medical decision-making. Explaining why this core of self-determination is of value and what this value is has been perceived as a “hard task” by some philosophers.⁵¹ However, as I discover in the next section, the value of self-determination to patients is fairly readily discernible with regard to both the making of autonomous decisions and having those decisions upheld.

⁴⁶ J. Feinberg, *The Moral Limits of Criminal Law, Volume 3: Harm to Self* (OUP, New York, 1986) 1-40 [*Harm to Self*] see particularly p.28.

⁴⁷ Christman, ‘Inner Citadel’, 110.

⁴⁸ Feinberg, *Harm to Self* as above, 28.

⁴⁹ Christman, ‘Inner Citadel’, 110.

⁵⁰ J. Taylor, *Practical Autonomy and Bioethics* (Routledge, UK, 2009) 50-51.

⁵¹ R. Young, ‘The Value of Autonomy’ (1982) 32(126) *Philos Q* 35-44, 35 [‘Value of Autonomy’] citing J. Feinberg, ‘Behaviour Control: Freedom and Behaviour Control’ in W.T.Reich, *Encyclopedia of Bioethics* (vol. 1, New York, 1979) 93-100.

The Value of Self-determination

Much of what is written on self-determination focuses on what it is and the conditions needed for it to be realised, rather than elucidating why it should be afforded value and what this value is. Those that do take a position on the value of self-determination seem to fall into two camps: those that consider it valuable for its own sake and those that claim its value lies in what it makes possible.⁵² However, this division is not as sharp as some authors claim. The value of self-determination for patients is both intrinsic and instrumental. Individual patients may value self-determination for its own sake and for the promotion of their well-being and the protection against iatrogenic harm which may result from its inclusion in healthcare practice.

Although the effects of self-determination on an individual's health are important, so is being the "architect and builder" of one's own life plan.⁵³ This may be particularly significant in circumstances where an individual is planning ahead to undergo interventions for the benefit of others in society. In these circumstances, making an autonomous decision may be worth experiencing for its own sake, suggesting that autonomy has an intrinsic value. However, this value may overlap with autonomy's instrumental value as the experience of making an autonomous decision can have a positive psychological effect on the individual, improving their sense of self-worth and affirming their personal identity. Autonomy not only affirms their personal identity but may also develop it, as the individual reflects on their own ethical commitments and values and is enabled to express these through their

⁵² Young, 'The Value of Autonomy' as above, 35; see also J. Rawls, 'Rational and Full Autonomy' (1980) 77 *J Philos* 515-35 & J. Friedman, 'Freedom has no Intrinsic Value: Liberalism and Voluntarism' (2013) 25(1) *Critical Review* 38-85.

⁵³ Young, 'Value of Autonomy' as above, 39.

decision.⁵⁴ Autonomy also protects against the negative psychological effects that often accompany “being the passive experiencer of...outcomes”.⁵⁵ Self-determination wards off the very real sense of a lack of control over future medical interventions and, ultimately, one’s own life and death. Both the positive effects on the individual’s personal identity and the protection against the negative effects that accompany constraints on self-determination are valuable functions of autonomy. The value of these functions remains, whatever the outcome of autonomous decision-making.

The effects of autonomous decision-making on the individual’s life and death, on undertakings that are important to them, and maybe on the lives of others in society, are also important considerations to determining the value of autonomy as self-determination. These effects often include an increase in intentional goals an individual achieves.⁵⁶ It is not just the making of the decision that is important but the achievement of an aspect of that individual’s life that is important to them. If a patient’s goal is to become a deceased organ donor at all costs, then the value to them of incorporating self-determination into donor optimisation policy could include an increase in their chances of achieving that goal. If, on the other hand, a patient’s goal was to die a dignified death unencumbered by medical technology, then the instrumental value of allowing them to make a decision in advance would include an improved chance of achieving that dignified death.

The instrumental value of self-determination is often conceived of as the promotion of well-being.⁵⁷ In the context of donor optimisation procedures, however, some of the

⁵⁴ T. Hurka, ‘Why Value Autonomy?’ (1987) 13(3) *Soc Theory Pract* 361-382, 364 [‘Why Value Autonomy?’].

⁵⁵ Young as above, ‘Value of Autonomy’, 39.

⁵⁶ Hurka as above, ‘Why Value Autonomy’ 367-368.

⁵⁷ See eg J. Varelus, ‘The Value of Autonomy in Medical Ethics’ (2006) 9 *Med Health Care Philos* 377-388, 377; see also J. Harris, ‘Consent and End of Life Decisions’ (2003) 29(1) *J Med Ethics* 10-15.

potential improvements in psychological well-being go hand-in-hand with the experience rather than the future consequences of making an autonomous decision. Although planning ahead to undergo donor optimisation procedures may be accompanied by positive psychological effects, it is not immediately obvious that it promotes the wellbeing of the donor once incapacitated. Choosing to undergo donor optimisation procedures does not promote the donor's medical wellbeing and may cause them harm.⁵⁸ It seems difficult to claim it will promote the psychological well-being of the patient once incapacitated, since it is not known whether they will be aware of undergoing donor optimisation procedures. However, both of these concerns can readily be addressed. First, having the option to refuse donor optimisation procedures does promote the medical well-being of the individual who could potentially be subject to these interventions in the future. It promotes their medical interests as the paramount consideration in their end-of-life care and protects them from the physical risks of invasive interventions at the end of life. Second, having the choice whether or not to undergo these interventions promotes the individual's values at the end of life, which can be encompassed within their broader psychological or axiological well-being.⁵⁹ It is also possible that some patients identified as potential organ donors may retain psychological interests, despite their apparent lack of capacity, and that their experiential psychological well-being could be promoted by having their decision followed.⁶⁰

Although most patients identified as potential organ donors do not have the ability to express any autonomy that they may retain, and are likely to have lost autonomy altogether, their antecedent autonomy – as I will argue in the next section - remains of value. The value of

⁵⁸ The physical risks of donor optimisation procedures were discussed in Chapter 1 and will be explored further in Chapter 4.

⁵⁹ By axiological well-being, I mean benefit gained by having their values realised. See E. Pellegrino, 'The Relationship of Autonomy and Integrity in Medical Ethics' (1990) 24(4) *Bull Pan Am Health Organ* 361-371 for an exploration of psychological and axiological integrity, or intactness of values. These concepts will be considered in the next section of this chapter.

⁶⁰ I will evaluate this further in Chapter 4.

treating an incapacitated potential organ donor as an individual with their own wishes and preferences is based on them retaining a moral status as a human being,⁶¹ one that is not diminished by their current incapacity. This moral status, and the related considerations of dignity and integrity, is upheld by measures that promote, protect, and realise precedent autonomy. Donor optimisation policies that exclude autonomy recognise neither the intrinsic moral worth of potential organ donors nor the role of precedent autonomy in securing the dignity and integrity of dying incapacitated patients. I explore the relationship between these concepts in the following section.

Self-Determination, Dignity, and Integrity

Self-determination, dignity, and integrity are all concerned with the protection of the moral status of the individual. The recognition of this moral status, as extending to all human beings, is an important protection against non-consensual interventions. As Warren remarks, “If an entity has moral status, then we may not treat it in just any way we please”.⁶² Even when the capacity to make an autonomous decision is lost, the individual – as I will outline in this section - retains an intrinsic moral worth and doctors are obliged to treat them with regard to this moral worth and not merely as a resource for others in society. This moral worth is the foundation of the concept of dignity, and is the reason why all incapacitated patients retain their bodily and psychological integrity. These concepts of dignity and integrity, and their relationship with moral worth, extend the concept of autonomy to cover the end-of-life care of the incapacitated potential organ donor.

I argue in this section that the close relationship with dignity and integrity requires that autonomy is included within donor optimisation policy. Dignity, as Dworkin recognises,

⁶¹ See M.A. Warren, *Moral Status: Obligations to Persons and Other Living Things* (OUP, 1997).

⁶² *Ibid*, 3.

upholds the “continued moral standing” of people who have lost capacity,⁶³ and requires that they are never “treated in a way that denies the distinct importance of their own lives”.⁶⁴ Integrity recognises the “steady, self-defining commitment[s]” the individual has made during their life and allows them to be met right up to, and maybe even beyond, the moment of death.⁶⁵ These considerations share with self-determination a concern with the intrinsic moral worth of the individual and with the values and commitments that are important to them. Both remain, or at least should remain, even when autonomy has gone. However, promoting and upholding future-orientated autonomy can be fundamental to their achievement.

Dignity is a concept that is inseparable from the intrinsic moral worth of the individual. The Latin for dignity, *dignitas*, itself derives from the Latin for worthy, *dignus*,⁶⁶ and this connection is also apparent in much of the philosophical literature.⁶⁷ For Kant, dignity is an “unconditional, incomparable worth” that is “infinitely above any price”.⁶⁸ All human beings have a legitimate claim to respect from others and “humanity itself is a dignity”.⁶⁹ Kant grounds human dignity in the ability of human beings to be autonomous and to have rational morality,⁷⁰ yet he presents dignity as a concept pertaining to all members of humanity. Dignity does not require that the individual retains autonomy, as it is grounded in the fundamental capacity of human beings to act morally rather than the individual’s actual capacity to act morally.⁷¹ Human dignity is understood as belonging to all human beings regardless of their

⁶³ Dworkin, *Life’s Dominion* as earlier 237.

⁶⁴ Ibid, 236.

⁶⁵ Ibid, 205.

⁶⁶ <http://www.oxforddictionaries.com/definition/english/dignity>, (last accessed 11/09/17).

⁶⁷ See B. Baertschi, ‘Human Dignity as a Component of a Long-Lasting and Widespread Conceptual Construct’ (2014) 11 *Bioethical Inquiry* 201-211, 202 [‘Widespread Conceptual Construct’].

⁶⁸ Kant, *Groundwork* as earlier, 47, [4:435-4:436].

⁶⁹ I. Kant, *The Metaphysics of Morals* (translated and edited by M. Gregor, CUP, 1996) p.209 [6:462].

⁷⁰ Kant, *Groundwork*, p.48 [4:436]; A. Edgar & L. Nordenfelt, ‘Dignity of the Patient’ in *Handbook of the Philosophy of Medicine* (Springer Science, Dordrecht, 2015) 1- 17, 6-8, [‘Dignity of the Patient’]; M. Rothhaar, ‘Human Dignity and Human Rights in Bioethics: The Kantian Approach’ (2010) 13 *Med Health Care Philos* 251–257, 254 [‘The Kantian Approach’]

⁷¹ Rothhaar as above, ‘The Kantian Approach’ 254.

observable capacities and qualities,⁷² and is a concept that recognises moral status as undiminished by a loss of capacity at the end of life.

Dignity marks the moral status of potential organ donors who have lost the capacity for autonomous action,⁷³ and restricts the way they can be treated. Having a moral status places certain moral obligations on healthcare professionals. Dignity, marking that moral status, is largely concerned with those obligations. These obligations can be summarised as a ban on instrumentalisation and a ban on degrading treatments.⁷⁴ Kant's ban on using humanity "merely as a means"⁷⁵ is an expression of the ban on instrumentalisation.⁷⁶ It obliges healthcare professionals and policy-makers to always treat potential organ donors as the individuals they are, with their own beliefs and values, and never merely as a source of organs. The ban on degrading treatments, which is absolute within human rights law,⁷⁷ obliges healthcare professionals and policy-makers to safeguard the dignity of potential organ donors. This includes avoiding treatments that are against the values by which they have lived their lives.

Dignity is closely related to autonomy, and in many circumstances dignity encompasses autonomy – either current or antecedent - as a constituent part.⁷⁸ This is sometimes articulated as the dignity of identity, which Nordenfelt defines as "the dignity that we attach to ourselves as integrated and autonomous persons, persons with a history and

⁷² *Edgar & Nordenfelt* as above, 'Dignity of the Patient', 6-7.

⁷³ *Ibid*, 1- 17.

⁷⁴ *Baerstschi* as earlier 'Widespread Conceptual Construct', 206; See Article 3 of the European Convention of Human Rights (ECHR).

⁷⁵ *Kant*, *Groundwork* p.41 [4:429] as earlier.

⁷⁶ *Baerstschi* as earlier 'Widespread Conceptual Construct', 206.

⁷⁷ Art. 3 ECHR; see eg. *M.S. v United Kingdom* (App no. 24527/08) (2012) 55 EHRR 23 [38-46].

⁷⁸ For a review of some of the ways that the relationship between autonomy and dignity can be construed, see M. Neal, 'Respect for Human Dignity as "Substantive Basic Norm' (2014) 10 *In J Law Context* 26-46, 30-31.

persons with a future with all our relationships to other human beings”.⁷⁹ This dignity, being grounded in the individual’s integrity and autonomy,⁸⁰ is often considered vital in the context of medical technologies at the end of life.⁸¹ Dignity at the end of life includes being treated as an individual who retains their own identity and whose values and preferences matter. Even for patients who lose autonomy as part of the dying process, individual choice is – in most if not all circumstances – a key component of achieving a dignified death.

There is a close connection between achieving dignity in end-of-life care and defending the integrity of the dying patient. Integrity, from the Latin *integer* – meaning wholeness or unimpaired unity⁸² – is often interpreted as referring to the narrative coherence of the patient’s life.⁸³ It is upheld as an untouchable core or personal sphere and is intrinsically related to self-determination.⁸⁴ This sphere of integrity encircles both psychological and physical integrity.⁸⁵ Psychological integrity, the unity or core of the psyche, can be further categorised to include axiological integrity, or the intactness of the values that the individual has embraced.⁸⁶ Defending that integrity requires that the values by which the individuals have chosen to live their lives are, like the individual’s body, upheld as inviolable. Integrity, like dignity, is a concept that applies to all patients, including those who have lost

⁷⁹ L. Nordenfelt, ‘The Varieties of Dignity’ (2004) 12(2) *Health Care Anal* 69-81, 74.

⁸⁰ *Ibid*, 76.

⁸¹ L. Brussel, ‘Autonomy and Dignity: A Discussion on Contingency and Dominance’ (2014) 22 *Health Care Anal* 174-191, 181.

⁸² E. Pellegrino, ‘The Relationship of Autonomy and Integrity in Medical Ethics’ (1990) 24(4) *Bull Pan Am Health Organ* 361-371, 365, [‘Autonomy and Integrity’].

⁸³ J. Rendtorff, ‘Basic Ethical Principles in European Bioethics and Biolaw: Autonomy, Dignity, Integrity and Vulnerability – Towards a Foundation of Bioethics and Biolaw (2002) 5 *Med Health Care Philos* 235-244, 237.

⁸⁴ *Ibid*, 237.

⁸⁵ J. Rendtorff, *Basic Principles in Bioethics and Biolaw* (Conference Paper, 20th World Congress of Philosophy, 1998) section 4 (The Principle of Integrity) available at <http://www.bu.edu/wcp/Papers/Bioe/BioeRend.htm> (last accessed 16/09/17).

⁸⁶ Pellegrino, ‘Autonomy and Integrity’ as above, 361-371 – although note that Pellegrino views axiological integrity as a separate facet of integrity than psychological integrity; also R. Fjellstrom, ‘Respect for Persons, Respect for Integrity’ (2005) 8 *Med Health Care Philos* 231-242, 233.

capacity or even consciousness itself.⁸⁷ Like dignity, the integrity of the patient's values, psyche, and body continues even if the patient is dying and no longer able to express an autonomous decision regarding their treatment. The narrative coherence of the patient's life persists and should not be replaced by another narrative imposed by others. The commitments by which the individual has defined themselves retain the same importance and demand that the patient is treated in accordance with what they had chosen or would have chosen for themselves in the circumstances.

Defending patient integrity and realising a dignified death is contingent on knowledge of the patient's preferences in the circumstances. In the context of the dying patient identified as a potential organ donor, the concepts of dignity and integrity demand that their wishes are determined – to the extent that this is possible - and upheld even when they are comatose and close to death. From the perspective of that patient's end-of-life care, incorporating self-determination into donor optimisation policy would be of value to that individual patient. It is needed because of the close relationship between autonomy, dignity and integrity. As I argued earlier in this chapter, it is of intrinsic and instrumental value to ODR registrants and the potential organ donors they become. In the remainder of the chapter, I will argue that it is also of value to others in society, particularly patients with organ failure who are reliant on the supply of organs for their own survival. I argue that this is because of the relationship between autonomy, trust and the supply of organs.

The Concept of Trust

Trust is a factor in organ donation that is not always fully appreciated, yet it is crucial to achieving and maintaining public cooperation with both the opt-in system that exists throughout most of the UK and the opt-out system that has recently been introduced in

⁸⁷ *Pellegrino*, 'Autonomy and Integrity' as earlier, 369.

Wales.⁸⁸ Any organ procurement programme that includes an element of individual choice is fundamentally reliant on trust and cooperation with that programme. A cooperative relationship between individuals who could potentially donate their organs, the relatives to whom the final decision often falls, and the healthcare institutions that oversee organ donation is central to achieving the aim of an adequate supply of organs. This cooperative relationship is based on the trust that those individuals and their relatives place in the organ donation programme.

Accounts of what trust entails, what its functions are, and why it should be considered important in relation to future eventualities, have until fairly recently been limited to the sociological literature.⁸⁹ However, the notion of trust is increasingly being recognised as a principle of significance to ethical decision-making in healthcare contexts.⁹⁰ The influence of trust on healthcare decision-making is contended to have important consequences for healthcare outcomes, including organ donation rates.⁹¹ Autonomy is often considered the most important principle to be upheld in healthcare decision-making, yet trust appears more important to securing the intended outcomes of healthcare policies. Without the cooperation that trust engenders, the outcomes of policies ranging from vaccination programmes to cancer screening would not be achievable without recourse to some kind of coercion or force. Trust, however, is not in opposition to autonomy. Autonomy and trust share common foundations and functions and both may be achievable within the organ donation programme.

⁸⁸ The Human Transplantation (Wales) Act 2013 came into effect in December 2015; see discussion in Chapter 1.

⁸⁹ See particularly *Luhmann, Trust and Power* as earlier.

⁹⁰ See particularly *O'Neill, Autonomy, Trust, Bioethics* as earlier.

⁹¹ See eg., Y-Y Lee & J. Lin, 'Trust but Verify: The Interactive Effects of Trust and Autonomy Preferences on Health Outcomes' (2009) 17 *Health Care Anal* 244-260; L. Schwettmann, 'Decision Solution, Data Manipulation and Trust: the (Un-)willingness to Donate organs in Germany in Critical Times' (2015) 119 *Health Policy* 980-989, 981-982.

Both autonomy and trust in the organ donation programme are reliant on the information that is available about the possible consequences of decision-making. Self-determination in relation to the organ donation process is only possible if the available information reflects the realities that the individual may face at the end of life. I will argue in this section that, in common with self-determination, appropriately directed trust in the organ donation programme is only possible if information about future eventualities reflects the realities that the individual may face. Currently, the organ donation programme relies on a more precarious form of trust. It is based on incomplete information regarding the consequences of signing up as a deceased organ donor, and risks being replaced by distrust should the realities of organ procurement policy be revealed by the media. In contrast, appropriately-directed or informed trust is a stable and enduring form of trust in the long-term and, I argue, has a safeguarding function for the outcome of organ procurement policy.

In his influential thesis on the necessity of trust in a complex society, Luhmann defines trust in relation to future events, equating it to “confidence in one’s expectations”.⁹² Trust is a means of coping with future uncertainties: “[T]o show trust is to anticipate the future. It is to behave as though the future were certain”.⁹³ Trust’s function in healthcare decision-making is to enable individuals to cope with a future characterised by the complexities generated by modern medical technologies.⁹⁴ Trust is needed if future eventualities exist that the individual might wish to avoid,⁹⁵ such as being “kept alive by machines”. It is not only the complexities of the medical technologies that accompany organ donation that suggest that trust is needed, but the potential for harm and the possibility that these technologies could begin before the donor is dead.

⁹² *Luhmann, Trust and Power* as above, 4.

⁹³ *Ibid*, 8.

⁹⁴ *Ibid*, 15-16, & 20.

⁹⁵ *Ibid*, 24.

There are several different constructions of trust in the sociological literature.

Although they approach trust from different angles, many of these constructions overlap with Luhmann's thesis rather than oppose it. Hardin, for example, views trust as the belief that others have the "right intentions toward us" and that they are competent to perform what they are trusted to do.⁹⁶ This belief in the trustworthiness of others enables individuals to achieve Luhmann's construction of trust as security in one's expectations. Sztompka defines trust as "a bet about the future contingent actions of others",⁹⁷ which implies that the future is less certain than may be acknowledged under Luhmann's definition. However, making a bet on future actions is also a means of coping with future uncertainties. A bet that these future actions will not be harmful or exploitative rests on a belief in the trustworthiness of others. This belief provides the individual with the sense of security needed to overcome any fears and concerns about medical technologies. However, this belief may in some circumstances be misplaced and bestowing trust - whether defined as a sense of security, belief in trustworthiness, or bet on future actions – can have detrimental consequences to the trusting individual.

Trust enables an individual to engage with healthcare practices. It is based on the information, if any, that is available about the nature and risks of those healthcare practices. The more accurate the information available, the closer the "bet" on the actions of healthcare professionals is likely to be and the more appropriately directed the trust. The information, or misinformation, on which trust is based is not limited to that directly provided to patients, or in this context to registrants on the Organ Donor Register (ODR), but encompasses all other sources that contribute relevant information. The reputation of the organ donation programme, based on its past record as reported in the media or spread by word of mouth,

⁹⁶ R. Hardin, *Trust* (Polity Press, UK, 2006) 17.

⁹⁷ P. Sztompka, 'Foundations of Trust', Chapter 4 in *Trust: A Sociological Theory* (CUP 1999) p. 69- 101 ['Foundations of Trust'].

contributes to the information that the ODR registrant has available and may be a determining factor in the level of trust they are willing to confer on it.⁹⁸ A reputation of having the “right intentions” towards potential organ donors, protecting their critical interests, treating them fairly, and not exploiting them before death, is crucial to achieving and maintaining trust in the organ donation programme. Any breaches to the past record of treatment of potential organ donors, no matter how minor or infrequent, cast doubt upon the trustworthiness of the organ donation programme and this doubt can have a devastating effect on the conferment of trust on the organ donation programme.⁹⁹

The information provided to potential ODR registrants and the reputation of the organ donation programme are key factors influencing whether or not an individual confers trust on and signs up to the organ donation programme.¹⁰⁰ These factors are external to the trusting or mistrusting individual. However, the inclination to trust in the organ donation programme may also be influenced by factors internal to the individual. The propensity for trustfulness may vary with the psychology of the individual,¹⁰¹ yet both the propensity and the psychology are influenced by the positive or negative encounters that individual has previously had with healthcare practices. Similarly, decisions whether or not to trust are sometimes viewed as grounded in “trust culture”,¹⁰² yet cultural influences on healthcare decision-making partly stem from the experiences that members of the community have had with healthcare practices. There may be good reasons not to trust. Although the potential ODR registrant’s decision may be influenced by psychology and culture, these influences are

⁹⁸ Sztompka identifies reputation as one of the bases on which trustworthiness is determined, ‘Foundations of Trust’ as earlier, 71.

⁹⁹ Examples of transplantation crises triggered by damage to reputation will be considered later in this chapter.

¹⁰⁰ Empirical evidence of the relationship between information, trust, and registration on the ODR will be presented in Chapter 6.

¹⁰¹ Sztompka, ‘Foundations of Trust’ as earlier, 70 & 97-99.

¹⁰² Ibid, 70 & 99-101.

partly derived from the past record of healthcare practices, which may include eventualities that the potential registrant might wish to avoid.

Decision-making about healthcare practices is based on the individual's perspective towards the information that is available about the practice. This information may be limited, in which case trust may be little more than a leap in the dark. For a belief in the trustworthiness of others to be well-founded, reliable information that "allow[s] us to judge where to place our trust" is needed.¹⁰³ This is recognised within most of the prominent conceptions of trust, including the conception that at first glance appears to pit autonomy and trust against each other.¹⁰⁴ O'Neill argues that gaining autonomy can result in the loss of trust, as there is an increased emphasis on autonomy in medical practice but also evidence that public trust has faltered.¹⁰⁵ However, she clearly acknowledges that the reasonable placement of trust requires information about the undertakings that individuals are invited to trust and about the proposers of the undertakings.¹⁰⁶ Her statement that "[t]he only trust that is well placed is given by those who understand what is proposed, and who are in a position to refuse or choose in the light of that understanding",¹⁰⁷ recognises two factors as being essential to well-placed trust. These two factors, understanding and the opportunity to make a choice, are defining attributes of self-determination. This self-determination is a necessary condition for well-placed trust. Well-placed trust relies on autonomy, and a gain in autonomy increases this form of trust. It appears that if any trust is lost by a gain in autonomy, it is not well-placed trust.

¹⁰³ O. O'Neill, *A Question of Trust* (CUP 2002) preface, p. vii, [*'Question of Trust'*].

¹⁰⁴ O'Neill, *Autonomy, Trust, Bioethics*, as earlier, see particularly Chapter 1.

¹⁰⁵ Ibid, Chapter 1, particularly p.3.

¹⁰⁶ O'Neill, *A Question of Trust* as above, 64.

¹⁰⁷ O'Neill, *Autonomy, Trust, Bioethics*, 18.

O'Neill differentiates between the blind placement of trust and the reasonable placement of trust.¹⁰⁸ The reasonable placement or non-placement of trust requires information and “the means to judge that information”.¹⁰⁹ She bases this second requirement on the need to distinguish “rumour from report, fact from fiction, reliable source from disinformant, truth-teller from deceiver”.¹¹⁰ The individual judging whether or not it is reasonable to trust in the organ donation programme needs information about the organ donation process, as well as some means of judging whether that information is accurate. This is difficult, as there is no apparent means for individuals considering deceased organ donation to judge whether the available information about the organ donation process is complete, yet alone accurate. In the specific circumstances of organ procurement policies there is very little openness and transparency. There is also little to suggest to the ODR registrant that the information provided about the organ donation process is incomplete or inaccurate. ODR registrants are not “gullible people” making decisions on the basis of “patently inaccurate evidence”,¹¹¹ but people who have no means of judging the accuracy of the information provided. They have been provided with so little information that they cannot know whether any trust they may confer on the organ donation programme is reasonably placed.

Although O'Neill's differentiation between blindly-placed and reasonably-placed trust suggests that she recognises that the latter is to be preferred to the former, some of her arguments imply a more paternalistic stance towards trust. This is most notable in her arguments that openness and transparency can result in a loss of trust. The “sorts” of openness and transparency that O'Neill highlights as being “bad for trust” are “misinformation

¹⁰⁸ O'Neill, *A Question of Trust*, 64.

¹⁰⁹ Ibid, 64.

¹¹⁰ Ibid, 63-64.

¹¹¹ O'Neill differentiates between gullible people worthy only of “pity or derision” from people more worthy of our sympathy. See O'Neill, *A Question of Trust*, 64.

and disinformation”.¹¹² However, misinformation and disinformation are not in reality openness or transparency, but inaccuracy and deception. These factors clearly present risks for trust, but those risks may not be presented by openness and transparency in relation to accurate information. Moreover, openness and transparency in relation to accurate information has a potential safeguarding role in relation to trust. This role is not recognised by O’Neill’s arguments that trust is not necessarily based on full disclosure, and that “mutual respect precludes rather than requires across-the-board openness between doctor and patient”.¹¹³ These arguments appear to endorse blind – or at least partially sighted – trust and a paternalistic stance on the doctor-patient relationship. This is despite her recognition that a critical appraisal of the traditional image of the doctor-patient relationship reveals just “how little this is a relationship of trust”.¹¹⁴ To safeguard and promote trust itself, and in particular to achieve a more adequate or reasonable basis for trust,¹¹⁵ a model of the doctor-patient relationship that is based on shared decision-making and information disclosure appears preferable.¹¹⁶

Asymmetries of knowledge and power between patients and doctors, as O’Neill recognises, create difficulties for patients in judging whether to trust doctors to have their interests as a fundamental concern.¹¹⁷ If patients are to access medical care, they “must place trust selectively and with discrimination” even though they “lack any guarantee[s]” regarding the trustworthiness of the doctors and medical institutions.¹¹⁸ How then are they to determine whether their trust is well-placed? If O’Neill is not in favour of “across-the-board openness”, how does she suggest that patients reach a decision on whether to trust their

¹¹² Ibid, 68.

¹¹³ Ibid, 69.

¹¹⁴ O’Neill, *Autonomy, Trust, Bioethics* as earlier, 18.

¹¹⁵ Ibid, 18.

¹¹⁶ See A. Papageorgiou, ‘Models of the Doctor-Patient Consultation’, Chapter 4 in J. Brown, L. Noble, A. Papageorgiou, & J. Kidd, *Clinical Communication in Medicine* (Wiley Blackwell, UK, 2016) 21-29.

¹¹⁷ O’Neill, *Autonomy, Trust, Bioethics*, 118.

¹¹⁸ Ibid, 122

doctors and medical institutions? Without ironing out some of the asymmetries in information, their options are limited to blindly accepting whatever healthcare is offered or to revert to distrust and withdraw themselves from the healthcare practice. O'Neill's arguments on the steps that can be taken to improve trustworthiness, such as by the rejection of coercion and deception,¹¹⁹ do not fully address the problem of how a patient is to determine whether or not doctors and institutions are trustworthy. In circumstances in which "an agenda of improving trustworthiness"¹²⁰ has not been pursued – such as in the regulation of donor optimisation procedures – individuals still face difficulties in determining whether or not their trust is well placed.

Trustworthiness can be damaged, as O'Neill acknowledges, by the lack of incorporation into legislation, regulation, and institutions of important bioethical obligations and their corresponding rights.¹²¹ Achieving or at least avoiding damage to trustworthiness would therefore seem to rely on the incorporation of these important bioethical obligations and rights into these structures. Respecting and promoting the right to make an autonomous decision about medical treatment is usually held to be an important bioethical obligation.¹²² This seems to suggest that improving trustworthiness relies on the incorporation of autonomous decision-making into law, policy, and practice. Yet O'Neill is also concerned that measures introduced to improve individual autonomy and to protect against non-consensual treatment may have a damaging effect on trust.¹²³ The relationship between trustworthiness and trust might not always be a positive one. Although trust may be based on the information available about the trustworthiness of the institution, it does not necessarily coincide with the

¹¹⁹ O'Neill, *Autonomy, Trust, Bioethics*, 123.

¹²⁰ Ibid, 127.

¹²¹ Ibid, 126.

¹²² See, for example, Article 5 of Universal Declaration on Bioethics and Human Rights 2005.

¹²³ O'Neill, *Autonomy, Trust, Bioethics*, 3.

trustworthiness of the institution. Trust is sometimes misplaced, but so is distrust.¹²⁴ Fears that facilitating autonomous decision-making – which would improve trustworthiness itself – might have a damaging effect on trust could explain NHSBT’s reluctance to introduce informed consent standards for donor optimisation procedures.¹²⁵

As Baier identifies, “[t]o increase trust, it is not enough to try to make people trustworthy; one also has to make them more willing to give trust”.¹²⁶ The inclusion of autonomy, openness, and transparency in organ procurement policy would demonstrate the trustworthiness of the organ donation programme. This fostering of active involvement in the organ donation programme could also promote the conferral of trust. As Ranson and Stewart argue, “[o]ur active participation in creating projects which are to shape our selves as well as the communities in which we live provides the sense of purpose to work together with others and to secure trusting relations with them”.¹²⁷ The sense of purpose and moral worth provided by measures to involve ODR registrants actively in decisions regarding donor optimisation procedures may incline them to trust.¹²⁸ The policy-makers’ fears could be addressed and proved unfounded by the introduction of measures that simultaneously encourage trust built on a sense of purpose and moral worth and develop the self-determination of potential ODR registrants.¹²⁹

¹²⁴ See K. Jones, ‘Distrusting the Trustworthy’, Chapter 11 in D. Archard, M. Deveaux, N. Manson & D. Weinstock, *Reading Onora O’Neill* (Routledge, London & New York, 2013) 186- 197, 186.

¹²⁵ See concerns expressed by the National Clinical Lead for Organ Donation in P. Murphy, ‘Optimizing Donor Potential in the UK’ (2011) 6(3) *Clin Ethics* 127–133, 128. This will be explored in more detail in Chapter 6.

¹²⁶ See A. Baier, ‘What is Trust?’, chapter 10 in Archard *et al*, *Reading Onora O’Neill* as earlier, 175-185, 178.

¹²⁷ S. Ranson, & J. Stewart, ‘Citizenship in the Public Domain for Trust in Civil Society’ in A. Coulson, *Trust and Contracts: Relationships in Local Government, Health and Public Services* (Bristol, The Polity Press, 1998) p.250.

¹²⁸ See L. Gilson, ‘Trust and the Development of Healthcare as a Social Institution’ (2003) 56(7) *Soc Sci Med* 1453- 1468, 1461.

¹²⁹ The likely impact of incorporating autonomy into donor optimisation policy is considered in Chapter 6.

Measures that make people more willing to confer trust are an essential component in increasing trust.¹³⁰ However, it is also important to consider what type of trust they are willing and able to confer. In the long term, the type of trust conferred may be crucial to achieving the aims of the organ donation programme. Active involvement in decision-making is crucial to enable ODR registrants to confer informed or well-placed trust. As O'Neill acknowledges, "[w]ell-placed trust requires discrimination: it is directed selectively at specific claims and at specific undertakings".¹³¹ Well-placed trust requires autonomy, without which the individual cannot be discriminating. Informed or well-placed trust requires that the potential ODR registrant has enough information to be able to direct their trust to specific undertakings, including those undertakings that may occur whilst they are still alive. ODR registrants are currently excluded from active involvement in end-of-life decision-making and not able to discriminate between that part of the organ donation process that occurs before and that part that occurs after death. The type of trust they are able to confer is not informed trust but uninformed trust. As I will argue in the final section of this chapter, the reliance of the organ donation programme on uninformed trust in the organ donation process poses significant risks for the achievement of its aim of securing an adequate supply of organs for transplantation.

Types of Trust, Distrust, and the Supply of Organs

In this chapter I have addressed two very different concepts, autonomy and trust, and argued that they are not in opposition to each other but that the latter flows from the inclusion of the former in healthcare decision-making. I have also distinguished between two types of trust.

¹³⁰ See A. Baier, 'What is Trust?', chapter 10 in *Archard et al, Reading Onora O'Neill as earlier*, 175-185, 178.

¹³¹ O. O'Neill, 'Justice, Trust and Accountability', as cited by Baier above, translated from 'Gerechtigkeit, Vertrauen und Zurechenbarkeit' in O. Neumaier, C. Sedmark, M. Zichy, *Gerechtigkeit: Auf der Suche nach einem Gleichgewicht* (Frankfurt: Ontos Verlag, 2005) 33-55, 42.

The first, autonomy-based or informed trust, is based on accurate information about the nature and risks of the relevant healthcare practice. The second, blind or uninformed trust, is conferred in the absence of accurate information about that healthcare practice. These types of trust are completely different notions, existing at opposite ends of the spectrum of what might be called trust. Both fulfil the definitions of trust in the sociological literature, providing the patient with the sense of security needed to engage with healthcare practices. However, they not only are conferred in different circumstances but have different consequences for the individual and for healthcare outcomes. In the context of organ procurement policy, as I will argue in this section, the risks of relying on blind trust include the potential for triggering a transplantation crisis.

Blind trust is something that is fallen back on when autonomous decision-making is denied. It is placed indiscriminately to cover the gaping hole left by the absence of information about a practice. The lack of accurate information leaves the patient, or ODR registrant, resorting to a blind act of faith that they can only pray does not result in unwanted outcomes. The potential unwanted outcomes include both iatrogenic harm and damage to the patient's ethical commitments and values. The consequences of bestowing blind trust on healthcare professionals and institutions may include the manifestation of these unwanted outcomes. In contrast, informed trust is a more enabling notion, facilitated by the inclusion of the patient in autonomous decision-making and providing a well-founded sense of security that only anticipated outcomes will ensue from engagement with a healthcare practice. The patient's expectations are based on accurate information about potential future eventualities and the confidence that results in those expectations is appropriately directed. The consequences of bestowing informed trust are limited to those future eventualities that the individual had anticipated and considered to be either acceptable outcomes or acceptable risks to take. The key advantage of informed trust is that it does not result in the unanticipated and unwanted outcomes that bedevil blind trust.

Current organ procurement policy is fundamentally reliant on trust. Trust is what makes it possible for people to register as organ donors and also what encourages relatives to consent to deceased organ donation. Individuals registering on the ODR are not currently informed about that part of the organ donation process that occurs before death, so the type of trust they can confer on the organ donation process is not informed trust. They cannot specifically direct their trust to the specific undertakings of ante-mortem donor optimisation procedures, and they cannot specifically consent to or refuse these procedures. They are entirely excluded from decisions about changes to their end-of-life care to facilitate organ donation. The trust they confer on the organ donation programme rests perilously over a huge void in information provision. Although the individual may be informed about deceased organ donation, they are not informed about ante-mortem interventions to facilitate organ donation, and the trust that they confer on the organ donation programme as a whole is much closer to the blind end of the spectrum.

The type of trust that the relatives of dying patients, who are usually afforded the final say about organ donation, are able to confer depends on the information provided to them about the organ donation process. NICE recommend that relatives are provided with some information, but only after donor optimisation procedures have been initiated,¹³² which in itself presents risks to trust. The information they are provided with focuses on an explanation of “what end of life care involves”,¹³³ rather than what alternatives are available and what their potential risks are. The NICE recommendations read as an all-or-nothing situation, i.e. consent to organ donation and whatever “interventions may be required”¹³⁴ or refuse all consent. If in practice relatives are not fully informed of the alternatives and their risks, then the type of trust that relatives can confer on the organ donation process is

¹³² NICE, *Improving Donor Identification* as earlier, p.7 [1.1.6-1.1.7].

¹³³ *Ibid*, p.11 [1.1.25]

¹³⁴ *Ibid*, p.10 [1.1.22].

relatively uninformed, although not quite as blind as that conferred by those signing up as deceased organ donors.

Blind or relatively uninformed trust may currently be fulfilling its role as a facilitator of both registration on the ODR and the consent of relatives to deceased organ donation. However, it rests on shaky grounds and is at risk of being withdrawn and replaced by distrust. This is not merely a theoretical concern. It is a practical concern based on the damage done in the past to organ donation programmes by media revelations regarding organ procurement policy. Media revelations regarding the way potential donors are treated before death can inflict serious and long-lasting damage on uninformed trust and can cause it to be replaced by the more pernicious concept of distrust. Over several decades and across several countries, there have been many examples of media reports that have legitimately raised concerns about organ procurement policy and these concerns have led to a withdrawal of trust, its replacement by distrust, and plummeting organ donation rates.¹³⁵

Fears of media revelations triggering public distrust exist in many countries.¹³⁶ One of the most recent countries in which this fear has been realised is Germany, where public trust in the organ donation programme has been badly affected by allegations that doctors have falsified medical records to bump their patients up the organ transplantation waiting list.¹³⁷

¹³⁵ See eg. E. Gordon, 'The Role and Responsibility of the Media in Relation to Organ Donation and Transplantation' in W. Shelton & J. Balint, *The Ethics of Organ Transplantation* (Elsevier Science, UK 2001) 293 & 301 ['Role and Responsibility']; R. Matesanz, 'Organ Donation, Transplantation, and Mass Media' (2002) 35 *Transplant Proc* 987-989 ['Mass Media']; A. Dufner & J. Harris, 'Trust and Altruism – Organ Distribution Scandals: Do They Provide Good Reasons to Refuse Posthumous Donation?' (2015) 40(3) *J Med Philos* 328-341 ['Trust and Altruism'].

¹³⁶ See eg. A. Aykas, A. Uslu, C. Simsek, 'Mass Media, Online Social Network, and Organ Donation: Old Mistakes and New Perspectives' (2015) 47 *Transplant Proc* 1070-1072.

¹³⁷ K. Connelly, 'Mass Donor Organ Fraud Shakes Germany' (The Guardian, Wed 9 Jan 2013) available at <https://www.theguardian.com/world/2013/jan/09/mass-donor-organ-fraud-germany> (last accessed 16/09/17) ['Mass Fraud']; see also Dufner & Harris, 'Trust and Altruism' as above; T. Rock, M. Bramkamp, K. Bartz-Schmidt, D. Röck, 'Organ Transplantation Scandal Influencing Corneal Donation Rate' (2017) 10(6) *In J Ophthalmol* 1001-1003; D. Shaw, 'Lessons from the German Organ Donation Scandal' (2013) 14(3) *JICS* 200-201 ['Lessons']; A. Hoisl, R. Barbey, B. Graf *et al*, 'Assessment of

This damage to trust is not due to sensationalist reporting but, in this particular case, due to the alleged criminal manipulation of patient records uncovered by investigations by Germany's medical council.¹³⁸ As with other cases in which public trust has been damaged by the media's exposure of the reality of organ procurement policy and practice, significant and longstanding drops in organ donation rates ensued.¹³⁹ In the UK, the most directly comparable events are the exposure of the practice of non-consensual organ retention, which triggered the drafting of the Human Tissue Act 2004,¹⁴⁰ and the oft-cited example of the 1980 BBC Panorama programme questioning the validity of brain-death criteria.¹⁴¹ Although these are different practices that are being exposed or debated, negative media reports all have the same result, which is the destruction of public trust and a reduction in the supply of organs.

The so-called "Panorama effect"¹⁴² on the supply of organs might be blamed on irresponsible reporting. However, its true cause may be a lack of openness and transparency surrounding organ procurement policy. Panorama viewers may not have torn up their donor cards, and the 15 month drop in donor referrals may have been avoided,¹⁴³ had they been fully informed about brain-death criteria prior to registration. Even more protection may have resulted from a public education and/or consultation programme about brain-death criteria. Similarly, openness and transparency about ante-mortem donor optimisation policy could well have prevented the damage to public trust and the drop in organ donation rates that followed media exposure of a USA Clinic's policy for treating brain-injured patients in a way

the Transplantation Scandal by the Media: Scientific Discourse Analysis of Selected German Newspapers' (2015) 64(1) *Anaesthetist* 16-25.

¹³⁸ Connelly as above, 'Mass Fraud' ; Shaw, 'Lessons' as above, 200-201.

¹³⁹ Shaw, 'Lessons' as above, 200.

¹⁴⁰ As discussed in Chapter 1.

¹⁴¹ R. Matesanz, 'The Panorama Effect on Altruistic Organ Donation' (1996) 62(11) *Transplantation* 1700-1701 ['Panorama Effect']; Matesanz, 'Mass Media' as above, 987; K. Green, 'Transplants – are the Donors Really Dead?' 281(6250) *BMJ Clinical Research* 1280 ['Are donors really dead?'].

¹⁴² Matesanz, 'Panorama Effect' as above, 1700.

¹⁴³ Matesanz, 'Mass Media' as above; Green, 'Are Donors Really Dead?' as above.

that facilitated organ donation.¹⁴⁴ This openness and transparency may have saved hundreds of lives in the years it took for organ donation rates to recover. It is lives that are put at risk by the current lack of openness and transparency in the UK about ante-mortem donor optimisation policy: lives that the organ donation programme cannot afford to gamble with.

Blind trust in organ donation is the result of a lack of openness and transparency and is easily damaged by media revelations. The gap in information is filled by the media revelations which lead previously trusting individuals to the conclusion that their trust in the organ donation programme was misplaced. This results in feelings of betrayal, the withdrawal of trust, and the replacement of trust by distrust.¹⁴⁵ Distrust involves expectations that the actions of others will be harmful or detrimental.¹⁴⁶ It results in individuals taking protective measures against the distrusted, the refusal of consent to healthcare practices, and other steps to avoid that healthcare practice.¹⁴⁷ This could include the withdrawal of their individual names from the ODR, campaigning to ensure that others are not subject to the same risks, and potentially the refusal of intensive interventions at the end of life. Should this distrust take hold within society, the supply of organs to those desperately in need could be drastically reduced. Distrust can take years to shift, even if accurate information about organ procurement policy is subsequently provided. It is too late by then – trust is already gone.

The initiation of donor optimisation procedures without the consent of either the individual or their relatives could have particularly damaging effects on trust if those procedures cause physical harm. The public already harbour low levels of trust in the organ donation programme, with many people fearing that they will be viewed as an organ donor

¹⁴⁴ Gordon, 'Role and Responsibility' as above, 293 & 301.

¹⁴⁵ See A. Baier, 'Trust and Antitrust' (1986) 96 *Ethics* 231-260; also K. Hawley, 'Trust and Distrust between Patient and Doctor' (2015) 21 *J Eval Clin Practice* 798-801.

¹⁴⁶ See Sztompka's definition of distrust as involving negative, defensive commitments, in *Trust: A Sociological Theory* as before, 26.

¹⁴⁷ *Ibid*, 26.

rather than a patient.¹⁴⁸ Media reports of dying patients being caused physical harm by non-consensual interventions for the benefit of third parties could be the last straw for trust. There is a real risk of this happening as a consequence of the distress caused to families by the discovery that their loved one has been harmed by invasive interventions that neither the patient nor their relatives had given informed consent for. Should just one family's distress cause them to inform the media about physical harm caused by non-therapeutic and non-consensual procedures, organ donation rates could plummet. However, as was established following the media revelations of the practice of non-consensual organ retention,¹⁴⁹ the lack of consent alone is enough to generate widespread public distrust. It is the non-consensual nature of current donor optimisation policy that generates the risk to trust, and not necessarily the risks of physical harm - which may be more acceptable to the public if they are risks that they can choose whether or not to take.¹⁵⁰

The potential for a transplantation crisis to be generated by the exposure of current organ procurement policy could be alleviated by the provision of information and the active involvement of ODR registrants (and maybe their relatives) in decisions about donor optimisation procedures. As Almassi comments, '[a]t its best, organ donation occurs within a social atmosphere of morally and rationally justified trust'.¹⁵¹ That moral and rational justification relies on evidence that the organ donation programme will act in the interests of the organ donor. This evidence could be provided by affording ODR registrants the informed decision whether or not to undergo donor optimisation procedures. Their informed trust in

¹⁴⁸ Optimisa Research, *Understanding Current Attitudes and Behaviours Towards Organ Donation Within England* (NHSBT research report, 2013) p.44 Figure 14. This and other empirical evidence will be evaluated in Chapter 6.

¹⁴⁹ As discussed in Chapter 1.

¹⁵⁰ The likely impact on the supply of organs of introducing a system of informed consent to donor optimisation procedures will be considered in Chapter 6.

¹⁵¹ B. Almassi, 'Trust and the Duty of Organ Donation' (2014) 28(6) *Bioethics* 275-283, 281.

the organ donation programme would be morally and rationally justified as they would have made their own decision regarding where their interests lay at the end of life.

Informed trust in the organ donation programme would not carry the same risks of being withdrawn and replaced by distrust that beset uninformed trust. It would be a real and well-founded confidence in one's expectations, reached by a process of deliberation on the available information regarding the timing, nature, and risks of the organ donation process. If trust was placed on the basis of accurate information, there would be no gap in information that could be filled by media exposure of the reality of the organ donation process. ODR registrants would already know about the nature and risks of donor optimisation procedures, and if a system of specific advance consent were available, some would have agreed to these procedures. Any physical risks would have been consented to, so the fall-out in terms of public distrust is likely to be lower and the supply of organs protected from media revelations regarding the complications of these procedures.

Informed trust would have a safeguarding role for the organ donation programme, and could also potentially have a facilitating role for organ donation. The provision of accurate information and the active engagement of potential ODR registrants in decisions about their end-of-life care could, if handled well, make them more inclined to trust in the organ donation process. The knowledge that healthcare professionals are only going to treat registered organ donors at the end of their lives in the ways that they have agreed to could provide that sense of security in one's expectations that often appears to be missing in relation to organ donation. The fear that one's own interests will be subjugated to others in society could be replaced by confidence that one's own active decision whether or not to undergo donor optimisation procedures will be upheld. The change in emphasis from the infliction of a non-consensual procedure to an altruistic decision to help others could improve trust in the organ

donation process. This is needed to protect the organ donation programme from the harms generated by distrust and could also potentially increase the supply of organs to patients dying from organ failure. It is acknowledged that the impact on the supply of organs cannot be definitively determined in advance but, as I will argue in the final chapter of this thesis, this should not prevent NHSBT from implementing a system of specific advance consent to donor optimisation procedures. Autonomy is too important an ethical principle to disregard without even establishing whether an autonomy-based framework could succeed in securing the supply of organs for transplantation.

3. Autonomy, Informed Consent, and Advance Decision-Making

Introduction

The primary rationale behind the opt-in system for deceased organ donation in England, Scotland, and Northern Ireland might be presumed to be the achievement of autonomous decision-making. However, as I identified in Chapter 1, the information provided to those opting in to deceased organ donation by adding their names to the Organ Donor Register (ODR) is insufficient for this presumed rationale to be realised. This is particularly true and particularly concerning in relation to that part of the organ donation process that begins before death. No mention is made of ante-mortem donor optimisation procedures, yet as I have argued, these are accompanied by risks of physical harm and, if non-consensual, also by risks of ethical damage to the dignity and integrity of the dying patient.¹ Although it has been long recognised by the National Clinical Lead for Organ donation that registration on the ODR does not constitute informed consent, and that there are particular concerns when registration is used to justify changes to end-of-life care, he nevertheless queries whether it is “an ethical imperative to improve the quality of consent” for organ donation.² I argue in this chapter that it is both an ethical and legal imperative to introduce a system of informed consent for the different interventions that may occur as part of the organ donation process, and in particular for those interventions that take place whilst the potential organ donor is still alive.

¹ See Chapter 2 for my arguments on autonomy, dignity, and integrity. The risks of physical harm were raised in Chapter 1 and will be further evaluated in Chapter 4.

² P. Murphy, ‘Optimizing Donor Potential in the UK’ (2011) 6 *Clin Ethics* 127-133, 128 [‘Optimizing Donor Potential’].

Although this chapter evaluates the concept of informed consent from a legal perspective, I argue that the ethical concept of autonomy, as elucidated in Chapter 2, provides the primary rationale for obtaining informed consent. This rationale provides the ethical foundation for my argument that a system of informed consent for donor optimisation procedures should be introduced. However, this chapter also provides a legal foundation for this overarching claim. By evaluating the civil law on clinical negligence, I demonstrate that the legal standards of informed consent are applicable to registration on the ODR and that these legal standards are themselves based on autonomy. I argue that the NHS organ donation programme is currently in breach of its duty of care to ODR registrants and assess what this duty of care requires in terms of information on the nature, timing, and risks of donor optimisation procedures.

The chapter begins with an evaluation of the ethical rationale underlying informed consent, followed by an exploration of the inherently prospective nature of informed consent. I argue that the ethical rationale behind obtaining the informed consent of ODR registrants to donor optimisation procedures is autonomy, as it is for any other medical interventions. I then look at the information and consent requirements needed to protect the organ donation programme against charges of battery and negligence.³ I argue that informed consent standards required by recent case law on clinical negligence are based on autonomy, and as such they require the introduction of a specific informed consent model for donor optimisation procedures. I evaluate what the current problems are meeting the requirements of the Mental Capacity Act 2005 (MCA) provisions on advance decision-making and how these problems could be addressed in relation to donor optimisation procedures. I conclude by exploring what a specific informed consent model based on autonomy would require in terms of information and consent procedures for donor optimisation procedures.

³ The alternative defence to battery of best interests is evaluated in Chapter 4.

The Concept of Informed Consent

The basic concept of informed consent is, as Brazier recognised back in the 1980s, “simple, self-evident and well-rehearsed”.⁴ The entitlement of a competent adult to make up their own mind whether to accept or reject a proposed medical treatment is “part and parcel of his or her autonomy, of sovereignty over one’s own body”.⁵ Protecting and enabling this autonomy is the primary rationale for giving the patient the information they need to make their own decision regarding medical treatment and the option to consent to or to refuse that treatment. Both the informational and the consent components of informed consent are first and foremost protecting and promoting the same ethical principle. This principle of autonomy, as detailed in Chapter 2, provides the basis for the arguments presented in this chapter that a system of informed consent for donor optimisation procedures should be introduced.

As explained in Chapter 1, the necessary conditions for informed consent to the organ donation process are not currently being met. The practice of registration on the ODR does not enable individuals to assume the sovereign authority over medical decisions that is fundamental to informed consent. In order to assume this authority in practice, ODR registrants need to be informed of the timing, nature and consequences of ante-mortem donor optimisation procedures and they need to understand that information. Crucially, they also need to be afforded decision-making power to make their own decisions about these procedures. Without these conditions being met, autonomy exists only as an abstract notion for ODR registrants rather than something that is achievable in practice.

⁴ M. Brazier, ‘Patient Autonomy and Consent to Treatment’ (1987) 7(2) *Legal Studies* 169-193, 172 [‘Patient Autonomy’].

⁵ *Ibid*, 173.

The clinical practice of obtaining informed consent evolved in response to legal judgements imposing it on doctors and healthcare institutions as part of their duty of care.⁶ However, protecting the organ donation programme from liability for any breach to that duty of care does not provide the primary rationale for the arguments presented in this chapter. Underlying my legal arguments is an aim to meet the original rationale of informed consent, as established in foundational documents such as the Nuremburg Code.⁷ This original rationale of self-determination is now accepted by most academics, doctors, and lawyers to be the “whole point” of informed consent.⁸ This rationale is now explicitly recognised in legal judgements relating to medical treatment and is also implicitly recognised in professional guidance issued to doctors.⁹ Informed consent is much more than a tick of a box on the ODR website but a process that is aimed at facilitating self-determination. This is the primary reason for obtaining informed consent and it underlies the autonomy-based model advocated in this thesis.¹⁰

⁶ The term “informed consent” was first used in *Salgo v Leland Stanford Jr. University Board of Trustees* (1957) 317 P.2d 170 (Court of Appeals of California) ; the US approach to informed consent was discussed in *Sidaway v Bethlem Royal Governors* [1985] AC 871, but it took longer for the doctrine to be fully accepted in the UK – see *Brazier*, ‘Patient Autonomy’ as earlier; also T.K. Feng, ‘Failure of Medical Advice: Trespass or Negligence’ (1987) 7(2) *Legal Studies* 149-168 & R. Schwartz & A. Grubb, ‘Why Britain Can’t Afford Informed Consent’ (1985) 15(4) *Hastings Cent Rep* 19-25; see W.A.Silverman, ‘The Myth of Informed Consent: In Daily Practice and in Clinical Trials’ (1989) 15 *J Med Ethics* 6-11, 7, for a critique of the “consent-seeking routine”.

⁷ *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*. (Nuremberg, October 1946-April 1949) provision 1 [‘Nuremberg Code’]; J. Miola, ‘The Need for Informed Consent: Lessons from the Ancient Greeks’ (2006) 15 *Camb Q Healthc Ethics* 152-160, 152-153, [‘Need for Informed Consent’].

⁸ T. Beauchamp, ‘Informed Consent: Its History, Meaning, and Present Challenges’ (2011) 20 *Camb Q Health Ethics* 515-523, 518 [‘Informed Consent’]; A. Farrell & M. Brazier, ‘Not so New Directions in the Law of Consent? Examining *Montgomery v Lanarkshire Health Board*’ (2016) 42 *J Med Ethics* 85-88.

⁹ See particularly *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 – as discussed later in this chapter; General Medical Council, *Consent: Patients and Doctors Making Decisions Together* (2008) particularly paragraphs 2,5, 7-12, 29-33, 37-44 & 52-53.

¹⁰ This model will be detailed further later in this chapter.

Considerations such as the promotion of patient well-being and protection from iatrogenic harm may, under some circumstances, provide additional reasons for obtaining informed consent.¹¹ However, they do not displace autonomy as the primary rationale for obtaining the informed consent of ODR registrants to donor optimisation procedures. Individuals providing informed consent to these non-therapeutic procedures are not going to obtain any medical benefit themselves and risk iatrogenic harm. Although their psychological well-being would be promoted by having a system of informed consent in place,¹² this entirely supports keeping autonomy as the ethical foundation for informed consent. Likewise, although a requirement to obtain informed consent would protect those individuals who opt to refuse donor optimisation procedures from iatrogenic harm, this also supports autonomy retaining its central position in informed consent. The prevention of physical harm is, like any potential improvement in psychological well-being, merely a constituent element of self-determination.

As I discussed in Chapter 2, considerations that are related to autonomy, such as dignity and integrity, are important ethical principles supporting my claim that a system of informed consent should be introduced for donor optimisation procedures. However, like the protection from harm and the promotion of well-being, they do not displace autonomy as the primary rationale for informed consent as they are contingent on that informed consent being grounded in autonomy.¹³ Similarly, the safeguarding of trust in the organ donation programme is an important consideration supporting my claim that a system of informed consent should be introduced. However, it does not displace autonomy as the primary

¹¹ For discussions regarding alternative or coexistent rationales for informed consent see J. Taylor, 'Autonomy and Informed Consent: a Much Misunderstood Relationship' (2004) 38 *J Value Inq* 383-391 & N. Eyal, 'Informed Consent' in E. Zalta, *The Stanford Encyclopedia of Philosophy* (Fall 2012 Edition).

¹² As discussed in Chapter 2 on the value of self-determination; psychological benefit will be considered further in Chapter 4.

¹³ The relationship between autonomy, dignity, and integrity is examined in Chapter 2.

rationale for informed consent because the long-term maintenance of trust is, as explicated in Chapter 2, dependent on that trust being based on autonomy.

The Prospective Nature of Informed Consent

The informed consent of ODR registrants to donor optimisation procedures is currently excluded from organ procurement policy. Informed consent standards, based on either the ethical concept of informed consent or the law, are not applied by NHSBT to the process of registration on the ODR. However, the treatment of incapacitated patients identified as potential organ donors is, under current donor optimisation policy, particularly determined by registration on the ODR.¹⁴ As I will argue in Chapter 4, the limitation of this registration to deceased organ donation itself generates significant problems in encompassing ante-mortem donor optimisation procedures within the MCA provisions on best interests. Current donor optimisation policy does not have a clear and unambiguous legal justification¹⁵ - despite the fact that, as I will argue in this chapter, both the ethical and legal standards of informed consent are applicable to registration on the ODR.

Informed consent is as relevant to donor optimisation procedures that may be performed as a consequence of ODR registration as it is to any other medical interventions. The ethical justification of autonomy is not diminished by the advance nature of decision-making. There is no bright line between advance and so-called contemporaneous consent, and all informed consent is given prospectively. This may be by a few minutes, as in the case of a minor procedure under local anaesthetic, or by many years, as in the case of most ODR

¹⁴ National Institute for Health and Care Excellence (NICE), *Organ Donation for Transplantation: Improving Donor Identification and Consent Rates for Deceased Organ Donation* (Clinical Guidance 135, 2011, updated 2016) p.7 [1.1.8] [*'Improving Donor Identification'*]

¹⁵ See arguments presented in Chapter 4; also S-J. Brown, 'The Legal Justification for Donor Optimisation Procedures' (2016) 11(4) *Clin Ethics* 122-129.

registrations. However, the length of time between informed consent and the intervention, and the capacity of the patient once it is performed, do not alter the ethical rationale for requiring informed consent.

Although informed consent requires that the individual giving it is competent, it is not a concept that only applies to procedures performed on competent individuals. For example, surgical interventions performed on previously competent patients incapacitated due to general anaesthesia require their prospective informed consent. A surgeon who has obtained informed consent to perform a mastectomy cannot simply decide to remove a kidney for organ donation,¹⁶ even if they do believe this to be in the patient's best interests. The law on informed consent, and the underlying principle of autonomy, remain applicable even though the patient is currently incapacitated. Likewise, the ethical and legal concept of informed consent remains relevant to other circumstances in which the patient is incapacitated but previously competent. It is a concept that is applicable to registration on the ODR, with its potential consequences of undergoing invasive interventions at the end-of-life. As these interventions are of a different nature and carry different risks to deceased organ donation, both patient self-determination and legal standards require that informed consent is obtained.¹⁷

It might be thought that the informed consent of potential organ donors doesn't matter as, unlike patients under general anaesthesia, they have permanently lost decision-making capacity and are on a fast-track to death. However, quite apart from the damage this would do to the ethical principles of autonomy, dignity and integrity, any such assumptions may not in all cases be correct. A proportion of patients under general anaesthesia suffer surgical complications that result in permanent loss of decision-making capacity or even

¹⁶ See *Davis v Barking, Havering and Brentwood Health Authority* [1993] 4 Med LR 85, 90.

¹⁷ The law on informed consent will be evaluated in more detail in the next section.

death.¹⁸ On the other hand, some patients identified as potential organ donors following brain injuries might not only survive, as is recognised by organ procurement policy-makers,¹⁹ but also retain or regain decision-making capacity.²⁰ The determination of whether any incapacity is permanent and whether death will result from a brain injury can only be made with hindsight. Whatever the outcome of the brain injury, the patient's previously competent views towards medical interventions retain the same value. This value lies both in the protection and realisation of their prospective autonomy and in the protection and realisation of their dignity and integrity.

The normative authority behind my claim that NHSBT should introduce a system of informed consent for donor optimisation procedures lies in the principle of autonomy, as delineated in Chapter 2. If upheld, this autonomy would withstand any loss of decision-making capacity and persevere throughout the end-of-life care of the potential organ donor. The potential organ donor themselves would remain the decision-maker, not doctors, nor policy-makers, nor relatives, nor designated representatives or attorneys. Upholding the advance directive would recognise the paramount authority of the ODR registrant to determine what, if any, non-therapeutic interventions they would wish to have, what risks they are prepared to accept, and under what set of circumstances.

Although all informed medical decisions are founded on the same ethical principle of autonomy, the law on informed decision-making is divided into several areas of law and not all of these areas of law afford the same degree of protection to autonomy. The civil law on

¹⁸ See eg. D. Cook & S. Bruggink, 'Cerebral Morbidity in Adult Cardiac Surgery', Chapter 12 in S. Ghosh, F. Falter & A. Perrino, *Cardiopulmonary Bypass* (CUP, 2nd edition, 2015) 168-185; N. Kotekar, C. Kuruvilla, V. Murthy, 'Post-operative Cognitive Dysfunction in the Elderly: A Prospective Clinical Study' (2014) 58(3) *Indian J Anaesth* 263-268; A. Heeney, F. Hand, J. Bates *et al*, 'Surgical Mortality – an Analysis of All Deaths Within a General Surgical Department' (2014) 12(3) *Surgeon* 121-128.

¹⁹ NICE, *Improving Donor Identification* as earlier p. 7, footnote 4 in original 2011 guidance or endnote 2 in 2016 update.

²⁰ This is explored in more detail in Chapter 4.

negligence, the civil and criminal law on battery, the MCA provisions on advance directives,²¹ and the encompassment of advance consent within best interests,²² are all applicable to registration on the ODR and the subsequent treatment of the potential organ donor. The consent standards required by the law on battery and the informed consent standards required by the law on negligence differ from one another and from the law on advance consent and refusal. The next section considers the law on battery, whilst the following three sections focus on the different elements of the tort of negligence. This is followed by an evaluation of the MCA provisions that would need to be met for an advance directive by an ODR registrant to be legally binding.

Real Consent and Battery

Two separate areas of tort law determine the informed consent standards required for donor optimisation procedures. In the first, the law on battery, the standard to be reached is that of real consent²³ - a standard that affords some respect to autonomy yet is satisfied by the giving of consent based on information in “broad terms” of the nature and effect of the procedure and in the absence of fraud.²⁴ In the second, the law on negligence, the standard is informed consent – a standard that, following recent case law, is now based on the ethical principle of autonomy.²⁵ In this section, I consider what the law on battery requires of the organ donation programme.

The civil law on battery is applicable to the incapacitated patient identified as a potential organ donor - even if the patient is unconscious, unaware of the physical violation,

²¹ S. 24-26

²² S. 4(6) (1).

²³ *Chatterton v Gerson* [1981] 1 QB 432, 442B-C.

²⁴ *Ibid*, 443A-B; *Davis v Barking, Havering and Brentwood Health Authority* [1993] 4 Med L R 85.

²⁵ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11.

and if no physical harm has occurred.²⁶ Without consent or other legal justification, any intentional acts causing direct contact with the patient's body fulfil the definition of a battery under the civil law, even if the intent is merely to commit the act rather than to cause harm.²⁷ Under the criminal law on battery, which is also applicable to the incapacitated patient, a *mens rea* must be established.²⁸ This requires either an intention to apply unlawful force or recklessness as to whether such force might be applied.²⁹ The force under both the criminal and civil law may be as minor as touching.³⁰ It is the lack of consent or other legal justification that renders an intentional act a battery, and not the degree of force or the causation of harm.

As I will show in Chapter 4, there are problems with the MCA provisions on best interests providing a legal defence to battery and these problems mostly stem from the lack of consent. Although the judiciary discourages the use of the tort of battery for clinical non-disclosure claims,³¹ there is a substantial chance of a successful claim under the civil law on battery and also the possibility of healthcare professionals being found guilty of the criminal offence of battery. This is particularly the case due to the initiation of ante-mortem donor optimisation procedures before the assessment of patient wishes,³² which could lead to the failure of an appeal to best interests as a legal defence.³³ Under these circumstances, the organ donation programme would have to demonstrate that registration on the ODR fulfils

²⁶ *Collins v Wilcock* [1984] 1 WLR 1172 (CA) 1177 per Goff LJ; See also R. Hardcastle, *Law and the Human Body: Property Rights, Ownership and Control* (Hart publishing, Oxford, 2007) 185.

²⁷ *Re F* [1992] AC 1 at 73B; A. Mclean, *Autonomy, Informed Consent and Medical Law: A Relational Challenge* (CUP, 2009) 150.

²⁸ Criminal Justice Act 1988 S. 39; Offences Against the Person Act 1861 S. 18, 20 & 47.

²⁹ *R v Venna* [1976] QB 421, 429 per James LJ; *R v Gladstone Williams* (1984) 78 Cr. App. R. 276, 279-280 per Lord Chief Justice; *D v DPP* [2005] EWHC 967 (Admin) [14] per Mr Justice Steel.

³⁰ *Cole v Turner* (1704) 90 ER 958; *Wilson v Pringle* [1986] QB 237

³¹ *Chatterton v Gerson* [1981] 1 QB 432, 443B-C, Bristow. J.

³² NICE, *Improving Donor Identification* as earlier, p.7 [1.1.6-1.1.7].

³³ This will be evaluated in more depth in Chapter 4.

the consent requirements of the civil and/or criminal law on battery in relation to ante-mortem donor optimisation procedures.

Most invasive medical and surgical interventions lie above the threshold that would normally be regarded as constituting actual bodily harm, yet doctors are not held criminally liable in battery if valid consent has been given.³⁴ In general, the criminal law regards consent as irrelevant if actual bodily harm was “intended and/or caused”.³⁵ However, “proper medical treatment” is recognised as being in “a category of its own”.³⁶ This is known as the medical exception to the criminal law, and it requires the existence of some form of valid consent.³⁷ If no consent has been given, and no other legal justification exists,³⁸ then the potential remains for doctors to be found criminally liable in battery for implementing current donor optimisation policy.

As Mr Justice Bristow explicated in *Chatterton v Gerson*, for consent to constitute a defence to what would otherwise be a civil wrong, that consent must be real.³⁹ The reality of consent depends on three conditions: the provision of information in “broad terms” of the nature of the procedure;⁴⁰ the giving of consent; and the absence of fraud.⁴¹ For the first condition to be met in relation to donor optimisation procedures, some reference must be made – even loosely – to their basic features, character or essence, which it is not. Neither is

³⁴ *R v Brown* [1994] 1 AC 212, 266, per Lord Mustill.

³⁵ *A-G's Reference (No 6 of 1980)* [1981] QB 715 (CA) 719, per Lord Lane.

³⁶ *R v Brown* as earlier, 266 per Lord Mustill.

³⁷ See S. Fovargue and A. Mullock, *The Legitimacy of Medical Treatment: What Role for the Medical Exception?* (Routledge, London, 2015).

³⁸ The MCA S. 5(2) only protects doctors from liability if they reasonably believe that the patient lacks capacity and it is in their best interests for the act to be done.

³⁹ [1981] 1 QB 432, 442B-C

⁴⁰ This was clarified to include the effect of the procedure in *Davis v Barking, Havering and Brentwood Health Authority* [1993] 4 Med L R 85.

⁴¹ *Chatterton v Gerson* as earlier 443A-B.

it met by information on the nature of deceased organ donation as this relates to the removal of organs from a dead body and not to medical interventions performed on a live patient. The reality of consent is vitiated both by the complete lack of information on donor optimisation procedures and by the fact that no consent has been given. As there is no opportunity to give consent to procedures before death, there can be no consent, a reality which will continue until both information disclosure and consent procedures are put into place.

The Tort of Negligence and the Duty of Care

The recognition by the National Clinical Lead for Organ Donation that registration on the ODR “falls well short of the standard of informed consent applied to other aspects of health care”⁴² raises questions regarding the potential for a successful claim to be brought under the tort of negligence. The first is whether legal standards of informed consent, as detailed in *Montgomery v Lanarkshire Health Board*,⁴³ apply to registration on the ODR. The duty of care acts as a gatekeeper to these standards, prescribing the circumstances in which they apply. If it can be shown to exist, then demonstrating a breach to that duty seems straightforward enough, yet proving that the requisite harm has been caused may be challenging. The failure to inform, as I argued in Chapter 2, causes ethical damage to the autonomy, dignity and integrity of the potential organ donor, yet the tort of negligence is constructed around the “traditional paradigm of physical harm”.⁴⁴ Although autonomy interests do influence judicial

⁴² Murphy, ‘Optimizing Donor Potential’, as earlier.

⁴³ [2015] UKSC 11 [86].

⁴⁴ V. Chico, ‘The Recognition of New Interests and Corresponding Duties of Care in English Negligence Law’ Chapter 2 in *Genomic Negligence: An Interest in Autonomy as the Basis for Novel Negligence Claims Generated by Genetic Technology* (Routledge, Abingdon & New York, 2011) 16-36, 16.

reasoning,⁴⁵ unlike under the tort of battery they are not usually treated as actionable on their own merits.

In this section I consider the potential challenges in establishing that NHSBT has a duty of care towards ODR registrants. I argue that, despite these challenges, a duty of care can be shown to exist. In the following two sections I consider what that duty of care requires in terms of information disclosure, and the potential problems in establishing causation. Before evaluating the challenges involved in bringing a claim in negligence, I first consider who might bring a claim and under what circumstances.

NICE's admission that "a proportion of patients identified" and treated as potential organ donors before death "will survive"⁴⁶ suggests that an individual who has suffered physical complications as a result of their treatment as a potential organ donor could survive to bring a claim in negligence. For example, an individual who had suffered vascular complications following femoral cannulation might not only survive but retain or regain the mental capacity to bring a claim.⁴⁷ A different individual who has suffered severe neurological damage as a result of non-therapeutic ventilation⁴⁸ might survive but lack mental capacity and only be able to have a claim brought on their behalf by a litigation friend.⁴⁹

⁴⁵ See particularly *Rees v Darlington Memorial Hospital NHS Trust* [2004] 1 AC 309 (HL), which will be evaluated later in this section.

⁴⁶ NICE, *Improving Donor Identification* as earlier p. 7, footnote 4 in original 2011 guidance or endnote 2 in 2016 update.

⁴⁷ The potential for retaining or regaining mental capacity is discussed in Chapters 1 and 4.

⁴⁸ The risks of severe neurological damage are evaluated in Chapter 4.

⁴⁹ Under the Civil Procedure Rules 1998 S. 21, special provisions apply to children and to patients whose mental incapacity fulfils the definition of mental disorder contained within the Mental Health Act 1983, including provisions detailing who may become a litigation friend.

But for the Law Reform (Miscellaneous Provisions) Act 1934 (LRA), the potential organ donor's claim in negligence would be extinguished upon their death.⁵⁰ However, subject to the provisions of this Act, on a patient's death "all causes of action...vested in him...shall survive... for the benefit of his estate".⁵¹ The personal representative of that estate may, as they did in the recent case of *Shaw v Kovac*,⁵² bring a claim for damages in respect of the patient's pain and suffering.⁵³ This might, for example, occur if a potential organ donor's trachea is ruptured from endotracheal intubation for non-therapeutic ventilation⁵⁴ and a relative who is appointed as representative of their estate witnesses their pain and suffering before death.

In most clinical negligence cases, the defendant is the healthcare professional or professionals who have been directly involved with the clinical care of the claimant and/or the NHS Trust for which they work. It is well established that all healthcare professionals owe a tortious duty of care to their patients.⁵⁵ NHS Trusts and hospitals have both a primary liability towards patients as the occupier of the hospital premises and a vicarious liability for the acts of its employees.⁵⁶ Should a patient (or the personal representative of their estate) wish to bring a claim against the healthcare professionals who identified and treated them as a potential organ donor and/or the NHS Trust for whom they worked, establishing a duty of care is straightforward. If the donor optimisation procedures were performed negligently and the patient suffered physical harm as a result of that negligence, there is a potential for a

⁵⁰ R. Mulheron, *Medical Negligence: Non-Patient and Third Party Claims* (Routledge, London & New York, 2010) p.11 & endnote 41 [*'Third Party Claims'*].

⁵¹ S. 1(1).

⁵² [2015] EWHC 3335 (QB) [13]; [2017] EWCA Civ 1028 [1-3].

⁵³ The claim (which was denied in *Shaw v Kovac*) for damages for loss of autonomy will be considered later in this section.

⁵⁴ H. Lim, J. Kim, D. Kim *et al*, *Tracheal Rupture after Endotracheal Intubation – A Report of Three Cases* (2012) 62(3) *Korean J Anaesthesiol* 277-280 [*'Tracheal Rupture'*].

⁵⁵ S. Hedley, 'Professional Liability' in A. Grubb, *The Law of Tort* (Butterworths LexisNexis, UK, 2002) 685-720, 700 [*'Law of Tort'*].

⁵⁶ *Ibid.*

successful claim against the healthcare professionals and/or the NHS Trust as their employers. However, if the claim is that NHSBT failed to inform them of the nature and risks of ante-mortem donor optimisation procedures and that they suffered physical harm as a result of this failure to inform, this is more complicated as it has not previously been established that NHSBT has a duty of care towards ODR registrants.

The test that is applied by the Courts whenever they are confronted with a new set of circumstances in which they need to establish whether or not a duty of care exists is the three-stage test originating from *Caparo Industries plc v Dickman*.⁵⁷ In this case, Lord Bridge's analysis of previous case-law leads him to specify the "necessary ingredients in any situation giving rise to a duty of care".⁵⁸ He details these necessary ingredients as foreseeability of damage; the existence of a relationship of proximity between the parties; and the situation being one in which the court considers it "fair, just and reasonable" to impose a duty of care.⁵⁹ These latter two elements are, as Lord Oliver comments, intended to control what could otherwise be a "limitness vista" of liability for professionals.⁶⁰

Should an ODR registrant, or the personal representative of their estate, bring a claim against NHSBT for negligence, NHSBT are likely to allege that there is a duty of care issue and that the law of negligence is inapplicable to the circumstances of organ donor registration. The "default position" in any new situation is that a duty of care does not exist.⁶¹ However, as recognised in *Barrett v Enfield London Borough Council*,⁶² in situations in which uncertainty exists, it is "important...to decide these cases on actual facts and not on mistaken

⁵⁷ *Caparo Industries plc v Dickman* [1990] 2 AC 605; C. Elliott & F. Quinn, *Tort Law* (8th edition, Longman, Harlow, 2011) 20.

⁵⁸ *Caparo* as above, 617-8.

⁵⁹ *Ibid.*

⁶⁰ *Ibid.*, 643.

⁶¹ *Stovin v Wise* [1996] AC 923, 949 per Lord Hoffmann.

⁶² [2001] 2 AC 500.

hypotheticals”.⁶³ What needs to be determined is whether the three elements of the *Caparo* test are fulfilled in the circumstances of ODR registration.⁶⁴

The first of the necessary components of the duty of care is the foreseeability of damage.⁶⁵ The claimant must show that a reasonable person or persons in NHSBT’s position would be able to foresee the risk of harm to ODR registrants from the failure to inform of the risks of ante-mortem donor optimisation procedures. As registration on the ODR is interpreted under current organ procurement policy as evidence that donor optimisation procedures are in the patient’s best interests,⁶⁶ and as these procedures carry risks of physical harm,⁶⁷ it is readily foreseeable that failing to inform potential ODR registrants about ante-mortem donor optimisation procedures is likely to result in some registrants suffering physical harm that they would not otherwise have suffered. Even if these risks are thought to be low, they are not “far-fetched”⁶⁸ and the reasonable foreseeability test is fulfilled. As has been confirmed by Lord Hope, “the concept of reasonable foreseeability embrace[s] a wide range of degrees of possibility, from the highly probable to the possible but highly improbable. As the possible adverse consequences of carelessness increase in seriousness, so will a lesser degree of likelihood of occurrence suffice to satisfy the test of reasonable foreseeability”.⁶⁹ As the possible adverse consequences of the failure to inform include the ODR registrant suffering a severe disability such as a permanent vegetative state or minimally conscious

⁶³ Ibid, 557-558, per Lord Browne-Wilkinson.

⁶⁴ *Caparo* as earlier, 617-8.

⁶⁵ Ibid, 617.

⁶⁶ *NICE, Improving Donor Identification* as earlier, p.7 [1.1.8]; NHSBT, ‘Taking Organ Transplantation to 2020: A UK Strategy’ (2013) p.7. available at <http://www.nhsbt.nhs.uk/to2020/the-strategy/> (last accessed 15/01/18) [‘UK Strategy’].

⁶⁷ As discussed in Chapters 1 & 4.

⁶⁸ *A-G of the British Virgin Islands v Hartwell* [2004] UKPC 12 [21] per Lord Nicholls.

⁶⁹ *Mitchell v Glasgow City Council* [2009] UKHL 11.

state,⁷⁰ even a low degree of likelihood of this occurring is enough to satisfy the reasonable foreseeability requirement.

The second and third components of the duty of care, the relationship of proximity and the fairness, justness, and reasonableness of imposing a duty, create uncertainty as to the circumstances in which the law would recognise a duty of care.⁷¹ In cases involving previously unexamined duty of care scenarios, there is no “one-size-fits-all” approach to determining whether these components are fulfilled.⁷² With regard to the first component, Lord Oliver comments in *Caparo*, “one looks in vain for some common denominator by which the existence of the essential relationship can be tested” and “proximity” is “merely a description of circumstances from which, pragmatically, the courts conclude that a duty of care exists”.⁷³ However, there are cases in which the judiciary have attempted to explain what they mean by proximity and,⁷⁴ as I will argue later in this section, these definitions support my claim that NHSBT are in a relationship of proximity with registered organ donors at the end of life.

Establishing a relationship of sufficient proximity between NHSBT and ODR registrants is complicated by the fact that a case in negligence is only going to be brought by or on behalf of a registered organ donor who has suffered harm as a result of the failure to inform. At the time that any physical injury is caused, the ODR registrant would be an inpatient under the care of clinicians and the NHS trust for which they work. However, this does not interrupt the relationship between NHSBT and the ODR registrant. NHSBT are the national organisation established to secure the effective provision of services under the National Health Service Act

⁷⁰ These risks will be further evaluated in Chapter 4.

⁷¹ *Mulheron, 'Third Party Claims'* as earlier, 30.

⁷² *Ibid.*

⁷³ *Caparo* as before, 633.

⁷⁴ *Donoghue v Stevenson* [1932] AC 562; *Sutradhar v Natural Environment Research Council* [2006] UKHL 33.

1977 in connection with “facilitating, providing and securing the provision of services to assist tissue and organ transplantation”.⁷⁵ NHSBT’s responsibilities towards ODR registrants do not end after they have added their name to the list of registered organ donors, as they have also accepted responsibility for “increas[ing] adherence to national standards and guidance”, “increas[ing] the number of people who are able to donate following circulatory death” and “ensur[ing] every donor’s care, prior to retrieval, optimises organ quality”.⁷⁶ Their relationship therefore extends to the end-of-life care received by registered organ donors.

Proximity has been said to be a “slippery word”,⁷⁷ and uncertainty surrounding its definition could potentially generate problems in establishing whether the relationship between NHSBT and registered organ donors at the end-of-life is sufficiently proximate to establish a duty of care. However, as was held in *Donoghue v Stevenson*,⁷⁸ proximity is “not confined to mere physical proximity” but “extend[s] to such close and direct relations that the act complained of directly affects a person whom the person alleged to be bound to take care would know would be directly affected by his careless act”.⁷⁹ The act complained of, i.e. the failure to inform, directly affects the registered organ donor whom NHSBT knows would be directly affected by the failure to inform. NHSBT are aware that the information provided to potential ODR registrants influences their decision whether or not to sign up,⁸⁰ and they interpret that registration as authorising changes to their end-of-life care to facilitate organ donation.⁸¹ The close and direct relationship between NHSBT’s failure to inform and the

⁷⁵ The NHS Blood and Transplant (Establishment and Constitution) Order 2005 S. 3 (1)(c).

⁷⁶ NHSBT, ‘Saving and Improving Lives: Strategic Plan 2016-2021’ (2016) available at https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/1499/strategic_plan_2016_21.pdf (last accessed 15/01/18) p.12 [‘Strategic Plan’].

⁷⁷ *Stovin v Wise* as earlier, 932, per Lord Nicholls.

⁷⁸ [1932] AC 562

⁷⁹ *Ibid*, 581, per Lord Atkin.

⁸⁰ See *Murphy*, ‘Optimizing Donor Potential’ as earlier, 128, & UKDEC, *An Ethical Framework for Controlled Donation after Circulatory Death* (2011) p.55, [3.1.1.].

⁸¹ NHSBT, ‘UK Strategy’ as earlier, p.7.

subsequent treatment of the registered organ donor establishes that this definition of proximity is met.

The law is said to be “wide enough to embrace any new category or proposition that exemplifies the principle of proximity”.⁸² This principle of proximity is defined in the case of *Sutradhar v Natural Environment Research Council*⁸³ “in the sense of a measure of control over and responsibility for the potentially dangerous situation”.⁸⁴ NHSBT certainly have a measure of control and responsibility over the situation, as they determine how much information is provided to ODR registrants and have considerable influence over the way that they are subsequently treated at the end-of-life. They have assumed responsibility for both ODR registration and for increasing adherence to donor optimisation guidelines.⁸⁵ Under both this definition and that of a close and direct relationship between the parties, there is sufficient proximity to generate a duty of care to ODR registrants.

The final element to be met in establishing NHSBT’s duty of care towards ODR registrants is the fairness, justice, and reasonableness to imposing a duty of care. This element overlaps to a degree with the proximity and foreseeability tests, which together aim to answer the “pragmatic question [as to] whether a duty should be imposed in any given case”.⁸⁶ The fairness, justice, and reasonableness of imposing a duty of care on NHSBT rests, as it did in relation to the supervision of boxing matches in *Watson v British Boxing Board of Control*,⁸⁷ on a number of factors. These include the relationship of proximity between the parties and NHSBT’s assumption of responsibility for overseeing organ donation and transplantation. They

⁸² *Hedley Byrne & Co. Ltd v Heller & Partners Ltd* [1964] AC 465, 531 per Lord Devlin.

⁸³ [2006] UKHL 33.

⁸⁴ *Ibid*, [38] per Lord Hoffman.

⁸⁵ NHSBT, ‘Strategic Plan’ as before, p.11-12.

⁸⁶ *Marc Rich & Co AG v Bishop Rock Marine Co Ltd* [1994] 1 WLR 1071, 1077 per Lord Justice Saville.

⁸⁷ 1162-1163, per Lord Phillips.

are the institution in charge of organ donation and it is fair, just, and reasonable to impose a duty of care. There are also public policy reasons for imposing a duty of care, as public trust in the organ donation programme could be badly damaged if the institution in charge of organ donation were afforded immunity from liability in negligence.⁸⁸

The fulfilment of the three prongs of the *Caparo* test establishes that NHSBT do have a duty of care towards ODR registrants. That duty of care requires them to provide ODR registrants with the information they need to make an autonomous decision about ante-mortem donor optimisation procedures and the opportunity to make that decision. Informed consent standards required under the tort of negligence are much higher than the “broad terms” that are sufficient under the law on battery. Informed consent standards, as detailed in the recent *Montgomery v Lanarkshire Health Board* judgement,⁸⁹ are based on the achievement of individual autonomy. It is this individual autonomy that, as part of NHSBT’s duty of care to ODR registrants, determines the information that needs to be disclosed about the organ donation process.

Legal Standards of Informed Consent

The *Montgomery* judgement means that NHSBT cannot simply deny self-determination to ODR registrants on the grounds that information disclosure falls within their professional judgement. This approach, as endorsed in a series of cases from *Bolam* to *Sidaway* and beyond,⁹⁰ has now been overturned.⁹¹ Bolam suffered serious iatrogenic harm following his

⁸⁸ Refer back to my arguments on trust and distrust in Chapter 3.

⁸⁹ [2015] UKSC 11

⁹⁰ *Bolam v Friern Hospital Management Committee* [1957] 1 WLR 582; *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, see Lord Diplock’s speech, particularly 892-895; A. Maclean, ‘From Sidaway to Pearce and Beyond: Is the Legal Regulation of Consent any Better Following a Quarter of a Century of Judicial Scrutiny?’ (2012) 20(1) *Med Law Rev* 108-29.

doctors' failure "to warn him of the risks which he was running when he consented to treatment".⁹² His name was misappropriated to justify an information disclosure model based not on patient autonomy but on what the medical profession themselves deemed to be "proper".⁹³ This model persisted for many decades, and despite some headway in other judicial speeches,⁹⁴ has only been completely rescinded by the finding in *Montgomery* that "[t]here is no reason to perpetuate the application of the Bolam test in [the] context [of risk disclosure] any longer".⁹⁵ Instead, the "correct position"⁹⁶ to be taken by NHSBT is one grounded in patient autonomy.

Recognising the social and legal developments over recent years,⁹⁷ the judicial speeches in *Montgomery v Lanarkshire Health Board* seek to unite the practice of informed consent with the goal of patient self-determination. The case exemplifies the difficulties that patients face obtaining the information they need to make an informed decision, as well as the serious consequences that can result from the denial of this information. Montgomery was an insulin-dependent diabetic pregnant woman who was denied information about a 9-10% risk of shoulder dystocia,⁹⁸ a "major obstetric emergency"⁹⁹ associated with a "high

⁹¹ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [86].

⁹² *Bolam v Friern Hospital Management Committee* as above, 583.

⁹³ *Ibid*, 582; see particularly *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871; also *Blyth v Bloomsbury Health Authority* [1993] 4 Med L R 151; *Gold v Haringey Health Authority* [1988] QB 481.

⁹⁴ See Lord Scarman's speech in *Sidaway* as above, 882-890; *Smith v Tunbridge Wells Health Authority* [1994] 5 Med L R 334; *Pearce v United Bristol Healthcare NHS Trust* [1999] PIQR 53 (CA).

⁹⁵ *Montgomery v Lanarkshire Health Board* [2015] UKSC 11 [86] per Lord Kerr & Lord Reed.

⁹⁶ *Ibid* [87] per Lord Kerr & Lord Reed.

⁹⁷ *Ibid* [81] per Lord Kerr & Lord Reed. Examples of these legal developments include *Chester v Afshar* [2004] UKHL 41; *Pearce v United Bristol Healthcare NHS Trust* [1999] PIQR 53 (CA); *Wyatt v Curtis* [2003] EWCA Civ 1779; *Birch v University College Hospitals NHS Trust* [2008] EWHC 2237; see also A. Farrell & M. Brazier, 'Not so New Directions in the Law of Consent? Examining *Montgomery v Lanarkshire Health Board*' (2016) 42 *J Med Ethics* 85-88; R. Heywood, 'R.I.P. *Sidaway*: Patient-Oriented Disclosure – A Standard Worth Waiting For?' (2015) 23(3) *Med Law Rev* 455-466.

⁹⁸ *Montgomery* as above, [13].

⁹⁹ Expert evidence given by Dr Owen in *Montgomery v Lanarkshire Health Board* as above [8].

perinatal mortality and morbidity” and an increased maternal morbidity.¹⁰⁰ Although Montgomery had raised concerns that the foetus might be too big to deliver vaginally, her obstetric consultant deprived her of information she needed to make an informed decision because “if you were to mention shoulder dystocia to every [diabetic] patient.....then everyone would ask for a caesarean section”.¹⁰¹ Labour was induced, the major obstetric emergency materialised, and Montgomery’s son was born with cerebral palsy and a brachial plexus injury. Neither of these birth injuries would have occurred had the obstetric consultant recognised that the choice between a medically induced labour and an elective caesarean was Montgomery’s informed decision to make.

The “correct position”¹⁰² of patient-orientated disclosure advocated by the unanimous Supreme Court judgement in *Montgomery* is that

[a]n adult of sound mind is entitled to decide which, if any, of the available forms of treatment to undergo, and her consent must be obtained before treatment interfering with her bodily integrity is undertaken. The doctor is therefore under a duty to take reasonable care to ensure that the patient is aware of any material risks involved in any recommended treatment, and of any reasonable alternative or variant treatments. The test of materiality is whether, in the circumstances of the particular case, a reasonable person in the patient’s position would be likely to attach significance to the risk, or the doctor is or should reasonably be aware that the particular patient would be likely to attach significance to it.¹⁰³

¹⁰⁰ Royal College of Obstetricians and Gynaecologists Guideline No 42 on *Shoulder Dystocia* (2005) as quoted by Lady Hale in *Montgomery v Lanarkshire Health Board* as above, [112].

¹⁰¹ *Montgomery v Lanarkshire Health Board* as above, [13]

¹⁰² *Ibid*, [87] per Lord Kerr & Lord Reed.

¹⁰³ *Ibid*, [87] per Lord Kerr & Lord Reed.

The ODR registrant is presumed competent and is entitled to decide which, if any, procedures to undergo as part of the organ donation process. These interventions impact on the bodily integrity of potential organ donors, are of no medical benefit to them, present serious physical risks,¹⁰⁴ and the consent of the individual who is to be subject to them should be obtained. The organ donation programme has the same duty of care towards potential organ donors as Montgomery's consultant had to her, and they are currently failing in this duty of care.

NHSBT's duty of care includes ensuring that potential ODR registrants are aware of any material risks involved in the organ donation process and of any alternatives or variants to this process. Following *Montgomery*, the test for materiality in these circumstances is whether a reasonable person considering registration on the ODR would be likely to attach significance to the risk, and/or whether NHSBT is or should reasonably be aware that the particular individual would be likely to attach significance to it. NHSBT could, for example, be aware of the significance of a risk to a particular individual if that individual has registered via the ODR phone line and discussed a particular concern. The assessment of the materiality of risk is based on those factors that may be significant to the patient, such as "the nature of the risk, the effect which its occurrence would have upon the life of the patient, the importance to the patient of the benefits sought to be achieved by the treatment, the alternatives available, and the risks involved in those alternatives".¹⁰⁵ The significance of these and other factors to the ODR registrant is that they contribute to their informed decision of which, if any, of the available interventions to undergo. The risks presented by the different donor optimisation procedures, and the nature of those risks, are highly significant to the reasonable person considering registration on the ODR. So also is the degree by which each procedure would

¹⁰⁴ Physical risks are outlined in Chapter 1 and will be further evaluated in Chapter 4.

¹⁰⁵ *Montgomery v Lanarkshire Health Board* as above, [89] per Lord Kerr & Lord Reed.

increase their chances of achieving successful organ donation, and what the alternatives are to undergoing donor optimisation procedures.

The position adopted in *Montgomery* is not a sudden step-change in the law but is built on a number of other judicial pronouncements.¹⁰⁶ These earlier judgements both provide the basis for the legal requirements imposed on NHSBT by the *Montgomery* judgement and further support for my claim that a system of informed consent based on patient self-determination should be introduced for donor optimisation procedures. The *Montgomery* judgement owes much to Lord Scarman's approach in *Sidaway*, which takes the patient's right to decide as its starting point¹⁰⁷ - an approach which Lord Kerr and Lord Reed recognise has been tacitly adopted by the courts over recent years.¹⁰⁸ The freeing of risk disclosure from the confines of clinical judgement is built on Lord Scarman's point that "a patient may well have in mind circumstances, objectives, and values.....which may lead him to a different decision from that suggested by a purely medical opinion".¹⁰⁹ As Lord Kerr and Lord Reed recognise, there are countless ways in which an individual's views or circumstances may affect their attitude towards treatment.¹¹⁰ These myriad ways, and the objectives and values that underlie them, are part of the self-determination that belongs to ODR registrants as it does to other competent individuals who may be subject to medical interventions.

¹⁰⁶ Lord Kerr & Lord Reed reference, amongst others, Lord Justice Sedley in *Wyatt v Curtis* [2003] EWCA Civ 1779; Lord Browne-Wilkinson in *Bolitho v City and Hackney Health Authority* [1998] AC 232; Lord Woolf in *Pearce v United Bristol Healthcare NHS Trust* [1999] PIQR 53 (CA); Lord Bingham, Walker & Steyn in *Chester v Afshar* [2004] UKHL 41; Lord Scarman in *Sidaway v The Royal Bethlem Hospital* [1985] AC 871; Lord Goff in *Airedale NHS Trust v Bland* [1993] AC 789; & the ECtHR judgements in *Glass v United Kingdom* (App no. 61827/00) (2004) 39 EHRR 15 & *Tysiac v Poland* (App no. 5410/03) (2007) 45 EHRR 947. Lady Hale also references *Rees v Darlington Memorial Hospital NHS Trust* [2004] 1 AC 309 (HL).

¹⁰⁷ *Sidaway v The Royal Bethlem Hospital* [1985] AC 871, 882-890.

¹⁰⁸ *Montgomery* as earlier, [63].

¹⁰⁹ *Sidaway* as above, [1985] AC 871, 885-886.

¹¹⁰ *Montgomery* as above, [46].

Lord Kerr and Lord Reed’s “undoubtedly right” finding that “the doctor’s duty of care takes its precise content from the needs, concerns and circumstances of the individual patient”¹¹¹ adds substantial weight to the protection offered to patient self-determination by the tort of negligence. The *Montgomery* judgement means that it is no longer mere rhetoric to claim that the legal interests protected by the law on informed consent are founded on patient autonomy. The legal standards of informed consent are now aligned with the ethical concept of informed consent, as explicated earlier in this chapter. As Lady Hale concludes,

It is now well recognised that the interest which the law of negligence protects is a person’s interest in their own physical and psychiatric integrity, an important feature of which is their autonomy, their freedom to decide what shall and shall not be done with their body.¹¹²

The *Montgomery* judgement only provides two exceptions to the autonomy-based model of informed consent, neither of which is applicable to donor optimisation procedures. The first exception permits a doctor to withhold information if they “reasonably consider that its disclosure would be seriously detrimental to the patient’s health”.¹¹³ This exception cannot apply to donor optimisation procedures as they are non-therapeutic in nature and there is no detriment to the health of any individual who decides not to undergo them. This is a therapeutic exception that, as the *Montgomery* judgement makes clear, “should not be abused.... to prevent the patient from making an informed choice where she is liable to make a choice which the doctor considers to be contrary to her best interests”.¹¹⁴ It should not be abused to prevent ODR registrants from making an informed decision no matter where organ procurement policy makers believe their best interests lie.

¹¹¹ *Montgomery* as above, [73].

¹¹² *Montgomery* as above, [108].

¹¹³ *Ibid*, [88].

¹¹⁴ *Ibid*, [91].

The second exception to the autonomy-based model of informed consent mentioned in the Montgomery judgement is “circumstances of necessity”, the only example given of which is “where the patient requires treatment urgently but is unconscious or otherwise unable to make a decision”.¹¹⁵ The scope of this exception is not detailed, but it does not appear to extend to non-therapeutic procedures. Even urgent treatment can only be performed if the doctor “reasonably believes” it to be in the best interests of the patient concerned.¹¹⁶ Section 5 of the MCA encompasses circumstances of necessity within the law on best interests, and it is these best interests that determine the lawfulness of treatment.¹¹⁷ These best interests may, in circumstances where medical interventions could be of clinical benefit to the patient, include undergoing treatment to prevent further deterioration and to sustain life.¹¹⁸ In emergency situations in which interventions are being considered for non-therapeutic reasons, best interests may include upholding any advance statements of wishes.¹¹⁹ However, in circumstances where the patient’s wishes about a non-therapeutic procedure are unknown, the defence of necessity cannot be fallen back on. Although the needs of potential organ recipients are grave and often urgent, the potential organ donor is not themselves in a circumstance of necessity and will not suffer if the non-therapeutic procedure is delayed or withheld.

Causation and Damage

Under the tort of negligence, it is not enough to show that NHSBT has a duty of care to ODR registrants and that they are currently in breach of that duty of care by failing to implement

¹¹⁵ Ibid, [88].

¹¹⁶ MCA S. 4(9) & S. 5.

¹¹⁷ This was recognised even before the MCA came into force in *St Helens BC V PE* [2006] EWHC 3460 (Fam) [12] per Justice Munby, citing *In re S (Adult Patient: Sterilisation)* [2001] Fam 15.

¹¹⁸ M. Brazier & E. Cave, *Medicine, Patients and the Law* (6th edition, Manchester University Press, 2016) 126.

¹¹⁹ S. 4(6) (a); this provision will be examined in more depth in Chapter 4.

informed consent standards as detailed in the *Montgomery* judgement. It also has to be shown that the failure to inform caused harm to the claimant. Causation often presents the most formidable hurdle for claimants to overcome. In the context of a potential organ donor's claim that NHSBT's failure to inform caused them physical harm, there may be difficulties in establishing that any physical deterioration was due to the failure to inform and not due to their pre-existing medical condition or to the treatment they would otherwise have received. However, this depends on the individual circumstances of the claim. As I will argue, it is likely that there will be some cases in which it can be established on the balance of probabilities that but for the non-disclosure the physical injury would not have occurred and/or that the non-disclosure made a material contribution to the injury.¹²⁰

The general rule in causation is that a sufficient causal connection is only established if the claimant can demonstrate "on the balance of probabilities that 'but for' the negligence of the defendant the injury would not have occurred".¹²¹ However, the judiciary have departed from a strict application of the "but for" test in cases where this probability could not be established and held that it is sufficient to demonstrate that "the contribution of the negligent cause was more than negligible".¹²² They also, in *Chester v Afshar*,¹²³ departed from traditional causation principles in circumstances where a claimant was unable to establish whether or not she would have consented to surgery had she been warned of the risk of the injury which materialised.¹²⁴ In this case, Lord Steyn recognised that "policy and corrective justice pull

¹²⁰ See *Bailey v Ministry of Defence and another* [2008] EWCA Civ 883, [35-46] for an analysis of the case-law on the but for and material contribution tests.

¹²¹ *Bailey* as above, [36] per Mr Justice Waller; S. Hedley, 'Negligence: Causation and Damage' ['Negligence'] in *Grubb, Law of Tort* as earlier, 635-660, 635-636.

¹²² *Bailey* as above, [46] per Mr Justice Waller, & [36-38] citing *Fairchild v Glenhaven Funeral Services Ltd* [2002] UKHL 22 & *McGhee v National Coal Board* 1 WLR 1.

¹²³ [2004] UKHL 41.

¹²⁴ *Ibid*, [11].

powerfully in favour of vindicating the patient's right to know"¹²⁵ and that the "right of autonomy and dignity can and ought to be vindicated by a narrow and modest departure from traditional causation principles".¹²⁶ So although the "starting point"¹²⁷ is to try and establish on the balance of probabilities that but for NHSBT's non-disclosure the potential organ donor would not have suffered the physical injury which they did, there are other avenues to pursue which include establishing that the non-disclosure made a material contribution to the injury and arguing that autonomy is of such importance as to justify a departure from traditional causation principles.

The chances of success are highest in circumstances in which the potential organ donor has suffered physical harm which can be clearly differentiated from the effects of their brain injury and pre-existing medical conditions. As I found in Chapter 1, some ante-mortem donor optimisation procedures carry risks which are specific to each procedure and,¹²⁸ should those risks materialise, would be readily discernible from both the patient's underlying condition and from any treatment they were receiving for the symptoms of that condition. Both the nature of the complication and the temporal relationship between that complication and the procedure would distinguish these complications as being caused by that procedure. For example, tracheal rupture may be due to either blunt trauma to the chest or to endotracheal intubation for mechanical ventilation.¹²⁹ In the absence of the former, it would be easy to establish that its occurrence during or following intubation was due to the intubation. As is the case with perforation of the femoral artery due to femoral cannulation,¹³⁰

¹²⁵ Ibid [22].

¹²⁶ Ibid [24].

¹²⁷ *Hedley*, 'Negligence' in *Grubb, Law of Tort* as earlier, 635.

¹²⁸ Refer back to section on ante-mortem interventions to facilitate organ donation.

¹²⁹ *Lim et al, Tracheal Rupture* as earlier.

¹³⁰ Refer back to Chapter 1.

the site of the injury would also help establish that but for the donor optimisation procedure the claimant would not have suffered the injury.

Establishing causation for severe neurological damage, such as a permanent vegetative state (PVS) or minimally conscious state (MCS),¹³¹ is likely to be more demanding than for complications occurring at the site of specific donor optimisation procedures. However, PVS is a known risk of non-therapeutic ventilation¹³² - which causes the patient to survive what would otherwise have been a fatal brain injury.¹³³ MCS has a similar aetiology and is also a possible complication.¹³⁴ Causation could be established if a patient identified as a potential organ donor progressed into a PVS or MCS, as but for the non-therapeutic intervention they would not have suffered such a state. The natural course of events would have been a more imminent death. But for their identification and treatment as a potential organ donor, the claimant would have received palliative care instead of intensive care and not survived in a state that many consider worse than death itself.¹³⁵

For potential organ donors who can establish that their physical injury was due to a donor optimisation procedure, a further stumbling block remains. Unless the judiciary permit a move away from the traditional rules of causation, they still have to establish the causal connection between NHSBT's failure to inform and them undergoing the procedure that caused the physical harm. There are two issues within this. First, they have to establish the

¹³¹ These potential complications are further evaluated in Chapter 4.

¹³² B. New, M. Solomon & R. Dingwall *et al*, 'A Question of Give and Take: Improving the Supply of Donor Organs for Transplantation' (Research Report 18, King's Fund Institute, UK, 1994) 64.

¹³³ A. Browne, G. Gillett, & M. Tweeddale, 'The Ethics of Elective (Non-therapeutic) Ventilation' (2000) 14(1) *Bioethics* 42-57 ['Non-therapeutic Ventilation'].

¹³⁴ This is discussed further in Chapter 4.

¹³⁵ See ABC News poll (2005) and Gallup poll (1997): data available at <http://www.gallup.com/poll/15448/americans-choose-death-over-vegetative-state.aspx> (last accessed 28/09/17); also C. Constable, 'Withdrawal of Artificial Nutrition and Hydration in a Permanent Vegetative State: Changing Tack', (2012) 26(3) *Bioethics* 157-163, 160.

connection between the failure to inform and their registration on the ODR. Second, they have to establish the connection between their registration on the ODR and them undergoing the procedure. The second issue appears less problematic than the first, as NHSBT strategy is to interpret registration as authorising changes to end-of-life care to facilitate organ donation.¹³⁶ However, the NICE guidelines do not limit donor optimisation procedures to registered organ donors,¹³⁷ so it may be difficult to prove that registration on the ODR was the cause of them undergoing the procedure. With respect to the connection between the failure to inform and registration on the ODR, a claimant who has survived with mental capacity may be able to provide evidence that they would not have signed up had they been informed of the risks. However, if the case depends on evidence recounted by relatives, it may be difficult to establish what the actions of the deceased or incapacitated patient would have been in the circumstances.

Although under some circumstances in which a potential organ donor suffers physical harm, it may be possible to establish that the requirements of the “but for” test are met, or if not that NHSBT’s negligence made a material contribution to the injury, in other cases the hurdles may seem insurmountable. However, the increased recognition of the legal wrong of injury to autonomy¹³⁸ suggests that it is not outside the realms of possibility that a court would compensate in circumstances where no physical harm to the potential organ donor could be proven. Although in the recent case of *Shaw v Kovac*,¹³⁹ it was found that an infringement to autonomy did not constitute a separate head of damage, this was on the basis that the infringement to autonomy had already been remedied by the award of damages for

¹³⁶ NHSBT, ‘UK Strategy’ as earlier p.7.

¹³⁷ NICE, ‘Improving Donor Identification’ as earlier p.7 [1.1.6- 1.1.8].

¹³⁸ *Chester v Afshar* as before; *McFarlane v Tayside Health Board* [2000] 2 AC 59 (HL); *Rees v Darlington Memorial Hospital NHS Trust* as before.

¹³⁹ [2017] EWCA Civ 1028

pain, suffering, and loss of amenities.¹⁴⁰ Under a different set of circumstances, in which the claimant could not otherwise be compensated, the judiciary could recognise that damage to autonomy should be compensated for on its own merits.

As I argued at the start of this chapter, autonomy is the rationale for informed consent and it is this rationale that underlies my arguments that NHSBT should implement informed consent standards. As was recognised in *Chester v Afshar*, “the law which imposed the duty to warn on the doctor has at its heart the right of the patient to make an informed choice”.¹⁴¹ In rare cases, some members of the judiciary have recognised that the denial of autonomy alone is a form of damage worthy of compensation.¹⁴² For example, in *McFarlane v Tayside Health Board* - a wrongful conception case - Lord Millett held that damages should be awarded for the denial of “an important aspect of (the claimants’) personal autonomy”.¹⁴³ He again awarded damages for loss of autonomy in *Rees v Darlington Memorial Hospital NHS Trust*,¹⁴⁴ commenting that “the parents have lost the opportunity to live their lives in the way that they wished and planned to do” and that “the loss of this opportunity....is a proper subject for compensation by way of damages”.¹⁴⁵ Although Lord Bingham denied that the award was compensatory, the majority decision was to make a conventional award of £15,000 to “afford some measure of recognition of the wrong done”.¹⁴⁶

¹⁴⁰ Ibid, [40], [54-55], [58] & [68-69].

¹⁴¹ Citation as earlier, [86] per Lord Hope; See also S. Devaney, ‘Autonomy Rules OK’ (2005) 13(1) *Med Law Rev* 102-107, 106-107.

¹⁴² *McFarlane v Tayside Health Board & Rees v Darlington Memorial Hospital NHS Trust* as above, particularly Lord Millett’s speeches; C. Purshouse, ‘How Should Autonomy be Defined in Medical Negligence Cases?’ (2015) 10(4) *Clinical Ethics* 107-114, 108; D. Nolan, ‘New Forms of Damage in Negligence’ (2007) 70(1) *MLR* 59-88, 77-80..

¹⁴³ *McFarlane* as above, 114.

¹⁴⁴ *Rees* as before, [123].

¹⁴⁵ Ibid.

¹⁴⁶ Ibid, [8] per Lord Bingham.

As noted by Purshouse, “*Rees* and *Chester* arguably hid the recognition of a new head of loss that of interference with patient autonomy, within the law relating to quantification of damages in *Rees* and causation in *Chester*”.¹⁴⁷ As he also notes, citing Lady Hale’s speech in *Montgomery*,¹⁴⁸ “the courts continue to perceive autonomy as something that already is, or might be capable of being, recognized as a form of damage protected by the tort of negligence”.¹⁴⁹ Two key questions are whether it would, and should, in the circumstances of a failure to inform an ODR registrant of the risks of donor optimisation procedures. The important position that autonomy holds in both bioethics and human rights law suggests that it should. As I argued in Chapter 2, self-determination is valuable in its own right and not just for the protection against physical harm which may ensue from including it in donor optimisation policy.¹⁵⁰ As Lord Millett recognises in *Rees*, autonomy is “an important aspect of human dignity, which is increasingly recognised as an important human right which should be protected by the law”.¹⁵¹ However, whether it would be protected as a standalone right in a negligence case brought by or on behalf of a registered organ donor is uncertain. It is possible that it might be implicitly recognised as a head of damage, as it was in *Rees*,¹⁵² but the judiciary are likely to be wary of explicitly recognising autonomy as a head of damage because of the wide-ranging implications for other cases.

If liability in negligence is established for NHSBT’s failure to inform, then the type of damage recognised may have implications for the level of compensation awarded. Although

¹⁴⁷ C. Purshouse, ‘Judicial Reasoning and the Concept of Damage: Rethinking Medical Negligence Cases’ (2015) 15(2-3) *Med Law Int* 155-181, 157 [‘Concept of Damage’]; see also C. Purshouse, ‘Liability for Lost Autonomy in Negligence: Undermining the Coherence of Tort Law?’ (2015) 22 *Torts Law J* 226-249 [‘Lost Autonomy’] & ‘Should Lost Autonomy be Recognised as Actionable Damage in Medical Negligence Cases?’ (PhD Thesis, University of Manchester 2015).

¹⁴⁸ As discussed earlier in this section, [108].

¹⁴⁹ Purshouse, ‘Concept of Damage’ as above, 173; see also Purshouse, ‘Lost Autonomy’ as above, 232.

¹⁵⁰ See section on the Value of Self-determination.

¹⁵¹ *Rees* as before, [123].

¹⁵² Purshouse, ‘Concept of Damage’ as earlier, 155; case citation as earlier.

the claimant would presumably seek to be compensated for the full costs arising from the infringement of autonomy, if “only” damage to autonomy is recognised then it is possible that – in line with *Rees* – damages would be limited to a lower-level conventional award.¹⁵³ Although it is arguable that autonomy is of such value that the full costs ought to be recoverable, this may be refused because of policy concerns.¹⁵⁴ However, if liability for physical injury is established, then the claimant is entitled to be fully compensated for both pecuniary and non-pecuniary loss.¹⁵⁵ If that physical injury is severe neurological damage, the level of compensation awarded could potentially be very high.

Although, as I have argued, NHSBT do have a duty of care towards ODR registrants and this duty of care requires them to implement informed consent standards, establishing that damage has been caused as a result of the failure to inform is likely to be challenging in practice. This may impact on whether a claim would be funded. Insurance companies might not agree to fund a claim against the national organisation in charge of organ donation, and solicitors might be reluctant to enter into a conditional fee agreement. There may be difficulties accessing legal aid, as it is not generally available for clinical negligence claims.¹⁵⁶ However, an exceptional case determination could be made that it is necessary to provide legal aid because to not do so would breach the individual’s Convention rights¹⁵⁷ or “that it is appropriate to do so” because of the risk of breaching the individual’s Convention rights.¹⁵⁸ There are hurdles to overcome in terms of means and merits criteria,¹⁵⁹ but an exceptional funding application could potentially be granted as the claim relates to important issues

¹⁵³ *Purshouse*, ‘Concept of Damage’ as earlier, 171.

¹⁵⁴ *Ibid*, 171-172.

¹⁵⁵ D. Howarth, ‘General Defences’ in *Grubb*, *Law of Tort* as earlier, 145-185, 187.

¹⁵⁶ Legal Aid, Sentencing and Punishment of Offenders Act 2012, Schedule 1 [21-23].

¹⁵⁷ *Ibid*, S. 10 (3)(a).

¹⁵⁸ *Ibid*, S. 10 (3)(b).

¹⁵⁹ The Civil Legal Aid (Merits Criteria) Regulations 2013; The Civil Legal Aid (Financial Resources and Payment for Services) Regulations 2013.

surrounding the autonomy rights of potential organ donors and has serious consequences for other members of the public.¹⁶⁰

As explained at the beginning of this chapter, the principle of autonomy underlies my arguments that NHSBT is currently failing in its duty of care to registered organ donors. This principle of autonomy is protected under Article 8 of the European Convention.¹⁶¹ Both NHSBT and the Courts have obligations under the Human Rights Act 1998 to avoid acting in a way which is incompatible with Convention rights.¹⁶² However, the Courts do not generally examine human rights issues in any depth when considering negligence cases. The tort of negligence provides several mechanisms to protect healthcare professionals and institutions from liability, but fewer to protect the patient's right to autonomy. Although the cases I have discussed in this section suggest that the direction of travel is towards strengthening the protection afforded to autonomy, I have also identified several difficulties in establishing causation in the circumstances. If liability is established, a Court ruling would provide the necessary impetus for NHSBT to introduce informed consent standards. However, should the claimant's case fail, there may be alternative routes to achieving this which include a human rights challenge¹⁶³ or, should this fail, a judicial review of donor optimisation policy. Either of these routes would allow a fuller examination of the lawfulness of current policy than can be achieved under the tort of negligence.

The tort of negligence is just one part of a legal system that, as a whole, claims to place importance on patient autonomy. There is the possibility for a successful claim to be brought in negligence, particularly if the patient has suffered physical harm which can only be

¹⁶⁰ Lord Chancellor's Exceptional Funding Guidance (Non-Inquests) (Legal Aid Agency, 2014), [9],[21],[27-29],[47-48].

¹⁶¹ As discussed in Chapters 1 & 5.

¹⁶² S. 6(1).

¹⁶³ The likelihood of success of an article 8 claim will be considered in Chapter 5.

due to the donor optimisation procedure and they are able to give evidence that they would not have registered as an organ donor had they been informed of the risks. However, bringing an action in negligence is not always an effective way of upholding the right to autonomy and other legal routes may need to be considered. The tort of battery, the law on best interests, human rights law, and the law on advance decision-making are all potential means of protecting the autonomy of the potential organ donor. The MCA provisions on best interests that need to be fulfilled to provide a defence to battery are considered in Chapter 4, while the potential for a successful human rights challenge is considered in Chapter 5. In the next section, I evaluate the law on advance decision-making as an avenue for upholding the autonomy of potential organ donors and conclude that if NHSBT does not introduce informed consent standards it would be difficult in practice for a member of the public to meet the requirements of the MCA provisions on advance directives.¹⁶⁴

The Law on Advance Decision-Making

The MCA contains several provisions on advance decision-making which, if all statutory requirements are met,¹⁶⁵ recognise the antecedent autonomy of the incapacitated individual and demand that it is upheld by healthcare professionals. These provisions might be thought to offer some protection to the autonomy of ODR registrants, yet both the provisions themselves and the system of ODR registration present barriers to this autonomy being protected in practice. The MCA provisions rely on the individual having knowledge and understanding of the relevant medical interventions, which ODR registrants are not provided with. ODR registrants are disadvantaged by the lack of information and public knowledge about donor optimisation procedures and the lack of opportunity to register a specific

¹⁶⁴ S. 25.

¹⁶⁵ S. 24-26.

advance decision. Any other advance decision about their end-of-life care risks being declared inapplicable to these procedures, as it is difficult to anticipate the circumstances of donor optimisation in advance.¹⁶⁶ MCA provisions are restricted to advance refusals only,¹⁶⁷ and present several barriers to access in the form of validity and applicability criteria which need to be complied with before the advance refusal is accepted as legally binding.¹⁶⁸ This section evaluates what the problems are achieving this compliance in relation to donor optimisation procedures.

The law claims to recognise that the normative authority of advance decision-making rests on patient autonomy. As Justice Munby puts it, “[a]n advance directive is, after all, nothing more or less than the embodiment of the patient's autonomy and right of self-determination”.¹⁶⁹ It not only embodies that autonomy but projects it into the future to cover a period of incapacity.¹⁷⁰ The legal force afforded to that autonomy is supposedly the same as that afforded to other autonomous decisions.¹⁷¹ The stated aims of the MCA 2005 suggest that its provisions on advance directives should afford the same status in law and practice to advance directives as to other forms of informed decision-making. The MCA Code of Practice, for example, begins with a declaration that:

The Mental Capacity Act 2005.... will empower people to make decisions for themselves wherever possible, and protect people who lack capacity by providing a flexible framework that places individuals at the very heart of the decision-making process.....It also allows people

¹⁶⁶ S. 25(4). Applicability criteria will be considered later in this section.

¹⁶⁷ S. 24-26.

¹⁶⁸ S. 25.

¹⁶⁹ *HE v A Hospital NHS Trust* [2003] EWHC 1017 (Fam), [37]

¹⁷⁰ See A. Maclean, ‘Advance Directives and the Rocky Waters of Anticipatory Decision-Making’ (2008) 16 *Med Law Rev* 1-22.

¹⁷¹ See A. Maclean, ‘Advance Directives, Future Selves and Decision-Making’ (2006) 14 *Med Law Rev* 291-320, 292, written in anticipation of the MCA 2005 coming into force, [‘Future Selves’]; Also MCA 2005 Code of Practice 2013 [9.1].

to plan ahead for a time in the future when they might lack the capacity, for any number of reasons, to make decisions for themselves.¹⁷²

The empowerment of individuals in making - and perhaps more importantly having upheld - decisions about future medical treatment is restricted by the MCA to advance refusals of treatment,¹⁷³ and it is only the advance refusal of an ODR registrant that would be legally binding. Advance consent to donor optimisation procedures could be overridden if doctors were not prepared to allow a patient to suffer the risks of physical harm to which they had consented or for some other reason did not consider the procedures to be in their best interests.¹⁷⁴ In some ways, this problem is opposite to that currently encountered by patients identified as potential organ donors. Initiating donor optimisation procedures is presumed to be in the best interests of all patients meeting certain clinical criteria, doctors are not specifically advised to weigh up the risk of harm, and advance consent to these procedures is neither possible in practice nor required by organ procurement policy.¹⁷⁵ Neither is there any opportunity to refuse these procedures in advance - a situation which can only be reversed by the introduction of a system that facilitates both advance consent and refusal of donor optimisation procedures.

The law emphasises the need to avoid obliging doctors to act against their clinical judgement above upholding the right of the patient to receive any medical treatment they have provided advance consent for.¹⁷⁶ However, doctors' wishes to avoid acting against their clinical judgement are given short shrift by current donor optimisation policy, which requires them to initiate non-therapeutic procedures before they have determined either the clinical

¹⁷² MCA 2005 Code of practice 2013 (TSO, London), Foreword per Lord Falconer.

¹⁷³ S. 24-26.

¹⁷⁴ Advance consent is just one element of the best interests decision, see S. 4(6) (a). This will be further discussed in Chapter 4.

¹⁷⁵ See evaluation of NICE Clinical Guidance on Organ Donation in Chapter 1.

¹⁷⁶ *R (on the application of Burke) v General Medical Council* [2005] EWCA Civ 1003, particularly [31], [50], [54-55], per Lord Phillips MR.

potential to donate or the patient's wishes.¹⁷⁷ Introducing a system of advance consent would help doctors resolve any feelings of conflict they may have in implementing procedures of no clinical benefit to their patient. If the patient had consented to the risk of a donor optimisation procedure that had been offered as an option, their autonomous decision would in most cases coincide with their best interests. Unless the risk of harm in the individual circumstances clearly outweighs the patient's wishes, the specific advance consent of the ODR registrant to donor optimisation procedures should – if at all possible in practice – be upheld.¹⁷⁸

Valid and applicable advance refusals of medical interventions are supposed to be determinative of the outcome, but this does not mean that they are always upheld in practice. Unless a doctor initiating donor optimisation procedures "is satisfied that an advance decision exists which is valid and applicable to the treatment",¹⁷⁹ section 26(2) of the MCA protects them from liability for any injury to autonomy, dignity, and integrity they may cause. This may include initiating donor optimisation procedures because they doubt the existence of an advance refusal due to the lack of a formal system by which they can be registered. It may include doubting the validity of an advance refusal due to a relative's concerns that the individual had since acted in a way that appeared inconsistent with the advance refusal remaining their fixed decision.¹⁸⁰ It may include them doubting the applicability of the advance refusal due to it not being specific enough to donor optimisation procedures and/or the individual not having had the information they needed to anticipate the circumstances of donor optimisation procedures.¹⁸¹ Any one of these doubts would be enough to remove the

¹⁷⁷ NICE, *Improving Donor Identification* p.7 [1.1.7], see evaluation in Chapter 1.

¹⁷⁸ The balance between advance consent and the risk of harm is considered further in Chapter 4.

¹⁷⁹ MCA S. 26 (2).

¹⁸⁰ S. 25 (2)(c). See S. Michalowski, 'Advance Refusals of Life-Sustaining Medical Treatment: the Relativity of an Absolute Right' (2005) 68(6) *Mod Law Rev* 958- 982, 971 ['Advance Refusals'].

¹⁸¹ S. 25(4)

protection afforded to patient autonomy, dignity, and bodily integrity by the MCA provisions on advance refusals of medical treatment.

The courts will only make a declaration on the existence, validity, and applicability of an advance refusal if asked to do so. The incapacitated patient identified as a potential organ donor is not in a position to do so, and their relatives may either arrive too late, not be aware of the possibility of court action, or be unable to secure the services of an appropriately qualified solicitor in such a short time-frame. Should the relatives be able to overcome these initial hurdles, there are several further hurdles to jump to convince a court of the legally binding nature of an advance refusal. To be accepted as a legally binding advance refusal meeting the provisions of the MCA, they first have to demonstrate the existence of an advance refusal made when the potential organ donor had capacity to do so.¹⁸² This may be difficult as there is neither a requirement to register advance refusals nor a system for doing so.¹⁸³ This is compounded by the lack of requirement to assess capacity at the time of an advance refusal and the difficulties proving it existed in retrospect.¹⁸⁴

To be legally binding, an advance refusal of donor optimisation procedures must satisfy doctors and/or the courts that it meets both the statutory validity and applicability criteria.¹⁸⁵ Any suggestion that the potential organ donor had withdrawn the decision,¹⁸⁶ even informally, or that the patient had acted inconsistently with the advance refusal remaining

¹⁸² This must fulfil the requirements of Section 24 (1).

¹⁸³ See C. Johnston, 'Advance Decision-Making –Rhetoric or Reality?' (2014) 34(3) *Legal Studies* 497-514, 498.

¹⁸⁴ R. Heywood, 'Revisiting Advance Decision-Making under the Mental Capacity Act 2005: A Tale of Mixed Messages (2014) 23 (1) *Med Law Rev* 81-102, 92. See also *A Local Authority v E* [2012] EWHC 1639 (COP) [55] per Mr Justice Jackson.

¹⁸⁵ S. 25(1).

¹⁸⁶ S. 25(2) (a)

their fixed decision,¹⁸⁷ could be enough to render the advance refusal invalid.¹⁸⁸ If a lasting power of attorney (LPA) is created after an advance refusal of donor optimisation procedures, and that LPA confers relevant authority,¹⁸⁹ the advance refusal could be overridden if the person granted the LPA believes donor optimisation procedures to be in the best interests of the patient.

Fulfilling the applicability criteria for advance refusals would be nigh on impossible for an individual who had not been informed about donor optimisation procedures. Even if the narrative by which the individual wishes to live their life is clearly expressed in the advance refusal, it can be overridden if it is not specific to the treatment in question,¹⁹⁰ any circumstances specified in the refusal are absent,¹⁹¹ or where there “reasonable grounds for believing that circumstances exist which [the patient] did not anticipate at the time of the advance decision and which would have affected his decision had he anticipated them”.¹⁹² The withholding of information by NHSBT means that it is entirely reasonable to believe that the patient identified as a potential organ donor had not anticipated the circumstances surrounding donor optimisation procedures. This means that any advance refusal of end-of-life care that they have made can, under MCA provisions, be declared inapplicable to donor optimisation procedures. The statutory safeguards built into the MCA, presumably with the aim of preserving life,¹⁹³ present significant barriers to the realisation of the autonomy of

¹⁸⁷ S. 25(2) (c).

¹⁸⁸ *Michalowski*, ‘Advance Refusals’ as earlier, 971.

¹⁸⁹ S. 25(2)(b). Under S. 9(2)(b) an LPA is not created unless it has been registered; this has been interpreted as rendering invalid any advance decision made before the LPA has been registered, which could be many years after the LPA was made, see *Re E* [2014] EWCOP 27 [48-49].

¹⁹⁰ S. 25 (4) (a)

¹⁹¹ S. 25 (4) (b)

¹⁹² S. 25 (4) (c).

¹⁹³ See C. Johnston, ‘Does the Statutory Regulation of Advance Decision-making Provide Adequate Respect for Patient Autonomy?’ (2005) 26 *Liverp Law Rev* 189-203, 191 citing Report by Age Concern Institute of Gerontology, Centre of Medical Law and Ethics, *The Living Will, Consent to Treatment at the*

potential organ donors and may result in dying patients undergoing non-therapeutic procedures that they would not want to have undergone.

As recognised by Mr Justice Charles in *Briggs v Briggs*, “an interpretation of these safety nets....that sets a low threshold to rendering an advance decision invalid or inapplicable would run counter to the enabling intention of ss. 24 to 26 of the MCA”.¹⁹⁴ Individual autonomy demands that barriers to its achievement, whether built on the lack of opportunity to formulate an advance decision or on the statutory safeguards, are removed where possible. Preservation of life concerns have no place in the regulation of procedures that are not carried out to prolong the patient’s life but to optimise the condition of their organs for transplantation. The paramount ethical concern is whether or not the patient would have wanted to undergo donor optimisation procedures and it is this that should determine the validity and applicability of an advance refusal of medical interventions.

Realising the Autonomy of Organ Donor Registrants

A key problem with the current system of registration for deceased organ donation is that policy-makers and healthcare professionals alike “predominantly regard consent to organ donation as consent for whatever procedures are required to facilitate this end”.¹⁹⁵ This generic consent model permeating policy and practice does not do enough to protect and enable the autonomy of ODR registrants. Autonomy matters most in relation to procedures that occur before death, place the potential donor at physical risk, and may conflict with their other ethical commitments, yet the ODR registrant is not given any information about the

End of Life, A Working Party Report (London, Edward Arnold, 1988) p.2; See also Lord Donaldson’s speech in *Re T (Adult: Refusal of Treatment)* [1993] Fam 95 (CA).

¹⁹⁴ [2016] EWCOP 53, [22].

¹⁹⁵ A. Gathani, G. Moorlock, H. Draper, ‘Pre-Mortem Interventions for Donation after Circulatory Death and Overall Benefit: A Qualitative Study’ (2016) 11(4) *Clin Ethics* 149-158, 153. Quote adapted for clarity.

procedures they will subsequently be presumed to have consented to. The nature, timing, and risks of ante-mortem donor optimisation procedures distinguish them from deceased organ donation and suggest that a specific consent model needs to be employed. This section evaluates what patient autonomy demands out of a specific consent model for donor optimisation procedures.

For the process of registering on the ODR to constitute informed consent for that part of the organ donation process that occurs before death, the information that is needed to make an autonomous decision about donor optimisation procedures should be disclosed and the consent process should facilitate that autonomous decision-making. The recognition that the rationale behind obtaining informed consent is to facilitate this autonomous decision-making helps to elucidate the aspects by which donor optimisation procedures can be differentiated from deceased organ donation and from each other as requiring separate informed consent. As Maclean recognises, the information elements relevant to achieving the purpose of informed consent are those which “allow patients the dignity of determining for themselves how far their bodies are interfered with”.¹⁹⁶ This dignity of self-determination is allegedly the purpose of the opt-in system for organ donation and achieving this purpose requires the introduction of a specific informed consent model.

When an attribute of a medical procedure is altered in a way that is relevant to the achievement of autonomy,¹⁹⁷ it cannot be dismissed as an ancillary procedure but requires specific informed consent. A generic consent system for deceased organ donation cannot simply subsume ante-mortem donor optimisation procedures within it. The attributes that are significantly altered include the timing of the procedures, their nature, and the physical risks to the patient. These attributes need disclosing to enable the autonomy of ODR registrants,

¹⁹⁶ A. Maclean, ‘Consent, Sectionalisation and the Concept of a Medical Procedure’ (2002) 28 *J Med Ethics* 249-254, [‘Consent, Sectionalisation’].

¹⁹⁷ *Ibid*, 251.

protect their dignity and integrity once incapacitated, and to meet the informed consent standards required by the law.

It is highly relevant to autonomous decision-making to know that the potential consequences of registration include procedures being performed whilst the potential organ donor is still alive. Not only does the time course differ from deceased organ donation, but so does the underlying theory unifying ante-mortem donor optimisation procedures.¹⁹⁸ Deceased organ donation involves the removal of organs after death, whereas ante-mortem donor optimisation procedures are interventions done before death to optimize the condition of the organs and manage the patient's end-of-life care in such a way as to maximize the chances of successful organ donation. Information about and understanding of this underlying theory is needed to make an autonomous decision about donor optimisation procedures.

Ante-mortem donor optimisation procedures may be performed on a range of anatomical sites and involve a range of different mechanisms, including cannulation, intubation, and injection.¹⁹⁹ The nature and mechanics of ante-mortem interventions are sufficiently different from that of deceased organ donation itself and from each other as to require specific informed consent. Potential organ donors may differ in the area and extent of medical procedures that they would be willing to undergo to facilitate organ donation. Some may be unwilling to undergo any such interventions; others may only be willing to undergo procedures in limited sites and of limited means; others may be willing to undergo interventions on any site and by any mechanism. Protecting and promoting autonomy in decision-making requires the provision of specific consent procedures for the different procedures that could be carried out on different sites and by different means.

¹⁹⁸ See *Maclean* as above, 'Consent, Sectionalisation', 251.

¹⁹⁹ See eg. C. Findlater & E. Thomson, 'Organ Donation and Management of the Potential Organ Donor' (2015) 16(7) *Anaesthesia and Intensive Care Medicine* 315-320.

Information about the consequences of procedures is critical to autonomous decision-making. Donor optimisation procedures all share the intention of maximising the chances of successful organ donation. However, there may also be negative consequences to the potential organ donor, and these differ between procedures. The different side-effects and risk profiles of donor optimisation procedures distinguish them as requiring separate consent from each other.²⁰⁰ Following *Montgomery*, the information that is needed is that of any material risks presented by donor optimisation procedures, and of any reasonable alternative or variant treatments.²⁰¹ The different donor optimisation procedures are alternatives or variants of each other, and if they vary to the degree that this is likely to affect autonomous decision-making, then separate informed consent procedures are required by both the law and the underlying rationale for informed consent.

The material risks presented by donor optimisation procedures are those that, in the particular circumstances of non-therapeutic procedures to facilitate organ donation, a reasonable person would be likely to attach significance to or NHSBT is or should reasonably be aware that the particular person would be likely to attach significance to.²⁰² Factors that may be significant to the ODR registrant include the nature of the risk and “the effect which its occurrence would have upon the life of the patient”.²⁰³ These factors acquire significance even if the chances of the risk occurring is thought to be remote. For example, the nature of the permanent vegetative state or minimally conscious state, and the devastating effect which their occurrence would have upon the life of the individual, is such as to influence autonomous decision-making even if the risks are currently unquantified by research.

²⁰⁰ The risk profiles of donor optimisation procedures were considered in Chapter 1 and will be discussed further in Chapter 4.

²⁰¹ *Montgomery v Lanarkshire Health Board* as earlier [87].

²⁰² *Ibid* [87] per Lord Kerr & Lord Reed.

²⁰³ *Ibid* [89] per Lord Kerr & Lord Reed.

It is not just risks to which the ODR registrant is likely to attach significance, but also the likely benefit of undergoing donor optimisation procedures. The ODR registrant's decision is likely to be influenced by "the importance to the patient of the benefits sought to be achieved"²⁰⁴ by donor optimisation procedures, i.e. the importance to them of benefiting others through becoming an organ donor. The importance they place on achieving this benefit affects the materiality of the risks to them as an individual in undergoing donor optimisation procedures. The materiality is also affected by the alternatives available, and the risks and benefits of these alternatives. One of these alternatives is the option of waiting until death before beginning the organ donation process, and the information that is likely to be significant to the patient in choosing between the alternatives includes the different chances of these alternatives in successfully achieving organ donation.

The introduction of a specific informed consent model for donor optimisation procedures would meet the "original rationale" of informed consent,²⁰⁵ which is patient self-determination. This does not mean that patients are required to consent to reams of "numerous, highly specific propositions",²⁰⁶ but that the ODR needs to identify and disclose the information that is relevant for the realisation of autonomy. Meeting this aim of autonomy should be possible with the provision of concise, relevant, and understandable information. The relevant – and readily understandable - information about ante-mortem donor optimisation procedures overall includes the fact that they occur before death, that they are performed solely for the clinical benefit of others, that they may alter the dying process, and that they may cause physical harm to the donor. Crucially, however, they may save the lives of

²⁰⁴ Ibid [89] per Lord Kerr & Lord Reed.

²⁰⁵ E. Bunnik, A. Janssens & M. Schermer, 'Informed Consent in Direct-to-Consumer Personal Genome Testing: The Outline of a Model Between Specific and Generic Consent' (2014) 28(7) *Bioethics* 343-351, 348 ['Specific and Generic Consent']

²⁰⁶ N. Manson & O. O'Neill, *Rethinking Informed Consent in Bioethics* (CUP, 2007) 6.

people dying from organ failure and this message also needs to be put across, but in a way that enables rather than constrains self-determination.

Meeting the goal of patient self-determination requires not only general information about donor optimisation procedures but specific information regarding the nature and risks of each procedure. Patient autonomy demands that the range of informed decisions that the individual is able to make and register on the ODR include informed consent to all donor optimisation procedures, informed refusal of all donor optimisation procedures, or informed consent to certain procedures and informed refusal of others.²⁰⁷ The realisation of the autonomy of ODR registrants depends not only on the introduction of a specific informed consent model, but also on their informed decision being upheld after the loss of capacity. This holds true whether the informed decision involves consent, refusal, or a combination of both, although – as I will consider in Chapter 4 – there may be some circumstances in which the risk of harm to the individual patient rivals autonomy as the deciding factor in an advance consent to a particular donor optimisation procedure.

At the time when incapacitated patients are identified as potential organ donors, their care falls to be determined according to the MCA provisions on advance decisions, LPAs, and best interests. Although the goal of advance decision-making is patient autonomy, the statutory provisions on advance refusals do not always enable this goal to be met. However, the registration of an advance refusal on the ODR would provide the requisite evidence of its existence, and if the ODR was set up in such a way as to facilitate the fulfilment of the validity and applicability criteria, it could not be overridden. Advance consents are not afforded this legally binding status in law, but if all ODR registrants were provided with information about

²⁰⁷ The likely impact on the supply of organs of such a system will be considered in Chapter 6.

the risks of harm and some individuals consented to these, then in most cases – as I will argue in Chapter 4 – their advance consent should be upheld.

Autonomy is at the centre of the ethical and legal challenges presented by donor optimisation procedures and it is at the heart of the solution. The model of specific informed consent proposed in this chapter is, like the basic concept of informed consent, “simple and self-evident”.²⁰⁸ It provides the much-needed ethical justification for donor optimisation procedures and also meets the requirements of the law on informed consent, advance directives, and best interests. All of these areas of law are relevant to the circumstances of non-therapeutic donor optimisation procedures and all can be fulfilled by the inclusion of individual autonomy in donor optimisation policy. This is needed as part of the legal duty of care owed to ODR registrants and potential organ donors, to provide a defence against charges of battery, and to provide a clear legal justification for donor optimisation procedures. As I will show in the next chapter, relying on best interests alone in the absence of knowledge of the patient’s specific wishes is insufficient to provide that clear legal justification.

²⁰⁸ *Brazier, ‘Patient Autonomy’* as earlier, 172.

4. The Best Interests of the Potential Organ Donor

Introduction

As I argued in the previous chapter, the introduction of a system of specific advance consent to ante-mortem donor optimisation procedures is needed to uphold the autonomy of organ donor registrants and to meet the informed consent standards required under the tort of negligence. However, once the individual loses decision-making capacity, the legal principle regulating what procedures can and cannot be performed is best interests. It is this principle that organ procurement policy-makers are relying on to provide a legal defence to claims of battery.¹ However, as I argued in Chapter 1, in the absence of knowledge of the individual's specific wishes regarding ante-mortem donor optimisation procedures, it is difficult for best interests to take on its ascribed role as the legal justification for these procedures.² The question I address in more detail in the current chapter is whether the specific advance consent of the potential organ donor to ante-mortem donor optimisation procedures is needed for best interests to provide a clear legal justification for such procedures.

Advance consent does not exist as a stand-alone justification, but as one possible component of best interests. According to the provisions of the Mental Capacity Act 2005 (MCA) and the common law,³ consent is not necessarily determinative,⁴ but must be balanced

¹ See eg. National Institute for Health and Care Excellence (NICE), *Organ Donation for Transplantation: Improving Donor Identification and Consent Rates for Deceased Organ Donation* (Clinical Guidance 135, 2011, updated 2016) ['Improving Donor Identification'] p.6-7 [1.1.5-1.1.8].

² See S-J. Brown, 'The Legal Justification for Donor Optimisation Procedures' (2016) 11(4) *Clin Ethics* 122-129, which is largely based on an earlier version of the current chapter.

³ MCA S. 4(6); *R (on the application of Burke) v General Medical Council* [2005] EWCA Civ 1003, particularly [31], [50], [54-55], per Lord Phillips MR.

against and demonstrated to outweigh the potential harms to the patient.⁵ Written advance statements are afforded particular consideration in the assessment of the patient's wishes and feelings,⁶ but those wishes and feelings are just one part of the best interests determination.⁷ However, evidence of benefit to the patient themselves is essential under the law on best interests.⁸ I argue in this chapter that in the absence of medical benefit from donor optimisation procedures, specific advance consent is crucial to providing clear evidence of social, psychological, and/or ethical benefit from donor optimisation procedures.

The current lack of consent is of concern in relation to all donor optimisation procedures, while the risk of physical harm is of specific concern in relation to specific donor optimisation procedures.⁹ These two factors, the lack of consent and the risk of physical harm, are the crucial concerns in encompassing elective (i.e. non-therapeutic) ventilation and other donor optimisation procedures within the current law on best interests. Whilst there have been significant changes in the law since these two concerns were first identified in relation to the original elective ventilation protocol in the early 1990s,¹⁰ there is no change in the significance of these concerns. The underlying rationale behind the formulation of best interests now incorporated into the MCA is not merely to facilitate medical interventions but

⁴ Although see Justice Munby's human rights based approach in *R (on the application of Burke) v General Medical Council* [2004] EWHC 1879 (Admin), which was overturned on appeal in *R (on the application of Burke) v General Medical Council* [2005] EWCA Civ 1003.

⁵ *Re A (Medical treatment: male sterilisation)* [2000] 1 FCR 193, 206.

⁶ S. 4(6) (a).

⁷ S. 4 (6).

⁸ I focus in this chapter on what the law on best interests claims to be saying with regard to the centrality of overall benefit to the individual patient; I consider in the next chapter the other factors that the judiciary sometimes take into account, such as benefit to others.

⁹ This will be expanded on in the 1st section of this chapter; some details of these interventions are provided within: UK Donation Ethics Committee, *Generic Interventions Guidance: Interventions Before Death to Optimise Donor Organ Quality and Improve Transplant Outcomes: Guidance from the UK Donation Ethics Committee* (December 2011); Department of Health (DoH), *Legal Issues Relevant to Non-Heartbeating Organ Donation* (2009).

¹⁰ T. Feest, H. Riad, C. Collins, M. Golby *et al*, 'Protocol for Increasing Organ Donation after Cerebrovascular Deaths in a District General Hospital' (1990) 335 *Lancet* 1133-5; B. New, M. Solomon & R. Dingwall *et al*, 'A Question of Give and Take: Improving the Supply of Donor Organs for Transplantation' (King's Fund Institute, Research Report 18, 1994) 64 ['King's Fund Report'].

to respect the autonomy of the patient and to protect them against physical harm. This rationale cannot easily be met without viewing best interests as an inclusive justification, encompassing specific advance consent, rather than an alternative justification refuting the need for specific consent.

Proponents of the view that donor optimisation procedures can be encompassed within the best interests of the potential organ donor - in the absence of specific advance consent - usually consider best interests as an alternative rather than inclusive justification.¹¹ The key claim made by Coggon and colleagues is that, if an individual wished to donate, best interests provides the legal justification for ante-mortem interventions, provided they “carry no harm”.¹² However, the first proviso within this claim, the individual’s wishes surrounding donation, may not be sufficient to determine their overall attitude towards ante-mortem interventions to facilitate organ donation. The second proviso, the absence of harm, may be difficult to achieve even for the most minimally invasive interventions. In this chapter, I address the questions of how specific the individual’s wishes must be and what evidence of those wishes is required to encompass donor optimisation procedures within best interests. I also address the question of at what point, if any, the risk of physical harm becomes so great as to outweigh even the most specific wishes to undergo donor optimisation procedures.

Acting in accordance with the individual’s wishes is central to the accommodation of donor optimisation procedures within the current law. Evidence of those wishes is vital to the determination of best interests, yet the National Institute for Health and Care Excellence (NICE) requires the initiation of donor optimisation procedures before any exploration of the individual’s wishes.¹³ Coggon addresses this conundrum with the argument that there is a

¹¹ J. Coggon, M. Brazier, P. Murphy, D. Price *et al*, ‘Best Interests and Potential Organ Donors’ (2008) 336 *BMJ* 1346-1347 [‘Best Interests’].

¹² *Ibid*, 1347.

¹³ NICE, *Improving Donor Identification* as earlier, p.7 [1.1.6- 1.1.7].

“good enough chance” that the patient would want to undergo the procedures and the extension of best interests to circumstances where it is not yet known what the individual’s wishes were.¹⁴ However, the law is clear that the determination of best interests must be made on an individual basis.¹⁵ Making a decision based on a “good enough” chance is not “good enough” for those individuals who would not wish to undergo donor optimisation procedures. As McGee and White recognise, a presumption cannot be erected that donor optimisation procedures are always in each and every patient’s best interests.¹⁶ Such a presumptive approach treats patients identified as potential organ donors as a group rather than the individuals they are and that the law requires they are treated as. The centrality of individual wishes to the accommodation of donor optimisation procedures within the law demands that any such presumption does not go unchallenged.

Whilst the challenges encompassing donor optimisation procedures within best interests have led McGee and White to the conclusion that specific statutory justification needs to be enacted,¹⁷ I argue in this chapter that knowledge of the patient’s specific wishes regarding donor optimisation procedures would render specific statutory justification unnecessary. A system of specific advance consent would provide a legal justification that is protective of the interests and rights of the potential organ donor. It would provide healthcare professionals with the information required to determine best interests and facilitate the wishes of those individuals who wish to undergo donor optimisation procedures for the benefit of others. It would protect the organ donation programme from the potential risks presented by moving away from a system of consent and therefore protect the interests of

¹⁴ J. Coggon, ‘Elective Ventilation for Organ Donation: Law, Policy and Public Ethics’ (2013) 39 *J Med Ethics* 130-134, 132, [‘Elective Ventilation’].

¹⁵ See *In Re M* [2009] EWHC 2525 (Fam) [35] per Judge Munby; A. McGee & B. White, ‘Is Providing Elective Ventilation In The Best Interests Of Potential Donors?’ (2013) 39 *J Med Ethics* 135-138, 135 & 136, [‘Providing Elective Ventilation’].

¹⁶ McGee & White, ‘Providing Elective Ventilation’ as above, 135 & 136.

¹⁷ *Ibid*, 138.

patients whose lives depend on the continuing supply of organs.¹⁸ If this can be achieved within the current legal framework, there will be no need to make statutory changes and no need to make an exception to the generally recognised principle of informed consent.

The remaining sections of this chapter each make a contribution to my overall claim that best interests can only provide a clear legal justification for donor optimisation procedures with the inclusion of specific advance consent. I begin with a section evaluating where the medical interests of the potential organ donor lie, with a particular focus on the potential for iatrogenic harm. I follow this with a section analysing the centrality of the individual to best interests and the determinants of the individual's attitude to donor optimisation procedures. In the third section, I evaluate the social and psychological benefit which may accrue from respecting the individual's wishes. I consider the balance of best interests in the fourth section, with a particular focus on what, if any, should be the decisive factor in determining the best interests of the potential organ donor. I follow this with a section exploring what evidence of the individual's wishes is required, how specific those wishes should be, and at what stage in the organ donation process these wishes need to be explored. I conclude the chapter by outlining my proposed system for determining the best interests of the potential organ donor.

Medical Interests

The story of elective (i.e. non-therapeutic) ventilation intertwines with the development of the law on best interests. The original elective ventilation protocol in 1990 was published just a few months after the judicial invention of the best interests of the incapacitated adult.¹⁹

¹⁸ The relationship between autonomy, trust and the supply of organs was evaluated in Chapter 2; Human rights and public interest will be considered in Chapter 5; the impact on the supply of organs will be evaluated in Chapter 6.

¹⁹ T. Feest, H. Riad, C. Collins, M. Golby *et al*, 'Protocol for Increasing Organ Donation after Cerebrovascular Deaths in a District General Hospital' (1990) 335 *Lancet* 1133-5; *In re F (Mental Patient)*:

Prior to this, any medical treatment involving “touching without consent” rendered the doctor liable in battery, whether or not the patient had capacity to consent.²⁰ The fundamental problem of a lack of consent was seemingly addressed by best interests, yet the court’s solution did not include any consideration of the individual’s wishes.²¹ The legal gap was filled (at least partially), doctors were protected, medical treatment was facilitated, yet the individual was excluded from the decision. The lack of consideration afforded to individual wishes and other non-medical factors meant that decision-makers could only encompass procedures within best interests by claiming some medical benefit to the patient themselves. The medicalised formulation of best interests resulted in the exclusion of procedures that the individual might have wished to undergo for the benefit of others. The practice of elective ventilation was declared unlawful by the Department of Health in 1994,²² a declaration that was based on the absence of consent and the limitation of best interests to medical concerns.²³

If best interests are viewed from a purely medical angle, elective ventilation and other donor optimisation procedures cannot be encompassed within best interests as they are of no medical benefit and may cause physical harm. Although some authors have tried to justify

Sterilisation) [1990] 2 AC 1; Best interests are also referred to in *T v T* [1988] Fam 52, but are limited to the “exceptional circumstances” of the case rather than recognised as the central principle regulating the treatment of the incapacitated. For a thorough history, see J. Munby, ‘Protecting the Rights of Vulnerable and Incapacitous Adults- the Role of the Courts: An Example of Judicial Law Making’ (2014) 26(1) *CFLQ* 64-77, 64-66 [‘Judicial Law Making’].

²⁰ See eg. *Collins v Wilcock* [1984] 1 WLR 1172; the problem of surgery being tortious without consent is recognised in *T v T* as above, see particularly [62]; See also *Munby*, ‘Judicial Law Making’ as above, 64-66.

²¹ See *Munby*, ‘Judicial Law Making’ as above, 66-68.

²² DoH Health Service Guidelines (94) 41, ‘Identification of Potential Donors of Organs for Transplantation’ (1994) [HSG(94)41].

²³ See S.A.M. Mclean, ‘Making Advance Medical Decisions’ (1995) 11 *Journal of the Medical and Dental Defence* 28-9; R.Francis, ‘Elective Ventilation of Potential Organ Donors. A Legal Comment.’ (1995) 310 *BMJ* 718.

elective ventilation on the grounds of medical benefit to the potential donor,²⁴ the reality of the practice is that - in common with other donor optimisation procedures - it is not performed with an aim of medical benefit and does not provide any medical benefit to the potential organ donor.²⁵ Whilst elective ventilation and some other donor optimisation procedures may succeed in maintaining some of the patient's vital organs, they neither improve the outcome for the patient nor palliate the patient's symptoms.²⁶ Invasive medical interventions such as elective ventilation are of no medical benefit to a patient facing inevitable death, nor do they coexist easily with a dignified death.²⁷

The potential for medical harm exists with all invasive medical interventions and with the vast majority of non-invasive medical interventions. Donor optimisation procedures are no exception to this: therefore decision-makers must always include the potential for medical harm within the determination of the best interests of the potential organ donor. This potential for medical harm will vary between procedures. However, there is little in the way of guidance available as to what procedures might be performed to facilitate organ donation, which makes it difficult to determine what the potential for medical harm is. The NICE guidance leaves open to interpretation what procedures might be included within the "clinical stabilis[ation]" of the potential organ donor, although it seeks not to limit life-sustaining treatments, and makes no mention of the physical risks involved.²⁸ While this is comparable to the original elective ventilation protocol, healthcare professionals may now have to make

²⁴ P. De Lora, A.P. Blanco, 'Dignifying Death and the Morality of Elective Ventilation' (2013) 39 *J Med Ethics* 145-148, ['Dignifying Death'].

²⁵ See eg. AB. Shaw, 'Non-Therapeutic (Elective) Ventilation of Potential Organ Donors: The Ethical Basis for Changing the Law' (1996) 22 *J Med Ethics* 72-7.

²⁶ See D. Clark, 'Between Hope and Acceptance: The Medicalisation of Dying' (2002) 324 *BMJ* 905-7.

²⁷ Contrary to the claims expressed by *De Lora & Blanco*, 'Dignifying Death', as above; see my arguments on dignity in Chapter 2.

²⁸ NICE, *Improving Donor Identification* as earlier, p.7 [1.1.6-1.1.7].

decisions about a range of interventions that have since been developed and need some way of ascertaining what the potential for medical harm is from these interventions.

The UK Donation Ethics Committee (UKDEC) generic interventions guidance only gives limited guidance on the physical harms that could result from donor optimisation procedures.²⁹ Examples given are “pain, discomfort, shortening the patient’s life and worsening the patient’s medical condition”.³⁰ They also give examples of potential distress as “feelings of suffocation, choking, gasping, panic, weakness, isolation, loneliness and invasion of privacy”.³¹ Although they recommend that the evidence relating to the risks associated with donor optimisation procedures is regularly reviewed,³² there is no clinical evidence provided to support the examples given of potential harm and distress. UKDEC have only produced one specific interventions guideline, on extubation,³³ and have since been disbanded.³⁴ The healthcare professionals who need to carry out the recommended “evidence-based assessments of... risks and benefits”³⁵ are now in a position where there doesn’t appear to be any central body reviewing the necessary evidence.

A search of the Cochrane library reveals no systematic reviews and no clinical trials evaluating the risks of harm from ante-mortem donor optimisation procedures.³⁶ The difficulties accessing specifically relevant data may mean that doctors can only estimate the

²⁹ UKDEC, *Generic Interventions Guidance: Interventions Before Death to Optimise Donor Organ Quality and Improve Transplant Outcomes: Guidance from the UK Donation Ethics Committee* (9/10/14), [9], [‘Generic Interventions’]

³⁰ Ibid [9].

³¹ Ibid [9]. N.B. it should not be assumed that patients identified as potential organ donors are incapable of experiencing physical and/or psychological distress. This will be explored later in the chapter.

³² Ibid, [17]

³³ UKDEC, *Extubation: An Application of UKDEC’s Generic Guidance On Interventions Before Death to Optimise Donor Organ Quality and Improve Transplant Outcomes* (October 2014)

³⁴ See discussion in Chapter 1.

³⁵ UKDEC *Generic Interventions* as above, [17].

³⁶ Cochrane database searched on 31/01/2017 using following search terms: organ donation, donor optimisation, donor management, elective ventilation, non-therapeutic ventilation, potential organ donors.

risk of harm to the potential organ donor from their knowledge of the risks of invasive interventions under other circumstances. For example, their knowledge of the risks of blood-taking can be extrapolated to the circumstances of blood-taking to match potential organ donors with suitable recipients and lead to a conclusion that the only significant physical risks are bruising and discomfort. Each intervention carries different risks and requires a separate best interests determination. Three procedures that I identified in Chapter 1 as being associated with significant risks are heparin administration, mechanical ventilation, and femoral cannulation.³⁷ Heparin carries a risk of haemorrhage.³⁸ Mechanical ventilation carries several different risks, including anoxic brain injury.³⁹ Femoral cannulation is associated with a range of vascular complications.⁴⁰ The general risks from these procedures and others which could be included within the clinical stabilisation of potential organ donors are known, yet there is a paucity of published evidence on the specific risks in the circumstances of donor optimisation.

One of the most feared risks of donor optimisation procedures is that of inducing a permanent vegetative state (PVS), a risk that has mostly been associated with non-therapeutic ventilation.⁴¹ Although the risk is unquantified by research, PVS is considered such a serious harm that it has been termed the Risk of Unacceptable Badness (RUB) of non-therapeutic

³⁷ See end of section on ante-mortem interventions to facilitate organ donation.

³⁸ E. Motta, 'The Ethics of Heparin Administration to the Potential Non-Heart-Beating Organ Donor' (2005) 21(2) *J Prof Nurs* 97-102, 99-100.

³⁹ A. Hasan *The Complications of Mechanical Ventilation*, Chapter 10 in A. Hasan, *Understanding Mechanical Ventilation: A Practical Handbook* (2nd edition, Springer, Dordrecht Heidelberg London New York, 2010) 305-341.

⁴⁰ A. Seto, M. Abu-Fadel, J. Sparling *et al*, 'Realtime Ultrasound Guidance Facilitates Femoral Arterial Access and Reduces Vascular Complications: FAUST Femoral Arterial Access with Ultrasound Trial' (2010) 3(7) *JACC: Cardiovascular Interventions* 751-758, 755; T. Bisdas, G. Beutel, G. Warnecke *et al*, 'Vascular Complications in Patients Undergoing Femoral Cannulation for Extracorporeal Membrane Oxygenation Support' (2011) 92(2) *Ann Thorac Surg* 626-631, 628.

⁴¹ *New et al*, 'King's Fund Report' as earlier, 64. This risk could also accompany other procedures that might potentially be considered solely to improve the chances of organ donation, such as cardiopulmonary resuscitation.

ventilation.⁴² For potential organ donors, the RUB of non-therapeutic ventilation is the potential for death itself to be denied and replaced by a state that many consider worse than death itself.⁴³ PVS is amongst the most disabling conditions known to and caused by medical science. The condition is known to be induced by medical technologies - often including mechanical ventilation - that cause the patient to survive brain injuries that would otherwise have been fatal.⁴⁴ The state in which they survive is one of continuing “wakefulness without awareness”: their vegetative functions are intact yet they are – or appear to be - entirely incognizant.⁴⁵ In this state they may languish for many years - unable to communicate and powerless to alter their daily reality. It should not be assumed that this would not be the case for patients identified as potential organ donors on the basis of clinical criteria that are not specific for imminent death let alone exclude the possibility of survival in a severely impaired state.⁴⁶ For those who would have progressed rapidly to death, that prompt death appears a relative benefit in comparison to survival in PVS – a view that opinion polls suggest is shared by many.⁴⁷ This relative benefit risks being removed forever by elective ventilation and a

⁴² A. Browne, G. Gillett, & M. Tweeddale, ‘The Ethics of Elective (Non-therapeutic) Ventilation’ (2000) 14(1) *Bioethics* 42-57, 46 [‘Non-therapeutic Ventilation’].

⁴³ W. Shakespeare, *Hamlet* (1603), Act III, Scene 1; G. Gillett, ‘Brain Death, Vegetative State and the RUB’ (1999) V11(2) *Issues Med Ethics*, 54-55; Browne *et al*, as above, ‘Non-therapeutic Ventilation’, 46 ; J. Kitzinger & C. Kitzinger, ‘The “Window of Opportunity” for Death After Severe Brain Injury: Family Experiences’ (2013) 35(7) *Sociol Health Illn* 1095-1112, 1095, [‘Window of Opportunity’].

⁴⁴ It is known to be increasing in frequency yet there is limited epidemiological data available, see eg. M. Leonardi, D. Sattin, A. Raggi, & Italian National Consortium on Functioning Disability in DOCS patients, ‘An Italian Population Study on 600 persons in Vegetative State and Minimally Conscious State’ (2013) 27(4) *Brain Injury* 473-484.

⁴⁵ PVS was originally termed persistent vegetative state: B. Jennett & F. Plum, ‘Persistent Vegetative State after Brain Damage. A Syndrome in Search of a Name’(1972)1 *Lancet* 734; PVS is now sometimes referred to as the Unresponsive Wakefulness Syndrome, see K. Jellinger, ‘Neuropathology of Prolonged Unresponsive Wakefulness Syndrome after Blunt Head Injury: Review of 100 Post-Mortem Cases’ (2013) 27(7-8) *Brain Inj* 917-923.

⁴⁶ The possibility of patients identified as potential organ donors surviving is recognised by NICE in *Improving Donor Identification* as earlier, footnote 4 in 2011 guidance or endnote 2 in 2016 updated version; see discussion in Chapter 1.

⁴⁷ See ABC News poll (2005) and Gallup poll (1997): data available at <http://www.gallup.com/poll/15448/americans-choose-death-over-vegetative-state.aspx> (last accessed 28/09/17); see also C. Constable, ‘Withdrawal of Artificial Nutrition and Hydration in a Permanent Vegetative State: Changing Tack’, (2012) 26(3) *Bioethics* 157-163, 160 [‘Changing Tack’].

further window of opportunity for death may only materialise after years of medical interventions.⁴⁸

The view that developing PVS is a very serious physical harm is supported by research into PVS and related disorders of consciousness. Since PVS was first highlighted as a potential risk of elective ventilation, research has demonstrated that many patients who are initially diagnosed with PVS are subsequently found to be in a minimally conscious state (MCS).⁴⁹ The aetiology behind both conditions appears to be the same, suggesting the potential for some patients surviving elective ventilation to retain or re-develop a degree of awareness and be capable of experiencing physical pain and psychological distress.⁵⁰ Although a risk of PVS from non-consensual non-therapeutic procedures is concerning enough, it is even more so if there is a possibility of some patients developing a MCS. This condition can take years to diagnose, and this delay in diagnosis leaves patients with a degree of awareness but no means of communicating this.⁵¹ The potential for this occurring presents a very serious physical risk from donor optimisation procedures and requires either quantifying or eliminating by large scale clinical research into the outcomes of donor optimisation procedures.

“Life-sustaining but non-restorative treatments”⁵² such as elective ventilation, which carry a RUB, are difficult to encompass within the best interests of any individual.⁵³ It may still

⁴⁸ See *Kitzinger & Kitzinger* as above, ‘Window of Opportunity’, 1095.

⁴⁹ MCS has been defined as “a condition of severely altered consciousness in which minimal but definite behavioral evidence of self or environment awareness is demonstrated”, see J.T. Giacino, S. Ashwal, N. Childs, R. Cranford *et al*, ‘The Minimally Conscious State: Definition and Diagnostic Criteria’ (2002) 58 *Neurology* 349-353 ; for research review and summary of ethical issues, see, M. Farisco & C. Petrini, ‘Misdiagnosis as an Ethical and Scientific Challenge’ (2014) 50(3) *Ann Ist Super Sanita* 229-233 [‘Misdiagnosis’].

⁵⁰ M. Farisco, ‘The Ethical Pain: Detection and Management of Pain and Suffering in Disorders of Consciousness’ (2013) 6 *Neuroethics* 265-276; A. Demertzi, E. Racine, M-A. Bruno, D. Ledoux *et al*, ‘Pain Perception in Disorders of Consciousness: Neuroscience, Clinical Care, and Ethics in Dialogue’ (2013) 6 *Neuroethics* 37-50.

⁵¹ See eg *Farisco et al*, ‘Misdiagnosis’ as above.

⁵² *Kitzinger & Kitzinger* as above, ‘Window of Opportunity’, 1096.

be possible to include them within an individual's best interests if that individual does not share the majority view that the risk is unacceptably bad.⁵⁴ However, this relies on the individual having being informed of the risk and on their views towards this risk being known. It is only with this information that decision-makers can attempt to weigh up the individual's views and wishes against the risk of physical harm. Even if an individual has accepted the risks of physical harm, it is possible that the potential harm of the most invasive donor optimisation procedures outweighs any benefit gained from respecting individual autonomy.⁵⁵

Centrality of the Individual

The law has recognised for over two decades that incompetent individuals, including those who are irreversibly comatose or in a permanent vegetative state, have "a recognisable interest in the manner of [their] life and death"⁵⁶ - an interest that it has sought to protect by counting their previous wishes as part of their best interests. This legal recognition of the individual's wishes has been developed through case law and given a statutory foundation in the Mental Capacity Act 2005 (MCA). Although the law does not seek to limit the considerations that may contribute to best interests, the checklist of factors provided to decision-makers places an emphasis on what the individual would have wanted in the circumstances.⁵⁷ Section 4(6) requires decision-makers to consider, "so far as is reasonably ascertainable"-

⁵³ D. Crippen, 'Medical Treatment for the Terminally Ill: The Risk of Unacceptable Badness' (2005) 9(4) *Critical Care* 317-8.

⁵⁴ See <http://www.gallup.com/poll/15448/americans-choose-death-over-vegetative-state.aspx> as before; also *Constable*, 'Changing Tack' as before, 160.

⁵⁵ The difficulty of weighing up these diverse concepts is discussed later in this chapter in the section on the balance of best interests.

⁵⁶ *Airedale NHS Trust v Bland* [1993] AC 789, 829 per Lord Justice Hoffmann, see also 833.

⁵⁷ S. 4(6).

- (a) the person's past and present wishes and feelings (and, in particular, any relevant written statement made by him when he had capacity),
- (b) the beliefs and values that would be likely to influence his decision if he had capacity, and
- (c) the other factors that he would be likely to consider if he were able to do so.⁵⁸

The formulation of best interests on which the MCA is founded reflects the move away from a purely medical formulation within the common law.⁵⁹ Within just a few years of elective ventilation being declared unlawful, best interests was recognised to include "a wide range of ethical, social, moral, emotional and welfare considerations",⁶⁰ potentially providing the legal grounds to justify the practice. Even before the MCA came into force, these wide considerations were recognised to include respect for the wishes and beliefs of the incapacitated patient, including circumstances in which the patient may be unaware that these wishes will be facilitated.⁶¹ It is this legal protection afforded to the previous wishes and beliefs of patients who have since lost decision-making capacity that both permits and demands the advance consent of the potential organ donor, or other evidence of their wishes and beliefs, to be taken into account as part of the best interests test.

The statutory protection afforded to the patient's wishes, feelings, values and beliefs proceeds not only from the development of the common law but also from the recommendations of the Law Commission.⁶² These recommendations, published just a few months after elective ventilation was declared unlawful, paved the way for the only potential

⁵⁸ S. 4(6)

⁵⁹ S. 1(5) and S. 4(6); *Re MB (Caesarean Section)* [1997] 2 FLR 426, 439, per Dame Butler-Sloss; *Re A (Male Sterilisation)* [2000] 1 FCR 193, per Dame Butler-Sloss; *In re S (Adult Patient: Sterilisation)* [2001] Fam 15, page 30, per Lord Justice Thorpe.

⁶⁰ *A v A Health Authority* [2002] 1 Fam 213, para 43, per Judge Munby; a formulation he reiterated in *R (on the application of Burke) v General Medical Council* [2004] EWHC, 1879(Admin), [90].

⁶¹ *Ahsan v University Hospitals Leicester NHS Trust* [2007] PIQR P19, [54-56] per Judge Hegarty.

⁶² The Law Commission (Law com no. 231, HMSO, London, 1995) *Mental Incapacity*, part III(2), p42-48.

statutory justification for the practice. The Law Commission's proposals were designed to protect the incapacitated adult from "improper usurpation of his or her autonomy and from inadequate or even abusive decision-making", ⁶³ an aim that is particularly pertinent to the incapacitated patient identified by others as a potential organ donor. The intention was that the individual and their individual circumstances should always determine the outcome of any best interests assessment. ⁶⁴ It is this focused consideration of the incapacitated patient as an individual that underlies the formulation of best interests now incorporated into the MCA, ⁶⁵ providing the potential statutory justification for donor optimisation procedures.

To achieve their aims, the Law Commission proposed a checklist of factors designed to focus consideration on each person as an individual. ⁶⁶ The requirement to consider past and present wishes and feelings was intended to establish the importance of individual views. ⁶⁷ The Law Commission emphasised that "altruistic sentiments and concern for others" might be included within the other factors that an individual would be likely to consider. ⁶⁸ However, their focus on the individual and their individual circumstances as determinative of the outcome of their own best interests ensures that there can be no presumption that any such altruistic desires exist. ⁶⁹ This focus on the individual both allows altruistic wishes to undergo donor optimisation procedures to be encompassed within best interests and precludes any such wishes from being presumed.

⁶³ *Mental Incapacity*, as above, p 42, [3.24].

⁶⁴ *Ibid*, p 43, [3.26]

⁶⁵ MCA 2005, s.4; see also The Stationery Office, *Making Decisions: The Government's Proposals for Making Decisions on Behalf of Mentally Incapacitated Adults*. (Cm. 4465, October 1999).

⁶⁶ The Law Commission, *Mental Incapacity*, as previously, p 43-48, [3.27-3.37]

⁶⁷ *Mental Incapacity*, as above, p 45, [3.29]; see also See N. Glover & M. Brazier, 'Ethical Aspects of the Law Commission Report on Mental Incapacity' (1996) 6 *Rev Clin Geront* 365-370.

⁶⁸ *Mental Incapacity* as above, p. 45-46, [3.31].

⁶⁹ *Ibid*, p.42, [3.26].

The concept of best interests within the MCA reflects both the common law and the Law Commission's proposals, but is identical to neither.⁷⁰ The MCA aims to resolve some of the inconsistencies and idiosyncrasies associated with the emergence of the concept through the mechanism of judicial deliberation.⁷¹ It provides a universal mechanism for decision-making in an incapacitated individual's best interests, detailing and focusing decision-making on certain key factors that place the individual at the centre of the decision.⁷² Whilst the Law Commission's original proposal emphasised the importance of the individual's wishes, feelings, and other factors they would be likely to consider, this emphasis on the individual was extended further by the addition of the patient's beliefs and values to the Mental Incapacity Bill.⁷³ This followed recommendations by the Medical Ethics Alliance and other organisations and predated any emphasis on beliefs and values within common law accounts of best interests.⁷⁴ The result was a statutory best interests checklist that specifies the crucial criteria that will "always be worthy of attention"⁷⁵ within a best interests determination - all of which are concerned with what the individual themselves would have decided.

Although the best interests formulation now incorporated into the MCA is intended to place the individual at the centre of the decision being made, there are problems realising this intention in practice. Best interests stands accused of being "the vehicle for poor decision-

⁷⁰ A. Szerletics, 'Best Interests Decision-Making Under the Mental Capacity Act' (University of Essex, Essex Autonomy Project, 2011) available at <http://autonomy.essex.ac.uk/best-interests-decision-making-under-the-mental-capacity-act> (last accessed 28/09/2017) ['Essex Autonomy Project'].

⁷¹ M. Dunn, I. Clare, A. Holland, & M. Gunn, 'Constructing and Reconstructing 'Best Interests': An Interpretative Examination of Substitute Decision-making under the Mental Capacity Act 2005', (2007) 29(2) *J Soc Welf Fam Law* 117-133, 122.

⁷² Ibid, 122; Explanatory Notes to Mental Capacity Bill 2004, [23,25], available at <https://www.publications.parliament.uk/pa/cm200304/cmbills/120/en/04120x--.htm> (last accessed 28/09/2017); MCA S. 4(6); MCA Code of Practice, [5.6].

⁷³ See Appendix A, *Mental Incapacity Bill*, to Law Commission report, *Mental Incapacity* (1995) as above, Section 3 (2)(a); Mental Capacity Bill 2004.

⁷⁴ Joint Committee on the Draft Mental Incapacity Bill, *Draft Mental Incapacity Bill* (Session 2002-03, Vol. 1, HL Paper 189-1; HC 1083-1) [90]. See *Ahsan v University Hospitals Leicester NHS Trust* [2007] PIQR P19, [54-56] per Judge Hegarty, for one of the earliest examples of encompassing the individual's religious beliefs within their best interests.

⁷⁵ Explanatory Notes to Mental Capacity Bill 2004 as earlier, [23].

making”,⁷⁶ used by healthcare professionals to justify treating patients in the way that accords not with the patient’s viewpoint but with that of the healthcare professionals.⁷⁷ Evidence presented to the post-legislative scrutiny committee suggests that there are real grounds behind such concerns. For example, empirical research presented by Kitinger and Kitinger suggests that medical interventions on patients with severe brain injury are often initiated without any consultation with relatives to ascertain whether or not the individual would have wanted them.⁷⁸ The apparent failure of some doctors to consider the individual’s viewpoint as part of best interests suggests that healthcare professionals may either lack understanding of the provisions and/or be reluctant to move away from the paternalistic medical model of decision-making.⁷⁹ For procedures with no medical benefit, such as donor optimisation procedures, adhering to the medical model will not allow them to be encompassed within the current law. It is only by embracing the empowering ethos of the Act and acknowledging the centrality of the individual that healthcare professionals will be protected from liability for initiating procedures for the benefit of others.

The centrality of the individual to best interests has been reaffirmed by the first case under the MCA 2005 to come before the Supreme Court, restoring some of the power to the individual.⁸⁰ In *Aintree University Hospitals NHS Foundation Trust v James*, Lady Hale recognises that all of the limited guidance provided by the MCA on determining whether a particular treatment is in an individual’s best interests is focused on “the need to see the patient as an individual, with his own values, likes and dislikes, and to consider his best

⁷⁶ Select Committee on the Mental Capacity Act 2005, *Mental Capacity Act 2005: Post-legislative Scrutiny* (Report of Session 2013-2014, HL Paper 139), p.44-45, [90] quoting Dr Claud Regnard.

⁷⁷ Ibid; see also M. Donnelly, ‘Best Interests, Patient Participation and the Mental Capacity Act 2005’ (2009) 17 *Med Law Rev* 1-29.

⁷⁸ Mental Capacity Act 2005 Select Committee: Post-legislative Scrutiny. Evidence Volume 1 (A-K), C. Kitinger & J. Kitinger – Written evidence, 889-890, citing research in preparation which has since been published, see C. Kitinger & J. Kitinger, ‘Withdrawing Artificial Nutrition and Hydration from Minimally Conscious and Vegetative Patients: Family Perspectives’ (2015) 41(2) *J Med Ethics* 157-160.

⁷⁹ Kitinger Written Evidence as above, 890; HL Paper 139 as above, p.8 [2], p.44-45, [90-91].

⁸⁰ *Aintree University Hospital NHS Foundation Trust v James* [2013] UKSC 67, [1] per Lady Hale; HL Paper 139 as above, p.49, [99].

interests in a holistic way”.⁸¹ Lady Hale provides detailed guidance on determining the best interests of the individual as follows:

[I]n considering the best interests of this particular patient at this particular time, decision-makers must look at his welfare in the widest sense, not just medical but social and psychological; they must consider the nature of the medical treatment in question, what it involves and its prospects of success; they must consider what the outcome of that treatment for the patient is likely to be; they must try and put themselves in the place of the individual patient and ask what his attitude to the treatment is or would be likely to be; and they must consult others who are looking after him or interested in his welfare, in particular for their view of what his attitude would be.⁸²

Lady Hale observes that the overall purpose of best interests is to “consider matters from the patient’s point of view”.⁸³ Although she clarifies that the patient’s wishes might not necessarily prevail, she emphasises that insofar as they are ascertainable, it is the patient’s wishes, feelings, beliefs, values “or things which were important to him”⁸⁴ that should be taken into account as they are a component in making a decision which is “right for him as an individual human being”.⁸⁵ In the context of donor optimisation procedures, these are the factors that bring these non-therapeutic procedures within the potential scope of best interests. It is the individual’s viewpoint towards undergoing these procedures that the law states it is concerned with, and not facilitating benefit to others,⁸⁶ and this individual viewpoint should not only be taken into account but placed at the heart of decision-making.

⁸¹ Ibid, [23-26] referring to section 4.

⁸² *Aintree University Hospital NHS Foundation Trust v James* as above, [39].

⁸³ Ibid, [45].

⁸⁴ Ibid.

⁸⁵ Ibid.

⁸⁶ I will consider whether this is sometimes merely a façade in Chapter 5, by looking at cases in which the judiciary have apparently take into account benefit to others.

The greater emphasis placed on the role of the individual in best interests determinations requires that efforts are made to limit *de facto* substituted decision-making in this context.⁸⁷ If it can be established what the individual would want in the individual circumstances, then it should be established.

Decision-makers applying Lady Hale's criteria to the individual identified as a potential organ donor must give priority to establishing what that individual's "attitude to the treatment is or would likely to be".⁸⁸ The treatment or treatments in question are the donor optimisation procedures themselves. There are three separate factors determining an individual's attitude to donor optimisation procedures: their wishes regarding organ donation; their wishes regarding their end-of-life care; and their views on the potential risks of the procedures. These three factors cannot be amalgamated into one. Taking the first of these factors as predictive of the individual's overall attitude to treatment may result in a decision that doesn't match what the individual actually would have wanted in the circumstances.

The first factor, the patient's wishes regarding organ donation, is the only one of the three that is specified in the NICE guidance on determining best interests.⁸⁹ This is especially determined by reference to any advance statement or registration on the Organ Donor Register (ODR) and also by any expression of views to family or friends.⁹⁰ There are several problems with this, which largely stem from the lack of information currently provided to potential registrants on the ODR. Registrants are given very few details about the organ donation process itself, resulting in a lack of opportunity to even formulate a view let alone express a wish regarding interventions before death. Due to the lack of information they are

⁸⁷ See HL Paper 139 as above, p.49, [99] citing Kirsty Keywood.

⁸⁸ *Aintree University Hospital NHS Foundation Trust v James* as above, [39].

⁸⁹ NICE, *Improving Donor Identification* as earlier, p.7 [1.1.8].

⁹⁰ *Ibid.*

not in a situation where they could express any views about donor optimisation procedures to their relatives. In addition, there is no way of telling whether they understood what they were signing up for or whether they have since changed their viewpoint. Not all registered organ donors might wish to undergo donor optimisation procedures and the current system provides no way of differentiating between those who do and those who don't.

The second factor, the individual's wishes regarding their end-of-life care, may have significant impact on their attitude to donor optimisation procedures. Alterations to end-of-life treatment are an integral part of donor optimisation procedures: the latter cannot be viewed in isolation from the former.⁹¹ The individual's views on deceased organ donation are only one consideration influencing their attitude towards their end-of-life care, and could potentially be outweighed by other considerations that the individual places more importance on. These other considerations may include their wishes and views on intensive and/or palliative care, their views on what constitutes a good death, fear regarding medical technology, their religious beliefs, and their ethical commitments other than organ donation.⁹² The balance of these considerations is unique to each individual and should not be presumed on the basis of the first consideration alone.

The third determinant of the individual's overall attitude to donor optimisation procedures - their views on the potential risks of the procedures - may be independent of both their views on organ donation and their views on end-of-life care. For example, one individual may both wish to donate organs after death and undergo changes to their end-of-life care but not wish to risk any physical harm. A second individual may be prepared to risk some physical harm but not the most serious physical harms. A third individual may be

⁹¹ For a thorough analysis see D. Price, 'End-of-Life Treatment of Potential Organ donors: Paradigm Shifts in Intensive and Emergency Care.' (2011) 19 *Med Law Rev* 86-116.

⁹² See, for example, T. Reyniers, D. Houttekier, J. Cohen, H. Pasman, L. Deliens, 'The Acute Hospital Setting as a Place of Death and Final Care: A Qualitative Study on Perspectives of Family Physicians, Nurses and Family Carers' (2014) 27 *Health & Place* 77-83.

prepared to risk the most serious physical harms from donor optimisation procedures. All of these individuals have some level of ethical commitment towards becoming an organ donor and are prepared to have changes to their end-of-life care to realise this commitment, yet the differing levels of risk they are prepared to accept changes the balance between their ethical commitments and values and the risk of physical harm. Under the best interests formulation incorporated into the MCA, fulfilling an individual's ethical commitments, wishes, and values is considered a benefit to them as an individual.⁹³ The balancing of benefit against risk,⁹⁴ however, is unique to each potential organ donor and these benefit-risk preferences may alter their overall attitude to treatment.⁹⁵

The three key determinants of the individual's attitude to donor optimisation procedures may overlap to some degree but remain sufficiently separate as to demand specific consideration as part of the best interests determination. As the individual's attitude to donor optimisation procedures is central to their accommodation within best interests, the three factors identified above are essential to decision-making about donor optimisation procedures. While the individual's viewpoint might not always prevail over other considerations, the individual's viewpoint is crucial to determining where the balance between the different considerations lies.

Social and Psychological Interests

The centrality of the individual's viewpoint to their own best interests, as now acknowledged by the law, allows the individual's interest in their own life and death to be protected,

⁹³ S. 4(6).

⁹⁴ The balancing of best interests will be evaluated later in this chapter.

⁹⁵ See A. Brett Hauber, A. Fairchild, F. Reed Johnson, 'Quantifying Benefit–Risk Preferences for Medical Interventions: An Overview of a Growing Empirical Literature' (2013) 11(4) *Appl Health Econ Health Policy* 319-329.

respected, and sustained. Upholding this interest is an integral part of safeguarding and promoting that individual's autonomy, their bodily integrity, and their dignity. The legal requirement to take into account the individual's social and psychological welfare is a key part in establishing where the individual's interest in their end-of-life care lies.

The social interests of many individuals identified as potential organ donors will include an interest in the wellbeing of potential organ recipients. The psychological interests of some individuals identified as potential organ donors may include an improved mental or emotional state from the anticipation of becoming an organ donor. However, neither of these considerations is problem-free: the primary concern with social interests is that of the potential for exploitation, whilst a key issue with psychological interests is the assumed lack of ability of the irreversibly comatose patient identified as a potential organ donor to experience psychological benefit. With respect to the first concern, this exploitative potential could be reduced by requiring that healthcare professionals determine the individual's actual wishes in the circumstances. With respect to the second concern, that of the assumed lack of experiential psychological interests, I will address this from three angles - one of which challenges the assumption on which it is based.

The formulation of best interests incorporated into the MCA reflects the principle of precedence of individual interests, this being the widely accepted ethical principle that it is not permissible to sacrifice individual interests for the sake of societal and/or scientific interests.⁹⁶ This principle is formulated in the Universal Declaration on Bioethics and Human Rights as:

⁹⁶ J. Piasecki, M. Waligora, V. Dranseika, 'Non-beneficial Pediatric Research: Individual and Social Interests' (2015) 18(1) *Med Health Care Philos*, 103-112, 103 ['Individual and Social Interests'].

The interests and welfare of the individual should have priority over the sole interest of science or society.⁹⁷

There is nothing in the wording of the MCA or the Universal Declaration to suggest that this principle is not as applicable to potential organ donors as it is to other human beings.

No matter how great the needs of others in society, the formulation of best interests incorporated into the MCA demands that donor optimisation procedures are only carried out if they can be demonstrated to be within the individual interests of the potential organ donor. Although these interests may include an interest in the wellbeing of potential organ recipients, this interest of the potential organ donor requires differentiation from the interests of others in society. To ensure that the social interest belongs to the individual undergoing the procedures, there needs to be evidence to substantiate that individual having a genuine social interest in undergoing procedures for the benefit of potential organ recipients. To ensure that the potential organ donor's interests remain paramount, this evidence needs to be weighed up against any potential harm to their individual interests.⁹⁸ If the evidence is missing or does not outweigh potential harms, then social interests cannot be relied on to encompass donor optimisation procedures within the MCA provisions on best interests.

Although the MCA requires individual interests to remain paramount, the judiciary has clarified that best interests are not confined to self-regarding interests.⁹⁹ In *Re G(TJ)*, Justice

⁹⁷ UNESCO 2005, Article 3(2).

⁹⁸ See M. Donnelly, 'Determining Best Interests Under the Mental Capacity Act 2005' (2011) 19(2) *Med L Rev* 304-313, 312-313. ['Determining Best Interests']; Also P. Lewis, 'Procedures that are Against the Medical Interests of Incompetent Adults' (2002) 22(4) *Oxf J Leg Stud* 575-618, ['Procedures Against Medical Interests'].

⁹⁹ In *Re G(TJ)* [2010] EWHC 3005 (COP) [56] per Justice Morgan; in contrast to *Samanta's* argument in J. Samanta, 'Lasting Powers of Attorney for Healthcare under the Mental Capacity Act 2005: Enhanced Prospective Self-determination for Future Incapacity or a Simulacrum' (2009) 17(3) *Med Law Rev* 377-409, 402; see discussion by Donnelly in 'Determining Best Interests' as above, p 312-313.

Morgan recognises both the actual and putative altruistic wishes of the patient as factors of relevance to their best interests - even if the patient is unaware or displays no reaction to those wishes being respected.¹⁰⁰ However, as he also recognises, relying on putative wishes only is a substituted judgement and in the circumstances of the case there were no countervailing factors.¹⁰¹ In the circumstances of organ procurement policy, there is a risk of harm and making decisions based on putative wishes leaves incapacitated patients at risk of exploitation. Relying on speculative or hypothetical wishes as the sole benefit to the individual may lead to the patient's best interests being misconstrued. It could potentially represent the values of the decision-maker rather than the values of the individual required to undergo the procedures. To protect against these concerns, there is a need to determine the actual wishes – altruistic or otherwise – of each individual identified as a potential organ donor.

Altruistic concern for others may be an important social interest of the individual in the well-being of others, but it may be intertwined with psychological motives and benefits for the potential organ donor.¹⁰² The psychological motivation of the potential organ donor may arise from empathic concern or from other factors, and may result in beneficial effects on the psychological health and well-being of the potential donor.¹⁰³ Some of these beneficial effects may be created by the motivation itself or from the anticipation of becoming an organ donor. This provides the first of three potential ways of addressing the problem of an assumed lack of ability of the irreversibly comatose to experience psychological benefit. Providing advance consent to donor optimisation procedures could allow the potential donor

¹⁰⁰ *Re G (TJ)* [2010] EWHC 3005, [56] per Justice Morgan.

¹⁰¹ *Ibid*, [65].

¹⁰² J. Challenor, 'It Seemed Churlish Not to': How Living Non-Directed Kidney Donors Construct Their Altruism' (2014) 18(4) *Health* 388-405, 388.

¹⁰³ C.D. Batson, L.L. Shaw, 'Evidence for Altruism: toward a Pluralism of Prosocial Motives', (1991) 2 *Psychol Inquiry* 107-122; M. Lozada, P. D'Adamo, M. Fuentes, 'Beneficial Effects of Human Altruism' (2011) 289(1) *J Theor Biol* 12-16, 12-13; M.D. Jendrisak, B. Hong, S. Shenoy *et al*, 'Altruistic Living Donors: Evaluation for Non-Directed Kidney or Liver Donation' (2006) 6 *Am J Transplant* 115-120; L. Wright, K. Ross, S. Abbey, G. Levy *et al*, 'Living Anonymous Liver Donation: Case Report and Ethical Justification' (2007) 7 *Am J Transplant* 1032-1035.

to experience beneficial effects in anticipation of donation. Involving potential registrants in the decision-making process could be of significant psychological benefit to them, affirming their personal identity as altruistic individuals and elevating their feelings of self-worth.

The second potential means of addressing the question of an assumed inability to experience psychological benefit is to consider the approach of the court to cases involving patients who are thought to be entirely unaware. The law on best interests has developed considerably since the suggestion made in *Bland* that a PVS patient has no interests.¹⁰⁴ For example, in *Ahsan v University Hospitals Leicester NHS Trust*, a case involving a Muslim patient in PVS, it was held to be in her best interests to be cared for and prayed for at home even though “no tangible benefit” was thought likely to result.¹⁰⁵ The benefit that encompassed this care plan within her best interests was that it was consistent with the wishes and beliefs that could be attributed to her.¹⁰⁶ This reliance on attributable wishes rather than actual wishes again raises the possibility of substituted decision-making, yet as there were no countervailing factors, the decision was not harmful to Ahsan - even if it was thought to provide “no tangible benefit”. The decision confirms that, under the law as it stands, benefits to the individual from donor optimisation procedures do not need to be tangible in the sense that they are physical or experiential. They may instead be tangible in the sense that they are discernible by reference to the individual’s wishes. However, as donor optimisation procedures do carry a risk of harm, these wishes should be their actual wishes and the benefit should be a tangible one by reference to them.

The third potential means of addressing the problem of an assumed inability to experience psychological benefit is that the assumption it is founded on may not in all cases be correct. Although consciousness may no longer be apparent in the individual identified as a

¹⁰⁴ *Airedale NHS Trust v Bland* [1993] AC 789, 829B-F.

¹⁰⁵ *Ahsan v University Hospitals Leicester NHS Trust* [2006] EWHC 2624, [43-56] per Judge Hegarty.

¹⁰⁶ *Ibid*, [43-56].

potential organ donor, this may be due to an inability to communicate retention of awareness rather than a complete absence of awareness.¹⁰⁷ Clinical identification of potential organ donors relies on the Glasgow Coma Scale (GCS),¹⁰⁸ one of the most commonly used behavioural instruments for assessment of consciousness, yet reliance on behavioural markers is problematic and may lead to misdiagnosis.¹⁰⁹ The GCS score depends on the patient's ability to open their eyes, respond verbally to a stimulus, and produce a motor response to stimuli.¹¹⁰ Each of these three components may be affected by conditions other than a lack of awareness. Eye opening may be impossible due to ocular trauma, cranial nerve injuries, or pain.¹¹¹ Verbal response cannot be assessed in intubated patients and may also be reduced due to tracheostomy, drug or alcohol intoxication, medications including sedatives, hearing impairments or mutism, damage to the language system consequent on brain injury, and a range of other confounding factors.¹¹² Many of these conditions may also reduce the motor response, as may spinal cord or peripheral nerve injuries or damage to the motor system due to brain injury.¹¹³ Consequent to these factors and others, some patients who meet the clinical criteria for entry into the organ donation pathway may have conscious experiences but be unable to express them.¹¹⁴

¹⁰⁷ See Foreword in C. Schnakers & S. Laureys, *Coma and Disorders of Consciousness* (Springer-Verlag, London, 2012).

¹⁰⁸ See NICE, *Improving Donor Identification* as before, p.6 [1.1.2]; See also discussion in chapter 1 on the identification of potential organ donors.

¹⁰⁹ Foreword as above & also C. Schnakers & S. Majerus, 'Behavioural Assessment and Diagnosis of Disorders of Consciousness' Chapter 1 in *Coma and Disorders of Consciousness* as above, 3-7, 'Behavioural Assessment'; also J. Giacono, C. Schnakers, D. Rodriguez-Moreno *et al*, 'Behavioural Assessment in Patients With Disorders of Consciousness: Gold Standard or Fool's Gold?' Chapter 4 in S. Laureys *et al*, *Progress in Brain Research* (Vol. 177, Elsevier B.V. 2009) 33-48, ['Fool's Gold?'].

¹¹⁰ See G. Matis & T. Birbilis, 'The Glasgow Coma Scale- A Brief Review Past, Present, Future' (2008) 108 *Acta Neurol Belg* 75-89, 75-76, ['GCS Review'].

¹¹¹ See Table IV, *Matis and Birbilis*, 'GCS Review', page 82.

¹¹² *Matis and Birbilis*, 'GCS Review', page 82, including Table IV as above; also *Giacino, Schnakers, et al*, 'Fool's Gold?', 33.

¹¹³ Table IV as above, also, *Schnakers & Majerus*, 'Behavioural Assessment', 3-7.

¹¹⁴ See M. Overgaard, 'How Can We know if Patients in Coma, Vegetative State or Minimally Conscious State are Conscious?' Chapter 2 in S. Laureys *et al*, *Progress in Brain Research* (Vol. 177, Elsevier B.V., 11-19.

The probability that some patients meeting the clinical criteria for entry into the organ donation pathway retain some degree of awareness is significant as a proportion of these patients may have enough awareness as to be able to experience psychological benefit or harm from donor optimisation procedures. As the clinical identification of potential organ donors does not exclude patients with experiential psychological interests, it cannot be presumed that any individual identified as a potential organ donor lacks experiential interests.¹¹⁵ Experiential psychological interests are heavily dependent on the individual's viewpoint towards intensive interventions at the end of life to facilitate organ donation. A patient whose wishes are to have a peaceful natural death may experience "death under intensive care"¹¹⁶ as a psychological harm. A different patient whose wishes and values are consistent with undergoing elective ventilation to maximise their chances of becoming a deceased organ donor may experience the same intensive regime as a psychological benefit. Under the current system of identification and treatment of potential organ donors on the basis of clinical criteria only, some patients will undergo interventions against their wishes and values. As behavioural assessment of consciousness does not exclude the possibility of some patients being partially or even fully conscious, some patients may experience psychological harm from undergoing interventions against their wishes and values. Without a framework incorporating knowledge of the individual's specific wishes in the circumstances, it cannot be determined on which side of the balance any psychological interests are likely to lie.

The Balance of Best Interests

For any medical intervention to be legally justified as being in the best interests of a patient identified as a potential organ donor, the benefits to that patient must be balanced against

¹¹⁵ See *Overgaard* as above, 11.

¹¹⁶ See I. Illich, *Limits to Medicine* (Marion Boyars, London, 1995 edition) 201-208.

and be demonstrated to outweigh the harms to that patient.¹¹⁷ This balance sheet is a common law approach that has received continued judicial approval, both before and after the enactment of the MCA.¹¹⁸ Despite this, there is no statutory guidance on the application of the balance sheet approach, reflecting the difficulties in legislating for the weight to be afforded to every consideration in every circumstance. The unwanted correlate of this is a lack of clarity on how the diverse considerations that contribute to best interests should be balanced against each other.¹¹⁹ The Code of Practice acknowledges that, although the best interests principle is intended to be flexible, that this flexibility could create problems in reaching a conclusion as to where an individual's best interests lie.¹²⁰ For the potential organ donor, this leaves them in a position of uncertainty in which there is no clear answer as to how their relevant interests will be weighed up in relation to each other and as to what conclusion will be drawn by those afforded decision-making power.

Two key considerations to be weighed up as part of the best interests determination for each donor optimisation procedure are the individual's viewpoint¹²¹ and the potential for physical harm from that procedure. If the individual's viewpoint is against having a particular procedure, the balance of these considerations lies in not having that procedure performed as both factors lie on the same side of the balance sheet. However, if the individual's viewpoint is in favour of having a particular procedure, it is not easy to determine how this viewpoint might be balanced against the risks of physical harm, as these factors are not readily comparable and there are no clear rules on the relative weight to be attached to each factor.

¹¹⁷ *Re A (Medical treatment: Male Sterilisation)* [2000] 1 FCR 193, 206; *M v N* [2015] EWCOP 76, [45].

¹¹⁸ See *Szerletics* as earlier, 'Essex Autonomy Project', 14; for analysis of case-law on balance sheet see *In Re M (Adult Patient) (Minimally Conscious State: Withdrawal of Treatment)* [2011] EWHC 2443 (Fam) [100-103].

¹¹⁹ *Szerletics* as above, 14 & 17.

¹²⁰ MCA Code of Practice (2013), p.88 [5.62].

¹²¹ Within viewpoint I include wishes, feelings, preferences, values, beliefs, ethical commitments, social interests and psychological interests.

As Mr Justice Munby recognises in *Re M (Statutory Will)*, the MCA “lays down no hierarchy”¹²² between the different factors to be taken into account in the best interests determination.¹²³ As he also recognises, the weight to be attached to the different factors will differ depending on the individual circumstances of each case.¹²⁴ However, there may be a particular case in which one or more factors are of “magnetic importance” in influencing or determining the outcome.¹²⁵ In some particular cases, the individual’s wishes and feelings may provide that magnetic factor and carry “preponderant weight”.¹²⁶ Despite the MCA laying down no hierarchy, the individual’s viewpoint, incorporating their wishes and values, may - in some circumstances - represent the most crucial determinant of best interests.

In the particular circumstances of donor optimisation procedures, the individual’s viewpoint is of magnetic importance in either bringing these non-therapeutic procedures within the scope of best interests or excluding them from best interests. The only potential benefit to the individual from these procedures is fulfilling the individual’s wishes, values, and ethical commitments. For individuals whose wishes, values, and commitments are against having donor optimisation procedures, their viewpoint determines the outcome as there is no benefit to be balanced against potential harms. There is no social or psychological benefit to the individual from interventions that are against their wishes, values, and commitments. For those individuals whose overall viewpoint is consistent with having particular donor optimisation procedures, there is no statutory guidance on the weight to be afforded to the individual’s viewpoint and to potential harms. However, the relevant case law that has emerged over the last few years has placed considerable emphasis on giving “proper

¹²² [2009] EWHC 2525 (Fam), [32].

¹²³ Ibid, [32].

¹²⁴ Ibid, [32].

¹²⁵ Ibid, [32]; citing Thorpe LJ in *Crossley v Crossley* [2007] EWCA Civ 1491, [15] and also in *White v White* [1999] Fam 304, p.314; see also discussion by Szerletics as above, 17-18.

¹²⁶ *Re M (Statutory Will)* as above, [35]

weight”¹²⁷ to individual wishes and values,¹²⁸ suggesting that the wishes and values of a patient who wants to undergo donor optimisation procedures should be emphasised in decision-making by doctors and in donor optimisation policy.

The judiciary’s emphasis on giving substantial weight to individual views, wishes, and values is derived from the focus on these matters within the MCA provisions on best interests.

As Judge Marshall muses:

What, after all, is the point of taking great trouble to ascertain or deduce P’s views, and to encourage P to be involved in the decision-making process, unless the objective is to try to achieve the outcome which P wants or prefers, even if he does not have the capacity to achieve it for himself?¹²⁹

If the objective is indeed to achieve the patient’s preferred outcome, rather than just give the appearance that this is what is happening, then the views and wishes of the potential organ donor should carry preponderant weight. However, the judiciary also leaves considerable discretion to decision-makers by stating that the “paramount objective”¹³⁰ of the MCA is the individual’s best interests and not necessarily the implementation of patient wishes.¹³¹ This means that an individual’s wish to undergo donor optimisation procedures could still be overridden in their best interests, yet fails to define the circumstances in which this might be considered justifiable.

¹²⁷ *M v N* [2015] EWCOP 76 [28] per Mr Justice Hayden.

¹²⁸ *M v N* as above [28]. See also *Wye Valley NHS Trust v B* [2015] EWCOP 60 ; *Sheffield Teaching Hospital Foundation Trust v TH and TR* [2014] EWCOP 4 ; *United Lincolnshire Hospitals NHS Trust v N* [2014] EWCOP 16; *Re S (protected persons)* [2010] 1 WLR 1082; *Briggs v Briggs* [2016] EWCOP 53.

¹²⁹ *Re S (protected persons)* [2010] 1 WLR 1082 [55].

¹³⁰ *Ibid* [56].

¹³¹ *Ibid* [56].

The malleability surrounding the weight to be afforded to individual wishes allows decision-makers to afford them anything ranging from no weight to “very significant weight”,¹³² depending on the outcome they wish to achieve. This can lead to a very “unsatisfactory balancing act”,¹³³ with decision-makers prioritising other factors over patient wishes. For example, in *Re M (Adult Patient)(Minimally Conscious State: Withdrawal of Treatment)*, the “decisive factor” was found to be the preservation of life, with no significant weight being attached to M’s past verbal statements of wishes,¹³⁴ a judgement which appears at odds with the requirements of section 4(6). In this case, there was clear evidence of M’s wishes which Mr Justice Baker discounted because of a reluctance to sanction withdrawal of artificial nutrition and hydration (ANH) from a patient who may have been capable of experiencing pleasure and pain.¹³⁵ Mr Justice Baker’s approach suggests that the only way for an individual to have any realistic hope that their wishes will be afforded significant weight is to write a legally valid and applicable advance refusal of treatment.¹³⁶

One recent case that demonstrates that the direction the common law is taking is away from the approach in *Re M* and towards one which recognises the significant weight to be afforded to the individual’s viewpoint is *Briggs v Briggs*.¹³⁷ In this case, Mr Justice Charles recognises that Mr Justice Baker’s judgement in *Re M* predates *Aintree University Hospitals NHS Foundation Trust v James*¹³⁸ and that his decision to accord no significant weight to M’s past verbal statements “runs counter to the holistic approach that the Supreme Court confirms is to be taken to enabling P to do what he would have wanted if of full capacity, and

¹³² *Wye Valley NHS Trust v B* [2015] EWCOP 60 [10].

¹³³ A. Mullock, ‘Deciding the Fate of a Minimally Conscious Patient: An Unsatisfactory Balancing Act’ (2012) 20(3) *Med Law Rev* 460-469, [‘Deciding the Fate’].

¹³⁴ [2011] EWHC 2443 (Fam), per Mr Justice Baker, [249-250].

¹³⁵ See *Mullock*, ‘Deciding the Fate’, 468-469.

¹³⁶ As recognised by *Mullock* as above, 469.

¹³⁷ *Briggs v Briggs* [2016] EWCOP 53.

¹³⁸ [2013] UKSC 67, as evaluated earlier in this chapter.

so to addressing the matters set out in s. 4(6)".¹³⁹ Mr Briggs, a patient in a minimally conscious state, had made verbal statements that enabled Mr Justice Charles to conclude that he would not have wanted continued life-sustaining treatments in the circumstances.¹⁴⁰ Following the Supreme Court's guidance, and preferring the approach of other judges who had applied it before,¹⁴¹ enables Mr Justice Charles to conclude that "the weightiest and so determinative factor in determining what is in Mr Brigg's best interests is what I am sure he would have wanted to do and would have concluded was in his best interests".¹⁴² What the patient would have wanted is now recognised to carry great weight, even in circumstances when this can only be deduced from verbal statements made to the family. However, the "clarity or certainty of conclusions that found competing factors"¹⁴³ is recognised to affect the weight afforded to them,¹⁴⁴ which implies that the strength of evidence available about a potential organ donor's wishes is still an important determinant of their best interests.

Recent proposals by the Law Commission have sought to clarify and elevate the weight given to individual wishes, and these proposals have resulted in a draft Mental Capacity (Amendment) Bill which would amend section 4(6) of the MCA to require that decision-makers "in making the determination must give particular weight to any wishes or feelings ascertained".¹⁴⁵ The draft Bill follows the Law Commission's recognition that although the policy intention behind the MCA was that of according no hierarchy between the factors that contribute to best interests, the Supreme Court's approach in *Aintree Hospitals v James*

¹³⁹ *Briggs v Briggs* as earlier, [80].

¹⁴⁰ *Ibid* [96-120].

¹⁴¹ *Ibid* [81] citing Pauffley J in *United Lincolnshire NHS Trust v N* [2014] COPLR 60 & Hayden J in *Re N* [2016] COPLR 88.

¹⁴² *Briggs v Briggs* as above [7].

¹⁴³ *Ibid* [58].

¹⁴⁴ *Ibid*.

¹⁴⁵ S. 8(4). Draft Bill provided in Law Commission, *Mental Capacity and Deprivation of Liberty: A Consultation Paper* (CP no. 222, 2015), Appendix A. The draft Bill was published in March 2017 and a response from the government is awaited (as of 06/09/2017).

“arguably attach[ed] some level of primacy”¹⁴⁶ to the patient’s wishes and feelings.¹⁴⁷

However, in their consultation paper, the Law Commission acknowledge that the current law “fails to give sufficient certainty for best interest decision-makers on how much emphasis should be given to the person’s wishes and feelings”.¹⁴⁸ One of the main drivers they identify for change is the ratification by the UK, since the MCA came into force, of the UN Convention on the Rights of Persons with Disabilities.¹⁴⁹ Article 12 of the Convention requires the UK to “recognise that persons with disabilities enjoy legal capacity on an equal basis with others in all aspects of life”¹⁵⁰ and to provide effective safeguards to “ensure that measures relating to the exercise of legal capacity respect the rights, will and preferences of the person”.¹⁵¹ Best interests has been interpreted by the UN Committee on the Rights of Persons with Disabilities as non-compliant with article 12 and they advise that it is replaced by a “wills and preferences paradigm”.¹⁵² Although the draft bill retains the best interests principle, it would if it becomes law give wills and preferences a higher statutory status than all other factors that contribute to best interests.¹⁵³

Although the MCA, as it is currently worded, does not explicitly give the individual’s viewpoint more weight than other factors, implicit in the judgements of both *Aintree Hospitals v James* and *Briggs v Briggs* is the notion that this is how its provisions should generally be interpreted.¹⁵⁴ However, Lady Hale also made it clear in *Aintree Hospitals v James* that there may be circumstances in which the individual’s viewpoint will not necessarily

¹⁴⁶ Law Commission Consultation Paper as above [12.42].

¹⁴⁷ Ibid.

¹⁴⁸ Ibid.

¹⁴⁹ Ibid [12.7]

¹⁵⁰ Article 12(2).

¹⁵¹ Article 12(4).

¹⁵² General Comment No.1 (UN Committee on the Rights of Persons with Disabilities, 2014), Article 12: Equal Recognition Before the Law, [21]. See also M. Donnelly, ‘Best Interests in the Mental Capacity Act: Time to Say Goodbye?’ (2016) 24(3) *Med Law Rev* 318-332.

¹⁵³ Law Commission, *Mental Capacity and Deprivation of Liberty* (CP no. 372, 2017) [14.17].

¹⁵⁴ Citations as earlier.

prevail over other considerations.¹⁵⁵ In the circumstances of an individual whose wishes, values, and commitments are consistent with undergoing donor optimisation procedures, the risk of physical harm also needs to be considered in the determination of best interests. The relative weighting of wishes and physical harm is not often considered in the case-law, as the conflicting considerations in a lot of court judgements are patient wishes and the preservation of life.¹⁵⁶ Donor optimisation procedures differ from these cases as the preservation of life is not a relevant factor, and the question is not whether life-sustaining treatment can be withdrawn but whether non-therapeutic procedures can be initiated. Non-therapeutic procedures risk physical harm and yet have no potential clinical benefit, and therefore contravene the general guiding principle to “first do no net [physical] harm”.¹⁵⁷ However, respecting individual autonomy has increasingly taken over from non-maleficence as the most crucial contributing factor to best interests. The shift from the paternalistic medical model to a model based on individual autonomy suggests that the risk of physical harm would have to be highly significant to take on the role of the decisive factor.

Determining where the balance lies between a risk of physical harm and the wishes of the potential organ donor is problematic as these considerations are not readily comparable. However, the individual’s attitude towards the risk of harm should, in line with recent case-law, be afforded significant weight. Unless in relation to a particular donor optimisation procedure that presents such serious physical risks as to outweigh all possible risk-benefit preferences,¹⁵⁸ knowledge of the individual’s own benefit-risk preferences is critical to the

¹⁵⁵ *Aintree University Hospital NHS Foundation Trust v James* as before, [45].

¹⁵⁶ See eg *Briggs v Briggs* [2016] EWCOP 53 as earlier, [128].

¹⁵⁷ This is a reformulation of *primum non nocere*, see D. Sokol, ‘“First do no Harm” Revisited’ (2013) 347 *BMJ* 6426.

¹⁵⁸ As best interests is individualistic, it is difficult to be certain that any one procedure is never in anyone’s interests. However, there might be procedures – such as cardiopulmonary resuscitation for

determination of best interests. Potential organ donors can only receive those donor optimisation procedures that policy-makers and healthcare professionals deem could potentially fall within the scope of best interests and their benefit-risk preferences are relevant to decision-making in relation to each of these available procedures. Currently, the specific wishes and individual acceptance of risk by each potential organ donor cannot be accurately determined due to the lack of opportunity for them to formulate and express a view regarding donor optimisation procedures. I argue throughout the remainder of this chapter that this problem can only be resolved by the introduction of a system that includes greater transparency surrounding the organ donation process and the opportunity to express and record specific wishes regarding donor optimisation procedures.

Evidence of Specific Wishes

The individual nature of best interests demands that decisions are made on the basis of individual wishes and not just clinical criteria for identification as a potential organ donor.¹⁵⁹

No presumption can be relied on that any particular procedure is always going to be in the best interests of every individual identified by these clinical criteria. The avoidance of a blanket approach to best interests, in conflict with the MCA provisions and their interpretation in recent case-law, requires knowledge of the individual's real and specific wishes about donor optimisation procedures before they are initiated. I explore in this section what evidence, and when, is needed to meet the legal requirements of best interests in these circumstances.

non-therapeutic reasons – that present such serious physical risks that they outweigh all possible benefit-risk preferences.

¹⁵⁹ Such as the clinical triggers for referral advocated by NICE in *Improving Donor Identification*, p.6 [1.1.2-1.1.3], as discussed in Chapter 1.

Although the holistic approach advocated in *Aintree Hospitals v James* has been interpreted as encompassing wishes expressed in “oblique and tangential ways”,¹⁶⁰ individual wishes about donor optimisation procedures cannot easily be extrapolated from what that individual has said about similar procedures in similar circumstances. Evidence of what they have said about life-sustaining treatments in the context of a brain injury may be insufficient to determine whether they would want donor optimisation procedures if they haven’t considered the specific issue of non-therapeutic procedures to facilitate organ donation. Similarly, evidence of what that they have said about organ donation may be insufficient to determine whether they would want donor optimisation procedures if they haven’t considered the question of non-therapeutic procedures before death. So although the movement of the law is in the direction of giving weight to a wider range of evidence on the patient’s views, in the circumstances of donor optimisation procedures that evidence needs to be specific on their views about ante-mortem interventions to facilitate organ donation.

The gold standard of advance consent for medical treatment is a “relevant written statement” made by the individual whilst they still have capacity.¹⁶¹ As such, advance written statements are afforded particular consideration under the MCA: consideration that is equal to that afforded to contemporary written statements.¹⁶² Decision-makers who do not follow a relevant written statement expressing treatment preferences are required to record their reasons and need to be able to justify these reasons.¹⁶³ However, if those treatment preferences include a refusal of some or all treatment options, and if that refusal fulfils the MCA provisions on validity and applicability, then the law requires decision-makers to follow

¹⁶⁰ *Sheffield Teaching Hospital Foundation Trust v TH and TR* [2014] EWCOP 4 [53] per Mr Justice Hayden; *Aintree Hospitals v James* as earlier.

¹⁶¹ S. 4(6)(a).

¹⁶² S. 4(6)(a); MCA Code of Practice (2013), [5.44].

¹⁶³ MCA Code of Practice(2013), [5.43].

the advance decision.¹⁶⁴ Whilst advance consent may not be afforded this legally binding status, there would need to be justifiable grounds for overriding an advance written statement of consent. Those grounds may, in the circumstances of donor optimisation procedures, include a risk of serious physical harm.

Whilst a written statement of consent would provide the highest level of evidence for encompassing donor optimisation procedures within best interests, other expressions of wishes - “through verbal communication....., behaviour or habits, or recorded in any other way”¹⁶⁵ may also be taken into account as part of the best interests determination. As with advance written consent, this relies on the individual having considered the relevant issues while competent. However, unlike recording a written statement on the ODR, it also relies on the individual communicating their wishes to relatives or other people with an interest in their welfare. Furthermore, it relies on those people being available and able to relate those wishes accurately to the healthcare professionals determining best interests. This chain of “Chinese whispers” could potentially lead to a misinterpretation of the individual’s wishes and a resultant decision that is not in the individual’s best interests. It is this potential for misinterpretation that demands that speculation on issues the individual had not been given an opportunity to consider when competent is not relied on as the sole evidence supporting the encompassment of donor optimisation procedures within best interests.¹⁶⁶

Although doctors are required to take into account the views of a range of people with an interest in the potential organ donor’s welfare,¹⁶⁷ the MCA does not oblige them to follow those views – unless the person(s) holds lasting power of attorney for health and

¹⁶⁴ S. 24-26; MCA Code of Practice (2013), [5.45]; see analysis in Chapter 3.

¹⁶⁵ MCA Code of Practice (2013), [5.41].

¹⁶⁶ See P. Lewis, ‘Procedures that are Against the Medical Interests of Incompetent Adults’ (2002)22(4) *Oxf J Leg Stud* 575-618, 586 [‘Procedures Against Medical Interests’].

¹⁶⁷ MCA (2005) Section 4(7).

welfare decisions.¹⁶⁸ In this context, the requirement to consult relatives does not provide an adequate safeguard to protect the individual from undergoing interventions which do not accord with their own individual wishes in the circumstances. This is primarily because, as discussed above, the individual has not been given an opportunity to formulate and discuss their views on donor optimisation procedures with relatives. Secondly, any viewpoint that does not accord with that of the doctors risks being interpreted as acting against the patient's best interests.¹⁶⁹ For example, a relative who believes that the patient would not have wished to undergo changes in their end-of-life treatment to facilitate organ donation risks being excluded from the decision if the patient is on the opt-in ODR and the doctor interprets this as determining their overall attitude to donor optimisation procedures.¹⁷⁰ Evidence recounted by a relative may not be enough in practice to facilitate the best interests of a potential organ donor.

Whilst evidence of the individual's viewpoint is vital to encompassing donor optimisation procedures within best interests, it is also vital that these wishes are specific to the procedures in question. As I argued earlier in the chapter, evidence of a wish to become a deceased organ donor is not sufficient to determine the individual's wishes in relation to donor optimisation procedures.¹⁷¹ Other factors, including their views regarding end-of-life care and their benefit-risk preferences, also influence their overall viewpoint regarding donor optimisation procedures. The determination of best interests requires evidence of these other crucial determinants of their viewpoint in the circumstances.

¹⁶⁸ MCA Section 4(7) & 9-11; See also HL Paper 139 as above, p.48 [98]. N.B. Doctors are not obliged to give any treatment against their clinical judgement.

¹⁶⁹ See HL Paper 139 as above, p.47 [93].

¹⁷⁰ Advice for healthcare professionals on the implementation of the NICE guidelines suggests this is a possibility in practice, see NICE, *Organ Donation: Clinical Case Scenarios for Improving Donor Identification and Consent Rates for Deceased Organ Donation* (April 2012); A recent study suggests that healthcare professionals do interpret consent for organ donation as consent for pre-mortem interventions, see A. Gathani, H. Draper & G. Moorlock, 'Pre-mortem Interventions For Donation After Circulatory Death And Overall Benefit: A Qualitative Study' (2016) 11(4) *Clin Ethics* 149-158.

¹⁷¹ Refer back to section on centrality of individual.

One of the fundamental problems posed by the NICE guidance on organ donation is that it requires the initiation of donor optimisation procedures before evidence of individual wishes has been assessed. “While assessing...best interests” the patient is “clinically stabilise(d)” in an intensive care unit, and “provided that delay is in the patient’s overall best interests” life-sustaining treatments are given prior to the exploration of the patient’s wishes.¹⁷² As the patient’s wishes are so crucial to encompassing these life-sustaining but non-therapeutic treatments within overall best interests, decision-makers are left with no means of determining whether any such delay is in that individual patient’s best interests. This will only become apparent after and not before the exploration of wishes.

Even in emergency medical situations, all acts done or decisions made must be taken in the individual’s best interests.¹⁷³ In circumstances where emergency medical treatment is required to save an individual’s life or protect them from serious harm, the Code of Practice advises that it will “almost always” be in an individual’s best interests to receive urgent treatment without delay.¹⁷⁴ There is no other legal justification apart from best interests to rely on. In the context of donor optimisation procedures, commencing medical interventions that may subsequently prove to be against an individual’s best interests cannot be justified on the grounds that it was done either to save their life or protect them from physical harm. It can only potentially be justified by reference to individual wishes, values, and ethical commitments. Because of the different justifications for initiating treatment, the probability of donor optimisation procedures being subsequently found to be within the individual’s best interests may differ from other emergency interventions. Even if this probability is thought to be high, initiating donor optimisation procedures without the information needed to make

¹⁷² NICE, *Improving Donor Identification* as earlier, p.7 [1.1.6-1.1.7].

¹⁷³ S. 1(5).

¹⁷⁴ MCA Code of Practice (2013), [6.35].

the best interests determination will inevitably result in some individuals undergoing procedures against their best interests.

Coggon argues that “epistemically complex” elective ventilation, in circumstances in which it is not known whether the patient wanted to become a deceased organ donor, falls within the potential scope of best interests as people are not merely benefited from substantial outcomes but also by exposure to probable benefits.¹⁷⁵ He considers that “there is a good enough chance in cases of meaningful uncertainty that a patient would want measures instituted to enhance posthumous donation”, leading him to conclude that “a best interests appraisal would indicate continued ventilation while the inquiry was made”.¹⁷⁶ However, this inquiry appears to relate only to their wishes regarding deceased organ donation, which as I argued earlier does not necessarily determine the individual’s overall wishes towards elective ventilation or other ante-mortem donor optimisation procedures. The lack of public consultation about donor optimisation policy means it is also unknown what the chances are of a patient wanting to undergo ante-mortem measures to facilitate organ donation. These factors present challenges in encompassing current donor optimisation policy within the law on best interests, as does the court’s interpretation of best interests as an individualistic rather than probabilistic test.¹⁷⁷ Both the MCA provisions themselves and the relevant case-law emphasise benefit to the individual themselves and not the probability of benefit to any one member of a group.

Best interests “must depend upon the individual circumstances of the particular case”¹⁷⁸ and “any attempt to test a decision by reference to what *P* would hypothetically have done or wanted runs the risk of amounting to a ‘substituted judgement’ rather than a decision

¹⁷⁵ Coggon, ‘Elective Ventilation’ as earlier, 131-2.

¹⁷⁶ Ibid, 132.

¹⁷⁷ See eg *In Re M* [2009] EWHC 2525 (Fam), [35].

¹⁷⁸ *In Re M* [2009] EWHC 2525 (Fam), [35], per Justice Munby.

that would be in P's best interests".¹⁷⁹ As the current law has best interests and not substituted judgement as its guiding principle, this risk needs to be avoided. There is a need to re-evaluate the timing of the exploration of wishes, to enable best interests' decisions to be made on the basis of actual individual wishes rather than hypothetical wishes. The presumption that initiating donor optimisation procedures is in every patient's best interests is not only unlawful but unnecessary. It can be eschewed in favour of a system that provides evidence of the individual's specific wishes at the time they are needed for the best interests determination.

A System for Determining Best Interests

Best interests can potentially provide the clear legal justification that is needed for ante-mortem interventions to facilitate organ donation. However, it is currently difficult for best interests to take on this role as policy and practice do not facilitate the timely provision of information that is essential to the best interests determination. To enable best interests to be used in a way that is both protective of the individual and facilitative of organ donation, changes need to be made to both the information that is provided to potential registrants on the ODR and to the information that is subsequently accessible to decision-makers.¹⁸⁰ To encompass donor optimisation procedures within the best interests of the individual, decision-makers must be able to ascertain not only the individual's wishes regarding organ donation, but crucially also their wishes regarding their end-of-life care and their viewpoint towards the potential physical risks of the procedures.

A system is needed that incorporates rapid access to information meeting the crucial criteria necessary for a clear assessment of the best interests of the potential organ donor.

¹⁷⁹ *Re P (Statutory Will)* [2009] EWHC 163 (Ch), [41], per Justice Lewison.

¹⁸⁰ The impact of such changes on the supply of organs will be considered in Chapter 6.

Rapidity of access could be secured by modern information technology, allowing decision-makers access to this information prior to the best interests decision. The crucial considerations of best interests could be met by providing potential registrants on the ODR with information regarding the timing, nature, and risks of donor optimisation procedures and the opportunity to register advance consent, refusal, or a combination of both. Their advance decision would provide a clear basis on which to make decisions about their best interests.

Transparency regarding the organ donation process may remove the speculative aspect of ascertaining the best interests of the potential organ donor. As public knowledge of donor optimisation procedures grows, it may be that relatives will be able to provide other evidence of the individual's specific wishes regarding donor optimisation procedures. If so, this could inform best interests determinations. However, relying on relatives to provide this information may be problematic in situations when donor optimisation procedures have not been discussed, relatives are not available, or if there is some dispute between relatives. Crucially, requiring evidence of specific wishes to be provided by relatives rather than recorded on the ODR demands that there is widespread public awareness and knowledge of donor optimisation procedures. One of the most effective ways of achieving public awareness and knowledge is likely to be by providing potential registrants on the ODR with information regarding donor optimisation procedures. As this information is crucial to the individual in determining their own interests, and as written statements receive particular consideration within best interests, the most effective means of ascertaining best interests is likely to be secured by providing potential registrants with the opportunity to record an advance decision regarding donor optimisation procedures.

Decision-makers can only proceed to balance the individual's wishes against the risk of physical harm after they have ascertained the individual's wishes. Without this information,

it is not at all clear where the balance lies. Even with this information, it may be difficult to weigh up the very different concepts of respect for individual autonomy against physical harm. However, the more information that is available about the individual's viewpoint towards the potential physical harm of donor optimisation procedures, the easier this balance may be for decision-makers. It is this balancing exercise that my proposed system incorporating the advance consent of the potential organ donor seeks to facilitate. Although advance consent is of magnetic importance in this context, the balance of best interests is unique to the individual and the individual circumstances. The system needs to be free of any presumption as to where the best interests of the potential organ donor lie.

The best interests of the potential organ donor are paramount in law, so no balancing exercise can take place between the interests of the potential organ donor and the interests of potential organ recipients. However, a system could be built that both facilitates the best interests of the potential organ donor and the interests of potential organ recipients. This is because these interests are not necessarily in conflict but may be interwoven. The social and psychological benefits gained through planning for and undergoing procedures for the benefit of others may be so great that the interests of the potential organ donor may run in parallel with those of potential organ recipients. A system that acknowledges this and allows competent individuals to make advance decisions regarding donor optimisation procedures may not only resolve the current legal challenges but could potentially also improve the supply of organs.¹⁸¹

¹⁸¹ The likely impact of my proposed system of advanced consent on the supply of organs is considered in Chapter 6.

5. The Public Interest in Donor Optimisation Procedures

Introduction

Although the law usually claims that the permissibility of medical interventions is conditional on either consent, when the individual has decision-making capacity, or on best interests (giving weight to individual wishes), when the individual lacks decision-making capacity, a third potential ground may exist behind these claims. This is the public interest - a concept that is not always expressed or explicated but that may nevertheless provide the underlying reason for the law's response to questions that deal not only with individual interests but also the interests of others in society. Although the public interest may be a determining factor in medico-legal decision-making, it can sometimes be obscured behind the law's deference to autonomy and individual interests.¹ This may generate problems in determining the law's response to questions that deal not only with the interests of the individual but also with the interests of others in society.

The previous two chapters have focused on the central importance of individual interests to decision-making. The overarching claim made in these chapters is that the potential donor's individual interests require the provision of information regarding the timing, nature and risks of donor optimisation procedures and the opportunity to register specific advance consent, refusal or a combination of both. It is self-evident, however, that potential organ donors are not the only individuals affected by the decisions about their medical care. The individual interests of potential organ recipients are also at stake, and often these interests include the interest in life itself. There may also be other individuals in society

¹ Huxtable refers to the three faces of medical law as it's "tripartite typology", see R. Huxtable, 'Autonomy, Best Interests and the Public Interest: Treatment, Non-Treatment and the Values of Medical Law' (2014) 22(4) *Med Law Rev* 459-493, 459 ['Autonomy, Best Interests, Public Interest'].

with an interest in these decisions – which they may base on their connections with either donor or recipient, altruistic concern, or simply their membership of the same society. Society itself has a collective interest in the integrity and functioning of the organ donation programme. All of these individual and collective interests make up the public interest – crucially including those of the donor, the recipient, and of society as a whole.

The key questions I address in this chapter are whether the public interest in donor optimisation procedures requires the inclusion of the consent of the potential organ donor, how the relationship between individual interests and the public interest is treated within medical law, and what model of the public interest is required to achieve compatibility with Article 8 of the European Convention on Human Rights (ECHR). I begin the chapter by attempting to delineate what the public interest is and what and whose interests may contribute to it. I then evaluate the legal approach to medical interventions that impact on the interests of others in society, with a view to establishing what - if any – model of the public interest is used within medical law. I then consider how the relationship between individual autonomy and the public interest is approached in the jurisprudence of the European Court of Human Rights (ECtHR). I conclude the chapter by evaluating the relationship between the autonomy of the potential organ donor and the public interest at a conceptual level, at the level of domestic law, and under the model required to achieve ECHR compatibility.

The Concept of the Public Interest

The public interest is a term that may be used and interpreted in different ways. Even pinning down a definition is difficult, let alone its precise content, scope and limits.² This ambiguity

² See eg. G. Schubert in 'The Public Interest in Administrative Decision-making: Theorem, Theosophy, or Theory?' (1957) 51 *Am Polit Sci Rev* 346-368 ['Theorem, Theosophy, or Theory?'] and *The Public Interest: A Critique of the Theory of a Political Concept* (Glencoe, IL: the Free Press, 1960) ['A Political Concept']; R. Box, 'Redescribing the Public Interest' (2007) 44 *Soc Sci J* 585-598, 585, ['Redescribing

could, in circumstances where medical interventions impact on others in society, lead to the notion being used to justify a course which is neither in the interests of those subjected to the intervention nor in the interests of society as a whole. To address the concern that this vague concept could be misused to justify whatever course of action policy and law-makers see fit, I try and identify in this section what the public interest is – or at least should be - at a conceptual level.

The public interest is one of several terms used, often inter-changeably, in political philosophy to express ideas relating to what is best for the public overall. Achieving this public interest is often considered to be the purpose of government.³ However, what the public interest is and what its relationship is with other related terms, such as the common good, can be difficult to determine from traditional accounts. For example, although Rousseau's account of the general will seems to have some relationship with the more modern concept of the public interest, it is not always clear from his account what the general will is.⁴ He relates it to "the common security and to the general welfare",⁵ yet this can be interpreted in many different ways.⁶ The disparate interpretations of Rousseau's account contribute to concerns that the general will, and the related notion of the common good, are concepts that could be used in whatever way the state sees fit – even if that effectively dissolves individual interests

Public Interest']; K. Simm, 'The Concepts of Common Good and Public Interest: From Plato to Biobanking' (2011) 20 *Camb Q Healthc Ethics* 554-562, [From Plato to Biobanking'].

³ See "Defining Public Interest" at <http://www.publicinterest.info/> (Public Interest in UK Law Courts project led by G. Anthony at Queen's University Belfast, last accessed 08/09/2017).

⁴ J.-J. Rousseau, *The Social Contract and The First and Second Discourses* (edited by Susan Dunn, Yale University Press, 2002) ['*The Social Contract*']; D.L. Williams, "On the General Will", Appendix A in *Rousseau's Social Contract: An Introduction* (CUP, 2014) 245-271.

⁵ Rousseau, *The Social Contract* as above, 227.

⁶ See, eg, criticisms by Jacob Talmon in *The Origins of Totalitarian Democracy* (Secker and Warburg, London, 1955) ['*Totalitarian Democracy*'] & Bertrand Russell in *A History of Western Philosophy* (Allen & Unwin, London, 1955).

and rights.⁷ The concern that these ideas will be used to subjugate and oppress individuals within society has led modern scholars to try and delineate what a “substantive vision”⁸ of the public interest would look like.⁹ Although some authors, for example Schubert, believe the public interest to be merely a rhetorical device,¹⁰ others, such as Box,¹¹ aspire to a model that will genuinely help to facilitate the best course of action overall for society and its individual members.

One of the first problems encountered in trying to delineate any vision of what the public interest might be is defining what the public is and if, in fact, it exists at all. Society is made up of individuals with their own separate concerns and it may not be reflective of this mass of discordant viewpoints to treat them as one body with one set of interests.¹² From this perspective, the public or the community as a whole is reduced to a “fictitious body”¹³, making it difficult to ascribe any substantive meaning to the term public interest. However, the reality of the public may rest not on the congruity of viewpoints but on the connections between individuals. Community ties are not mere “happenstance”¹⁴ but - as Dewey recognises, “indirect, extensive, enduring and serious consequences of conjoint and interacting behaviour”.¹⁵ Individuals retain their own interests and concerns, but the connections between individuals provide an investment in the community as a whole. It is

⁷ See D.L.Williams, Introduction to *Rousseau's Social Contract: An Introduction* (CUP, 2014), 1-25, 2 citing D.Bell, *The Coming of Post-Industrial Society: A Venture in Social Forecasting* (Basic Books, 1976, New York) 436.

⁸ Box, ‘Redescribing Public Interest’ as earlier, 586.

⁹ See eg. R. Flathman, *The Public Interest : An Essay Concerning the Normative Discourse of Politics* (New York, Wiley, 1966)

¹⁰ Schubert, *A Political Concept* as earlier & ‘Theorem, Theosophy, or Theory?’ as earlier, 346-368. See also analysis by R. Box in “Redescribing Public Interest” as above, 585.

¹¹ Box, ‘Redescribing Public Interest’ as earlier

¹² See eg. A. de Grazia, *The Elements of Political Science* (1st edition, Knopf, New York, 1952)103.

¹³ See J. Bentham, *Introduction to the Principles of Morals and Legislation* (Bensley, Bolt Court, Fleet St, 2ND edition, 1823) 4.

¹⁴ See B. Capps, A. Campbell & R. ter Meulen, ‘Access to the UK Biobank Resource: Concepts of the Public Interest and the Public Good’ (UK Biobank, 2008) 4-5 [‘UK Biobank Report’], for a comparative analysis of Bentham’s and Dewey’s theories of the public.

¹⁵ J. Dewey, *The Public and Its Problems* (Henry Holt & Co., New York, 1927) 126.

these community ties that bring the public into existence and define it not according to synchrony of autonomous viewpoints but according to what affects individuals *qua* members of the public.¹⁶ This provides the foundation for one plausible definition of the public interest, namely that the public interest is simply the interest that members of society have in what could potentially affect them *qua* members of that society.

The public interest in medical interventions, as defined by reference to what could potentially affect members of society *qua* members of society, operates at several levels. These include the level of the individual or individuals who may undergo the intervention, characterised by Huxtable as the micro-level of the public interest.¹⁷ The meso-level, which covers the interests of others,¹⁸ can be subdivided to include other individuals or groups of individuals who are either directly or indirectly affected by the intervention. These may, for example, include potential organ recipients, the relatives of potential organ donors, the healthcare professionals required to implement donor optimisation policy, other people in society who may themselves be subject to similar interventions in the future, and groups with an interest in organ procurement policy. The macro-level, which covers the collective interests of society,¹⁹ might be considered to define the public interest *stricto sensu*. However, how society's individual members are treated contributes to what is best for other members of society and to what is best for the public overall. Other individuals and/or groups of individuals within society could potentially themselves be subject to the same healthcare policy, and they have a stake in what could happen to them. Society as a whole has an interest in how its individual members are treated. The collective interests of a liberal society are not in opposition to the interests of its individual members, but instead encompass the interests of its individual members.

¹⁶ See analysis by *Capps et al*, 'UK Biobank Report', 4-5.

¹⁷ *Huxtable*, 'Autonomy, Best Interests, Public Interest' as earlier, 477.

¹⁸ *Ibid*.

¹⁹ *Ibid*.

Individuals and/or groups of individuals have an interest in what happens to them, or could potentially happen to them, as members of society. They have a stake or involvement in something happening or not happening if that action could be to their advantage or disadvantage.²⁰ They may also have an interest in an action that could be to the advantage or disadvantage of others. This interest could be based on their connections with these other individuals, their membership of the same society, altruistic concern, or other factors. In the same way that individual interests extend further than self-regarding interests,²¹ the public interest also includes both self-regarding and other-regarding interests.²² Some of these other-regarding interests may be influenced by the possibility of being personally affected by a particular action. Others may exist even if the individual or group of individuals is never going to be directly affected in their capacity as members of society by a particular issue. They may still harbour deep concerns about the treatment of others within society and these concerns may contribute to the public interest. So although the public interest includes the individual interests that members of society have in what could potentially affect them *qua* members of that society, it also includes individual or group interests in what affects others in society.

The public interest is neither a simple aggregate of individual interests, nor the subjugation of individual interests to the “common good”. There are problems with both of these models. An aggregative model is let down by a lack of consideration of the weight to be afforded to the various interests and by the difficulties in calculating what the aggregate is when some of these interests appear to be in conflict. Amalgamating a wide range of interests

²⁰ V. Held explicates interest in terms of an interest in action in *The Public Interest and Individual Interests* (Basic Books, New York/London, 1970) 19-21, ‘Public and Individual Interests’.

²¹ S-J Brown, ‘The Legal Justification for Donor Optimisation Procedures’ (2016) 11(4) *Clin Ethics* 122-129, 125; M. Donnelly, ‘Determining Best Interests under the Mental Capacity Act 2005’ (2011) 19 *Med Law Rev* 304-313, 312-313.

²² See R. Flathman, *The Public Interest: An Essay Concerning the Normative Discourse of Politics* (New York, Wiley, 1966) 26-28.

into one overarching interest, that is “greater than the sum of its ‘selfish’ parts”,²³ simply isn’t possibly in many circumstances. Those parts constitute different public interest factors that often pull in different directions. There is no easy formula that eliminates conflict and combines all interests to produce one compendious public interest.

Unitary theories of the common good do not place importance on what members of society would choose were they in a position to do so but assume that there is only one answer – the rightness of which cannot be challenged – that takes precedence over the individual interests of members of society.²⁴ The notion of a single common good has in non-democratic societies been used as a means for elite decision-makers to keep people whose individual interests are not served by this so-called common good in their place.²⁵ The phrase “common good” carries with it the idea that the state knows better than its people what is of objective benefit to them and that this objective benefit carries all the weight.²⁶ In contrast, the liberal conception of interests refers not only to what is objectively beneficial but to what people think is beneficial,²⁷ and these interests belong to the individual members of society that its government is elected to uphold. Included within a liberal conception of the public interest is what individual members of the public would choose if they were in a position to make an autonomous choice.²⁸ Rather than being subjugated to the good of all, individual choice is an important individual interest to be upheld as part of any liberal interpretation of the public interest.

²³ F. Sorauf, ‘The Conceptual Muddle’ in C. Friedrich, *The Public Interest* (Atherton Press, New York, 1962) 183-190, 184 [‘Conceptual Muddle’] as cited by Box in ‘Redescribing Public Interest’ as earlier.

²⁴ See B. Douglass, ‘The Common Good and the Public interest’ (1980) 8(1) *Polit Theory* 103-117, 104-109; also *Simm*, ‘From Plato to Biobanking’ as earlier, 555-556; .

²⁵ See *Talmon*, *Totalitarian Democracy* as earlier.

²⁶ *Douglass*, ‘Common Good’, 104-108.

²⁷ *Ibid*, 104-108.

²⁸ *Ibid*, 109.

A liberal model of the public interest would assess the relationship of the public interest overall with the various individual interests that contribute to it and facilitate the achievement – to the extent that this is possible – of all the important interests at stake. One model that seeks to do this is founded on the individual interests that provide the moral imperatives of liberalism and which apply to or could potentially apply to any member of the public.²⁹ This scrutinises the interests that could apply to individuals *qua* members of the public and gives precedence to those that accord with moral imperatives such as liberty, equality, bodily integrity, and self-determination. This imperative-grounded public interest aims to preserve the core common values that are shared by all (or at least the majority of) individuals *qua* members of the public in a liberal society.³⁰ Preserving these core liberal values encompasses actions that directly impact on an individual or group, indirectly affect them via their connections with others, and/or concern them as members of the same society. It is in the interests of most people in society to preserve these core values in most circumstances and this is what a liberal conception of the public interest sets out to do.

The ideal model – from a liberal perspective – of the public interest is one that derives from an understanding of the function of society as being to facilitate the realisation of the different life plans pertaining to its individual members.³¹ This model strives to ensure the promotion, protection, and realisation of the individual interests of each member of the public and to protect the integrity and functioning of institutions that make individual life plans achievable.³² Nevertheless, it is not always easy to determine what the best course is to achieve these objectives and it is difficult to eliminate conflict between the interests of the

²⁹ Capps *et al*, 'UK Biobank Report', 6.

³⁰ Capps *et al*, 'UK Biobank Report', 5-9.

³¹ R. Hoedemaekers, B. Gordijn, M. Pijnenburg, 'Does an Appeal to the Common Good Justify Individual Sacrifices for Genomic Research?' (2006) 27 *Theor Med Bioeth* 415-431, 418.

³² See B. Jennings, D. Callahan & S. Wolf, 'The Professions: Public Interest and Common Good' (1987) 17(1) *Hastings Cent Rep* 3-10, 6.

public overall and the interests of its individual members. Determining the public interest in any medical intervention is a process of weighing up apparently divergent interests both in relation to each other and with the public interest overall.

Because of the problems presented by unitary theories of the common good and by aggregative models of the public interest, an alternative model has been suggested in which the public interest is viewed as a process.³³ This model recognises individual members of the public as “participants in dialogue about what is in the public interest and what the public sector should do about it”.³⁴ However, the dialogue between individual members of society and policy-makers is often unequal and the state doesn’t always give significant weight to the views of its individual members. A further problem with the process view is that “the public interest as means and procedure replaces the public interest as end and goal”.³⁵ Although public consultation and dialogue are useful in determining the public interest, the process view does not give a clear answer as to what the public interest actually is.

Any judgement on the public interest is not simply a statement of fact but, as Held recognises, a normative claim.³⁶ Not everyone will agree with the judgement or its underlying justifications. Normative claims that an action is or is not in the public interest may be met by rival claims, and these claims may validly conflict.³⁷ In some cases, resolution between rival claims may be possible by appeal to the strength of justificatory considerations.³⁸ Claims asserted on weak or unreasonable grounds may be distinguished from claims asserted on more solid or reasonable grounds,³⁹ and a settlement reached without compromising any significant ethical principles. However, to achieve resolution between conflicting claims

³³ Box, *‘Redescribing Public Interest’* as earlier, 588.

³⁴ Ibid.

³⁵ Sorauf, *‘Conceptual Muddle’* as earlier, 185.

³⁶ Held, *‘Public and Individual Interests’*, 168.

³⁷ Ibid, 187-190.

³⁸ Ibid, 185

³⁹ Ibid, 185.

asserted on equally strong grounds may be intensely problematic. For example, a claim founded on equality and justice may be difficult to weigh up against an autonomy-based claim. In circumstances such as this, a judgement may have to be made between core liberal values and this may be difficult to call.

The potential for rival claims exists at the level of individual interests, at the level of the interests of others, at the level of the collective interests of society, and between these different levels.⁴⁰ Reconciling rival claims operating at different levels may require a complex balancing act. At the level of individual interests, rival claims might be put forward, for example, first that potential organ donors should be protected from the potential physical risks of donor optimisation procedures, and second that potential organ donors should be able to undergo donor optimisation procedures if they have made an informed decision to do so. At the level of the interests of others, rival claims might be asserted, first that donor optimisation procedures are justified even in the absence of consent, and second that the interests of potential recipients demand that consent is not abandoned. At the level of the collective interests of society, rival claims might be put forward, first that non-consensual procedures are justified to increase the supply of organs, and second that the inclusion of consent is justified to maintain trust in the organ donation programme. Reconciling the different public interest claims – which may not be limited to those given above – within and between levels requires a normative judgement. In this context, this normative judgement is dependent on the importance that is afforded by decision-makers to autonomy and other individual interests and to their perceived relationship with the public interest overall.

The public interest is a concept that is understood and used in many different ways. Although the liberal model I have presented in this section is one that emphasises the

⁴⁰ Refer back to *Huxtable*, 'Autonomy, Best Interests, Public Interest', 477, as discussed earlier in this section.

importance of individual autonomy to the public interest overall, this is not always how it is understood by law- and policy-makers. What the public interest is cannot even be agreed upon by public interest theorists, and this lack of agreement may be useful to law and policy-makers in making the decisions that they feel best fit the circumstances. However, public authorities are obliged to follow the approach of the ECtHR when making policies or laws that impact on the individual rights of its members.⁴¹ Even if they do think that a particular approach is best in the public interest, the onus is on the state to establish that any restriction of individual rights is both necessary and proportionate in the circumstances.⁴² To establish this, law and policy-makers can no longer mask the public interest dimension of their decision-making but must instead establish what the relationship is between individual rights and the rights of others in society.

In the following sections, I will explore the legal response to questions that address wider interests than those of the individual patient. I will look at who the law acknowledges as having an interest in a medical intervention, what interests they may claim, and to the perceived relationship between these interests and those of the individual patient. In doing so, I will attempt to establish what model – if any – of the public interest is used in medical law. I will then consider how the relationship between individual interests and the interests of others is treated in ECtHR judgements and what obligations this places on domestic law-makers. I will conclude the chapter by evaluating where the public interest in donor optimisation procedures lies, where domestic law and policy treats it as lying, and how an ECtHR-based approach suggests the relationship between individual autonomy and the public interest should be treated.

⁴¹ Human Rights Act 1998 S. 2,3 & 6.

⁴² *Funke v France* (App no. 10828/84) (1993) 16 EHRR 297 [55].

Medical Law and the Public Interest

In some areas of law, decisions are subject to a test that is specified and named for what it is - a public interest test. For example, the term “public interest” pervades the provisions of the Freedom of Information Act 2000 and it is clear to those reading and interpreting the legislation that the right to information held by public authorities can be restricted in circumstances where this is assessed to be in the public interest.⁴³ The relevant case law is primarily focused on what are acknowledged to be public interest factors. The public interest in disclosing information is weighed up against the public interest in keeping it confidential, and the judgements handed down accord with where the judiciary assess the balance of the public interest to lie.⁴⁴ This is in marked contrast to medical law, in which it is not clearly stated in the relevant domestic legislation and case-law that the right to autonomy and/or the individual interests of the patient can be restricted in what is deemed to be the public interest.

The right to autonomy is supposedly the basis for the opt-in system of organ donation that exists throughout most of the UK, and the principle of “appropriate consent” pervades the provisions of the relevant legislation, the Human Tissue Act 2004 (HTA). This emphasis on consent was a response to the public furore surrounding the lack of consent for organ retention practices.⁴⁵ The primary aim of the Act appears to be to reassure the public that their consent will be required in relation to all activities relating to human tissue, organs, and bodies.⁴⁶ However, a closer examination reveals that this is not necessarily true in relation to deceased organ donation and that public interest factors are afforded weight by the legislation. For example, when the reason for post-mortem interventions is to preserve organs

⁴³ The public interest test appears in S.2(1), S.17(3), S.19(3), S.35(4), S.46(3).

⁴⁴ See eg *Anderson v Information Commissioner* [2011] NIQB 44 [16] & [22].

⁴⁵ See section on Human Tissue Legislation in Chapter 1.

⁴⁶ Schedule 1 details the purposes requiring consent.

for transplantation, Section 43 authorises non-consensual interventions⁴⁷ until it has been determined that consent for deceased organ donation “has not been, and will not be, given”.⁴⁸ The “associated intention”⁴⁹ of meeting transplantation needs is, in these circumstances, afforded priority over the requirement for consent. Although the primary aim may still be to reassure the public regarding the essential nature of their consent, any reassurance is misleading in circumstances where consent is moved into a secondary position by public interest factors.

The public interest factors afforded weight under the HTA are not limited to the collective interests of society in having an adequate supply of transplantable organs. They include the interests of a group to which all members of the public with relatives or longstanding friends potentially belong, i.e. the relatives and friends of the deceased. Appropriate consent refers not necessarily to the prior consent of the deceased but may instead refer to the consent of a nominated representative or a person in a “qualifying relationship”,⁵⁰ defined as either a relative or longstanding friend.⁵¹ If a decision by the deceased to consent or not to consent is not in force, proxy consent is sufficient under the HTA and this consent does not need to be based on what the individual would have wanted.⁵² The right to autonomy is abandoned in favour of reassuring the relatives and friends that their consent is of paramount importance. In contrast, the consent of an individual to deceased organ donation is not considered of paramount importance under the legislation. It is not essential to them becoming a deceased organ donor and, even if given, may in practice be vetoed by relatives.⁵³ Although the HTA does not explicitly accord relatives the right to veto,

⁴⁷ S. 43(1).

⁴⁸ S. 43(3).

⁴⁹ *Bell*, ‘Emergency Medicine’, 824.

⁵⁰ HTA S. 3(6); HTA Code of Practice 1: Consent (2014 version) p.8 [32].

⁵¹ HTA S. 27(4) provides a ranking system for relatives and longstanding friends.

⁵² S. 3(6).

⁵³ See discussion in Chapters 1 & 6.

neither does it protect the right to autonomy from being overruled by relatives, leaving this to the discretion of healthcare professionals. This has resulted in the interests of relatives in avoiding personal distress being treated as a higher priority than both the consent of the individual and the transplantation needs of others in society. The lack of reference to the public interest in the HTA means that there is no requirement to weigh up these different factors and reach a decision that is in the public interest overall.

Although both the transplantation needs of others in society and the interests of the relatives of the deceased are afforded weight under the HTA in decision-making relating to deceased organ donation, ante-mortem interventions such as non-therapeutic ventilation are accorded no statutory footing within the HTA. A clause authorising a move away from consent for non-therapeutic ventilation at the end of life was rejected on several grounds, one of these being that it was unnecessary.⁵⁴ This suggests that an adequate supply of organs was considered achievable without recourse to non-consensual non-therapeutic ventilation. However, policies have now been introduced that encompass a move away from consent for non-therapeutic ventilation and other ante-mortem interventions to facilitate organ donation.⁵⁵ This implies that non-consensual ante-mortem donor optimisation procedures are now considered necessary – at least by policy-makers – to meet the public interest in having an adequate supply of transplantable organs. The rejection of the clause authorising non-therapeutic ventilation within the HTA has, however, left decisions about ante-mortem donor optimisation procedures to be made under the individualistic provisions of the Mental Capacity Act 2005 (MCA). As I identified in Chapter 4, the MCA is primarily concerned with the individual interests of the patient identified as a potential organ donor and does not, at least

⁵⁴ Human Tissue Bill third Reading HC Deb (28th June 2004) vol. 423 col. 88 (Ms Winterton); refer back to section on Human Tissue Legislation in Chapter 1.

⁵⁵ See particularly National Institute for Health and Care Excellence (NICE), *Organ Donation for Transplantation: Improving Donor Identification and Consent Rates for Deceased Organ Donation* (Clinical Guidance 135, 2011, updated 2016) [*Improving Donor Identification*]. Also see evaluation of policy framework in Chapter 1.

on the face of it, allow for any weight to be afforded to societal interests in achieving an adequate supply of organs.

Although the MCA claims to give precedence to individual interests,⁵⁶ its provisions are sometimes interpreted by the judiciary in a way that allows them to give weight to the interests of others in society. The best interests test is by its loosely-defined nature at risk of being extended further than the individual interests the MCA claims to protect. There are no limits on the considerations that could be encompassed within the “other factors that he would be likely to consider if he were able to do so”.⁵⁷ This extensibility might, in the hands of some decision-makers, encompass a range of “other” interests within the supposedly individualistic concept of best interests. For example, although decisions regarding the medical treatment of mentally incapacitated expectant mothers are nominally made in the best interests of the patient, these best interests are often interpreted by the judiciary as requiring the delivery of a healthy baby.⁵⁸ The malleability of the best interests test provides a means of encompassing foetal interests within the law, even though the judiciary acknowledges that the law does not allow them to take foetal interests into account.⁵⁹ It might also be that, in some cases, the interests of healthcare professionals in avoiding the difficulties presented by an uncooperative labouring mother impact on judicial decision-making, even if this remains unstated.

There are other situations in which interests wider than that of the individual to be subjected to medical interventions might be encompassed within best interests. One well-

⁵⁶ Refer back to Chapter 4.

⁵⁷ S. 4(6)(c).

⁵⁸ See eg. *Re AA (Compulsorily Detained Patient: Elective Caesarean)* [2012] EWHC 4378 (COP) [5] & *Re P* [2013] EWHC 4581(COP) [17]. I acknowledge Sara Fovargue for these citations and for her helpful discussion during a seminar on “Pregnancy, Best Interests, and the Mental Health Act 1983” at the University of Manchester on 22/03/2017.

⁵⁹ *Re AA* [2012] as above, per Mr Justice Mostyn [1]; *Re P* [2013] as above, [17] per Mr Justice Peter Jackson.

known, albeit pre- MCA case, is that of *In re Y (Mental Patient: Bone Marrow Donation)*.⁶⁰ In this case, the best interests of a mentally incapacitated woman were stretched to accommodate the interests of her sister and mother. Non-consensual donation was held to be of benefit to the incapacitated woman “because in this way her positive relationship with her mother is likely to be prolonged” and transplantation would be likely to “improve her relationship” with her sister, the recipient, “who will be eternally grateful to her”.⁶¹ As Wicks recognises, this reasoning set a “dangerous precedent” for forcing incapacitated individuals to “act selflessly in order to save a relative’s life”.⁶² Furthermore, the lack of acknowledgement of public interest factors in this judgement means that issues such as the necessity of this particular course of action are not considered.⁶³ The perceived need to present a façade that decisions are only ever made in the individual interests of the patient means that it can be difficult to establish what the legal rules are relating to the interests of others and/or the public interest.

The interests of a diversity of third parties have impacted on medico-legal decision-making in a range of circumstances. These third parties may, for example, include healthcare professionals who do not feel able to switch off a ventilator,⁶⁴ parents who would have to provide care to their child after organ transplantation,⁶⁵ and “vulnerable” people in society who might feel pressurised into assisted death.⁶⁶ In each of these examples, the interests of those third parties have been accommodated within the law, effectively giving a range of

⁶⁰ [1997] Fam 110.

⁶¹ *In re Y* as above, [115 G-H].

⁶² E. Wicks, ‘The Greater Good? Issues of Proportionality and Democracy in the Doctrine of Necessity as Applied in *Re A*’ (2003) 32(1) *Common Law World Rev* 15-34, 26.

⁶³ The alternative of donation from other compatible individuals is not fully evaluated. *In re Y* as above, [111 H- 112 A; 115 D –E].

⁶⁴ *Ms B v An NHS Hospital Trust* [2002] EWHC 429 (Fam).

⁶⁵ *Re T (A Minor) (Wardship: Medical Treatment)* [1997] 1 WLR 242.

⁶⁶ *Pretty v United Kingdom* (App no. 2346/02) (2002) 35 EHRR 1; *R (On the Application of Purdy) v DPP* (2009) UKHL 45; *Nicklinson v Ministry of Justice* [2014] UKSC 38.

public interest justifications a legal foundation. However, the language used to accommodate public interest justifications is protean, the circumstances ill-defined, and the legal response is not always consistent. This makes determining what – if any – model of the public interest exists within medical law challenging and, although it often seems that this model is one that views the interests of the patient as being in conflict with the interests of others in society, it is unclear in what circumstances such a model exists.

It is markedly rare for medico-legal decisions to include reference to the term “public interest” or for any attempt to be made to determine the scope and limitations of this concept. The pre-eminent decision-making tools of medical law – informed consent and best interests – do not allow the judiciary to acknowledge the public interest grounds for their decisions. To incorporate the interests of others within these individualistic tools, the judiciary may create a smokescreen as they did *In Re Y*⁶⁷ or use a disparate range of other approaches. Appeals may be made to public policy, state interests, or to other factors, yet these considerations may themselves be ill-defined and their relationship with the public interest can be unclear. The limited reference to the public interest, the range of approaches to public interest considerations, and the lack of examination of the relationship between these approaches and the public interest, generates problems in determining the legal basis for public interest justifications.

References to state interests are rare within medical jurisprudence and, when they do occur, they are almost inevitably viewed as in opposition to individual autonomy. For example, in *R (on the application of B) v SS*,⁶⁸ a case in which a patient challenged his non-consensual treatment under the Mental Health Act 1983 (MHA),⁶⁹ state interests in protecting

⁶⁷ As referenced earlier.

⁶⁸ [2005] EWHC 86 (Admin).

⁶⁹ Achieving compatibility with Article 8 of the ECHR will be considered later in this chapter.

others and/or the patient are described as “countervailing” the right to autonomy.⁷⁰ This term is also used in *Secretary of State for the Home Department v Robb*,⁷¹ in which state interests are described as being in a countervailing relationship with a prisoner’s right to refuse nutrition.⁷² There is little in the case law to suggest that consideration is ever given to a state or public interest in protecting self-determination.

The legal basis for the state interests that are identified in the jurisprudence, such as “protecting innocent third parties”,⁷³ is not gone into in any depth. For example, although in *Secretary of State for the Home Department v Robb* there was found to be no countervailing interest to the prisoner’s right to self-determination, Mr Justice Thorpe states that protecting innocent third parties is “undoubtedly recognised in this jurisdiction” as a factor that could outweigh self-determination.⁷⁴ However, the only domestic judgement he refers to as evidence of this recognition is *In re S (Adult: Refusal of Treatment)*, a forced caesarean case in which it was not acknowledged that the third party, a foetus, had no legal rights to protect.⁷⁵ Although Mr Justice Thorpe’s recognition of a state interest in protecting third parties suggests that the right to refuse medical treatment is not as absolute as the criminal and civil law on battery would have us believe,⁷⁶ the limited jurisprudence on who those third parties might be and in what circumstances leaves it unclear in what situations - if any - the state may legally override the right to refuse treatment.

⁷⁰ *R(on the application of B) v SS* as above, 179 per Justice Silber.

⁷¹ [1994] Fam 127.

⁷² *Ibid*, 131-132, per Justice Thorpe.

⁷³ *Ibid*, 132.

⁷⁴ *Ibid*, 132.

⁷⁵ [1993] Fam 123; N.B. in *St Georges Healthcare NHS Trust v S* [1998] 3 All ER 673 it was held that a foetus is not a separate person from its mother and that its need for medical assistance does not prevail over her right to autonomy (per Judge LJ, at [957]). See also *Re F (In Utero)* [1988] 2 All ER 193; *C v S* [1988] QB 135; *Re MB (Caesarean Section)* [1997] 2 FCR 426.

⁷⁶ Refer back to Chapter 3.

The judicial approach to the interests of third parties extends not only to imposing non-consensual interventions, such as in forced caesarean cases,⁷⁷ but also to preventing individuals from undergoing interventions that are deemed to be against public policy. The paradigm example of public policy considerations being invoked as a justification for restricting patient autonomy is the continued ban on assisted suicide. In support of this ban, two factors are typically appealed to, namely the sanctity of life and the protection of vulnerable others in society.⁷⁸ These factors provide the basis for the current categorisation of assisted suicide as contrary to public policy.⁷⁹ This categorisation is maintained by a moral and social judgement of the relative importance of individual autonomy on one hand and the sanctity of life and the protection of others in society on the other.⁸⁰ It is the protection of vulnerable others in society that has proved the greatest challenge in overturning the ban on assisted suicide. The precedence afforded to the interests of others clarifies that in this, and maybe in other circumstances in which patient autonomy is at stake, public interest considerations can be afforded more protection under the current law than individual autonomy.

The prohibition on assisted suicide implies that a model of public interest is incorporated into medical law, or at least some areas of medical law, that is diametrically opposed to individual autonomy. However, the support given by five out of nine Supreme Court justices to a change in the law reveals a more liberal approach to the public interest.⁸¹ In the *Nicklinson* judgement, both Lady Hale and Lord Kerr recognise that the blanket ban on

⁷⁷ Although guidelines were issued in *St Georges Healthcare NHS Trust v S* [1998] 3 All ER 673 which recognise the right to refuse medical treatment of competent individuals, the judiciary continue to authorise forced caesareans on the basis of mental incapacity. See *Bolton Hospitals NHS Trust v O* [2003] 1 FLR 824; *Re AA* [2012] as earlier; *Re P* [2013] as earlier.

⁷⁸ *Pretty v United Kingdom* (App no. 2346/02) (2002) 35 EHRR 1; *R (On the Application of Purdy) v DPP* (2009) UKHL 45; *Nicklinson v Ministry of Justice* [2014] UKSC 38.

⁷⁹ *Nicklinson v Ministry of Justice* as above [213] per Lord Sumption.

⁸⁰ See *Nicklinson* as above, [229] per Lord Sumption.

⁸¹ *Nicklinson* as above; E. Wicks, 'The Supreme Court Judgement in *Nicklinson*: One Step Forward on Assisted Dying; Two Steps Back on Human Rights' (2015) 23(1) *Med Law Rev* 144-156, 144-145, ['Two Steps Back'].

assisted suicide is incompatible with article 8 of the ECHR, and three other judges also imply that a declaration of incompatibility could be forthcoming should parliament fail to satisfactorily address the issue.⁸² Lady Hale's exploration of the relationship between the individual interests of those who seek assisted suicide and the interests of vulnerable others concludes with a recognition that a system could be devised that protects the interests of others whilst allowing an exception for some individuals – who fulfil certain requirements - to make an autonomous decision to end their lives.⁸³ This is a judicial acknowledgement that there is a public interest in finding ways to protect the interests of all individuals affected by medico-legal decision making. For all medico-legal decisions with a public interest dimension, what needs to be established is not whether the interests of others trump those of the individual but whether a system can be developed that allows all the important interests at stake to be protected, respected, and realised.

One further branch of medical law in which the interests of others in society are used to justify overriding or forestalling the individual's decision about where their own interests lie is public health law. The Public Health (Control of Disease) Act 1984, as amended by the Health and Social Care Act 2008, sanctions the deprivation of liberty from infectious individuals, not in their own interests but to prevent harm to the health of others.⁸⁴ Although the legislation does not authorise mandatory medical treatment,⁸⁵ once the individual is detained they may not perceive themselves to have a genuine choice whether or not to accept treatment.⁸⁶ They can either submit to treatment or risk a longer period of detention in

⁸² See critical analysis by Wicks, 'Two Steps Back' as earlier.

⁸³ *Nicklinson* as above, [314]. N.B. The issue of incompatibility and the potential for a system allowing assisted dying was reconsidered in *Conway v Secretary of State for Justice* [2017] EWHC 2447 (Admin). Section 2 of the Suicide Act was held to be compatible with Conway's Article 8 rights and his application for a declaration of incompatibility was dismissed.

⁸⁴ Public Health (Control of Disease) Act 1984, c. 22, S.37-38.

⁸⁵ Public Health (Control of Disease) Act 1984 (as amended by Health and Social Care Act 2008 S. 129) Part 2 A S. 45E.

⁸⁶ See analysis by M. Brazier & J. Harris, 'Public Health and Private Lives' (1996) 4 *Med Law Rev* 171-192, 175-176. N.B this was written before the amendments to the 1984 Act but the issues raised remain.

the public interest: a choice between bodily integrity and liberty. This effectively compels them to sacrifice at least one core liberal value to the interests of others in society. The public interest in maintaining the core liberal values of the patient is side-lined in favour of the interests of others in society. In public health law and practice, the interests of others in avoiding the risk of infection are treated as the paramount public interest consideration in the circumstances.

Whilst public health legislation provides only an illusion of choice to infectious individuals, mental health legislation removes choice entirely from competent individuals with mental disorder. Section 63 of the Mental Health Act 1983 subjugates the “incontestable” principle that “every person’s body is inviolate”⁸⁷ to the treatment of their mental disorder. Bodily integrity and self-determination are abandoned, presumably either in the interests of the patient and/or that of others in society. However, the legislation does not include any need to justify the abandonment of autonomy interests by reference to either the individual’s personal welfare interests or the interests of others in society. This means that decisions made under Section 63 may not always transpire to be in the patient’s individual interests, the interests of others, or in the public interest overall. This is why human rights law is so crucial to these and other decisions which impact on individual autonomy and wider interests within society. Achieving compatibility with Article 8 of the ECHR has been recognised in mental health case-law to require that non-consensual treatment is only done within carefully prescribed limits.⁸⁸ The conditions under which the individual’s right to self-determination and bodily integrity can be restricted will only achieve compatibility with Article 8 if they are not only lawful but also proportionate to a legitimate public interest aim under Article 8(2).⁸⁹ This

⁸⁷ *Collins v. Wilcock* [1984] 1 W.L.R. 1172 at 1177 per Goff L.J.

⁸⁸ See *An NHS Trust v Dr A* [2013] EWCOP 2442, [80].

⁸⁹ Article 8(2); G. Letsas, ‘Rescuing Proportionality’, Chapter 17 in R. Cruft, D. Liao, & M. Renzo, *Philosophical Foundations of Human Rights* (1st edition, OUP, 2015), 316-340, 316-317, [‘Rescuing Proportionality’].

proportionality requires that the different factors that contribute to individual interests, the interests of others, and the public interest overall are identified and weighed up in relation to each other.⁹⁰

There are inconsistencies between the models of public interest used in the different areas of medical law I have examined in this section, but it is possible to draw two main conclusions. The first is that the judiciary, and in some circumstances the legislature, acknowledge and seek to protect the interests of others in a range of medico-legal decisions relating to the medical treatment of individual patients. In decisions that the law requires are made in the individual interests of the patient, as it currently demands for donor optimisation procedures, the judiciary does have a history of recognising and protecting the interests of third parties by stretching the law to fit the circumstances.⁹¹ This judicial interpretation of best interests does not always appear to correlate with the remit of the law. In other medico-legal decisions, however, the judiciary can achieve this acknowledgement and protection of the interests of third parties within the remit of the legislation relating to assisted suicide, public health, and mental illness. The model of public interest used both in interpreting and devising legislation is often one that views individual interests, including patient autonomy, as an opposing factor to achieving the interests of others and the public interest overall. However, the judiciary is increasingly recognising that both the legislation and their interpretation of it need to be compatible with the requirements of the ECHR. This leads to the second conclusion, which is that the requirements of human rights law demand that medical law moves towards a model of public interest that is compatible with the approach of the ECtHR. However, as I discover in the next section, determining what that model of the public interest

⁹⁰ Proportionality will be explored in more depth in the next section of this chapter.

⁹¹ The best known example of this is *In re Y (Mental Patient: Bone Marrow Donation)* [1997] Fam 110, as discussed earlier; if third parties are also interpreted as including foetal interests then it also includes forced caesarean cases including those cited earlier in this chapter.

is, and delineating its relationship with individual rights, is not as straightforward as might be supposed.

Human Rights Law and the Public Interest

Universality and inalienability are two terms that are often used together to describe human rights.⁹² Human rights might, under this description, be thought of as those rights that apply to all members of society and that are not subject to forfeiture under any circumstances. However, of the two ECHR rights most applicable to non-consensual donor optimisation procedures, only the Article 3 right to be free from inhuman or degrading treatment is what is known as an absolute right and even this could potentially be limited by declaring that a high enough threshold has not been reached. Although there are no public interest grounds contained within the wording of Article 3 on which this right could be overridden, the judiciary's approach - particularly their emphasis on the high threshold - suggests that the right might not be as absolute as the wording of the ECHR suggests.⁹³ The Article 8 right to private life, including the right to autonomy, is explicitly recognised within the text of the ECHR to be qualified or limited by external circumstances. Article 8(2) specifies a range of public interest grounds on which it might be deemed necessary to interfere with the right to autonomy, without defining the circumstances in which the ECtHR will find that this necessity exists. Although this does clarify that the right to autonomy is not always treated as universal and inalienable, it leaves questions as to when any interference with the right to autonomy will be upheld as necessary in the public interest.

⁹² See eg The Office of the United Nations High Commissioner for Human Rights website, <http://www.ohchr.org/EN/Issues/Pages/WhatAreHumanRights.aspx> (last accessed 08/09/2017).

⁹³ This will be further evaluated later in this section.

Human rights law is concerned not only with the protection of individual rights but also with the protection of societal or collective interests.⁹⁴ Human rights law seeks to address these dual concerns by imposing qualifications on certain human rights, including the Article 8 right to private life, whilst only permitting these qualifications in circumstances in which the interests of others cannot otherwise be achieved. However, it is not always articulated in ECtHR judgements what the relationship is between the rights of the individual, the rights of others in society, and the public interest overall. Although the doctrine of proportionality is referred to, and this appears to be a manifestation of the model of public interest used within human rights law, what proportionality is and what its relationship to the public interest is often only receive cursory attention in the judgements of both UK courts and the European Court of Human Rights (ECtHR).⁹⁵

Achieving compliance with human rights law is full of ambiguities, many of which revolve around the relationship between individual rights and the rights of others in society. Achieving a “fair balance”⁹⁶ between individual rights and the rights of others is fundamental to achieving compliance with human rights law, yet what this balancing process entails is unclear. Although the ECtHR speaks of balancing individual rights against public benefit, this might not always imply a utilitarian trade-off between the two.⁹⁷ Instead, it could plausibly be interpreted as referring to a process of consideration of the effect of the state measure upon the rights and interests of both the individual and others in society.⁹⁸ This process of consideration provides a framework for determining what individual rights should be upheld and under what circumstances, yet doesn’t clearly stipulate how this should be determined.

⁹⁴ F. Klug, ‘The Human Rights Act – A “Third Way” or “Third Wave” Bill of Rights’ (2001) *EHRLR* 361-372, 364, [‘Third Wave’].

⁹⁵ Proportionality and its relationship with the public interest is evaluated later in this chapter. There appears to be little in the academic literature on this relationship.

⁹⁶ See eg. *Tysiac v Poland* (App no. 5410/03) (2007) 45 EHRR 947 [111].

⁹⁷ *Letsas*, ‘Rescuing Proportionality’ as above, 325-326.

⁹⁸ *Ibid.*

The qualification of Article 8 rights generates uncertainty over whether or not the ECtHR would find any interference with the right to private life of potential organ donors to be justified. Whether or not an Article 8 claim will be upheld depends on considerations that are external to the human rights issue in question.⁹⁹ The non-absoluteness of Article 8 rights, as made explicit by Article 8(2), leaves the right vulnerable to circumstances such as an inadequate supply of organs in society. It is these external circumstances, rather than the human right being interfered with, that determine whether organ procurement policy is compatible with Article 8. This implies that Article 8 is “context-sensitive” and by its “nature in a commensurate conflicting relationship with communal aims and interests”.¹⁰⁰ However, this view of Article 8 rights being in conflict with communal aims does not necessarily, in all circumstances, reflect the reality of the relationship between the rights of the individual and those of others in society.

The approach of the ECtHR to qualified rights appears – on the face of it - quite formulaic, breaking the wording of Article 8(2) down into four distinct stages,¹⁰¹ with stringent requirements that need to be met before progression to the next stage is permitted. Briefly, these stages are: establishing an interference, the lawfulness of the interference, the purpose falling within a legitimate public interest aim, and the necessity and/or proportionality of the interference.¹⁰² The first stage establishes a violation of Article 8(1), whilst the latter three stages establish that the requirements imposed by Article 8(2) have been met. Although the use of the four-stage test and the wording of the provisions on which it is based seem clear enough, the ECtHR has retained a significant degree of flexibility in determining the answers

⁹⁹ B. Cali, ‘Balancing Human Rights? Methodological Problems with Weights, Scales and Proportions’ (2007) 29 *Human Rights Quarterly* 251-270, 252, [‘Balancing Human Rights?’].

¹⁰⁰ Cali as above, 259.

¹⁰¹ G. Letsas, ‘Two Concepts of the Margin of Appreciation’ (2006) 26(4) *Oxf J Leg Stud* 705-732, 710-11.

¹⁰² See Letsas as above, 711, for a delineation of the four stages.

to each of these stages. This means that claims as to their likely response to an individual set of circumstances, such as donor optimisation policy, rest on uncertain grounds.

The first stage of the ECtHR's approach, establishing an interference with an Article 8 right, has been interpreted quite widely and is perhaps the least disputable in the context of non-consensual donor optimisation procedures.¹⁰³ Non-consensual medical interventions are recognised not only to interfere with personal autonomy, but also with the patient's physical and psychological integrity, and as such fall squarely within the scope of Article 8(1).¹⁰⁴ However, if non-consensual donor optimisation procedures are deemed to be non-arbitrary in nature and a legitimate means of achieving the public interest they could potentially fulfil the requirements of Article 8(2). This is what the remaining stages of the ECtHR's approach seeks to clarify by establishing the lawfulness, public interest aim, and necessity of the interference with autonomy. Of these remaining stages, it is the final stage of establishing the necessity of the interference that presents the most difficult hurdle for NHS Blood and Transplant (NHSBT) to overcome.¹⁰⁵

The legitimate public interest aims of interfering with the Article 8 right to private life are listed in Article 8(2) as "national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others". The ECtHR has clarified that the exceptions afforded by the aims are to be interpreted narrowly and that the need for the interference must be "convincingly established".¹⁰⁶ The reason given for interpreting these aims narrowly is that they provide for an exception to a right guaranteed by the ECHR.¹⁰⁷

¹⁰³ *Pretty v UK* as earlier [63]; *Herczegfalvy v Austria* (App no. 10533/83) (1992) 15 EHRR 437; *Tysiac v Poland* as earlier. Also see discussion on Article 8 in Chapter 1.

¹⁰⁴ *Pretty v UK* as above [63].

¹⁰⁵ The lawfulness of the interference will be considered in the final section of this chapter; the ECtHR's approach to necessity is considered both later in the current section and in the final section.

¹⁰⁶ *Funke v France* (App no. 10828/84) (1993) 16 EHRR 297 [55].

¹⁰⁷ *Klass v Germany* (App no. 5029/71) (1979-80) 2 EHRR 214 [42].

However, these aims are painted with a broad brush, which lends them to being interpreted more widely than the ECtHR might acknowledge. For example, the protection of morals is interpreted by the ECtHR as including the protection in Ireland of the right to life of the foetus.¹⁰⁸ This encompassment of the foetal right to life within morals seems to be quite a wide interpretation of what morals are, and sits awkwardly with one of the key functions of human rights, which is to exclude “moralistic majoritarian preferences as grounds for coercive prohibitions”.¹⁰⁹ Nevertheless, the ECtHR is happy to defer to the state seeking to maintain restrictive prohibitions on abortion to determine the “exact content of the requirements of morals”.¹¹⁰ Rather than providing guidance on the interpretation of this public interest aim, this passes the buck back to the relevant state and fails to ensure that exceptions to guaranteed rights are only afforded for valid public interest purposes.

Only in rare cases do ECtHR judges question the validity of public interest aims invoked to justify overriding Article 8 rights and, even then, they may be a lone dissenting voice. For example, in *Dubská and Krejzová v Czech Republic*,¹¹¹ the state claimed that a prohibition on medical assistance during home births was designed to protect the health of newborn and mother.¹¹² Judge Lemmens comments that the absence of a prohibition on home births “says something about the validity of the public-health reasons invoked to justify” a prohibition on midwives providing assistance in home births.¹¹³ Recognising that other considerations, such as a “power struggle between doctors and midwives” also “came into play”, he found that “the public-health argument put forward by the government should

¹⁰⁸ See eg *A, B, & C v Ireland* (App no. 25579/05) (2011) 53 EHRR 13 [227].

¹⁰⁹ I. Trispiotis, “Two Interpretations of Living together in European Human Rights Law” (2016) 75(3) *Camb Law J* 580-607, 580.

¹¹⁰ *A, B, & C v Ireland* as above [223]; *Open Door Counselling v Ireland* (App no. 14234/88 & 14235/88) (1993) 15 EHRR 244 [68].

¹¹¹ (App nos. 28859/11 & 28473/12)(2015) 61 EHRR 22.

¹¹² *Ibid*, [84].

¹¹³ *Ibid* [O111-2].

not be overestimated”.¹¹⁴ However, his was a dissenting opinion from a majority judgement which found that there were no grounds for doubting that the prohibition on medical assistance at home was designed to protect the health of the newborn and the mother and that it accordingly served the legitimate aim of the protection of health and of the rights of others.¹¹⁵ This majority judgement was issued despite the observation that the prohibition on medical assistance during home births may increase rather than protect against risks to the health of the newborn and mother.¹¹⁶ This implies that the ECtHR is more concerned at this stage with whether a potentially legitimate aim has been put forward rather than whether the public interest is actually served by a healthcare policy. So if a government states that a measure has been undertaken with one of the Article 8(2) aims in mind, this may be enough to pass the legitimacy test and proceed to the question of necessity.

The ECtHR judgements have interpreted the provision that any Article 8 interference is “necessary in a democratic society”¹¹⁷ to require that it answers a “pressing social need”¹¹⁸ and is proportionate to the legitimate aim pursued.¹¹⁹ They clarify that, although it is for the state to make the initial assessment of necessity, the final evaluation “as to whether the reasons cited for the interference are relevant and sufficient” to conform with Convention requirements is subject to review by the ECtHR.¹²⁰ The Court relies on the intertwined principles of necessity and proportionality to review whether the reasons put forward by a government are enough to justify providing an exception to a guaranteed right. These principles are two elements of the same test,¹²¹ usually referred to as the doctrine of

¹¹⁴ Ibid [O111-3]

¹¹⁵ Ibid [86].

¹¹⁶ Ibid [96].

¹¹⁷ Article 8(2).

¹¹⁸ *Handyside v United Kingdom* (App no. 5493/72) (1979-80) 1 EHRR 737 [48].

¹¹⁹ See, amongst other legal authorities, *Connors v United Kingdom* (App no. 66746/01) (2005) 40 EHRR 9 [81].

¹²⁰ Ibid [81].

¹²¹ D. Kyritsis, ‘Whatever Works: Proportionality as a Constitutional Doctrine’ (2014) 34(2) *Oxf J Leg Stud* 395-415, 396 [‘Proportionality as a Constitutional Doctrine’].

proportionality, yet these terms seem to signify different things. Necessity implies that an exception to a guaranteed right is the only way of achieving a public interest aim,¹²² whereas proportionality implies that the exception is proportionate to the benefit to the public interest it generates.¹²³ However, within the ECtHR jurisprudence, the meaning of and relationship between these terms is not always entirely clear.

Proportionality is the central legal doctrine used by the ECtHR to regulate state interference with non-absolute rights,¹²⁴ and is intended to achieve “the fair balance that is inherent in the Convention”.¹²⁵ What this balancing process entails – and the circumstances in which individual rights could be subjugated to the public interest – is difficult to determine from the ECtHR jurisprudence. However, the ECtHR have confirmed that any balancing exercise should “ensure the fair and proper treatment of minorities and avoid any abuse of a dominant position”.¹²⁶ The ECtHR also holds that “where a particularly important facet of an individual’s existence or identity is at stake, the margin allowed to the state will be restricted”.¹²⁷ These statements together imply that, although no Article 8 rights are outside the scope of potential interference, the emphasis should be on protecting the individual rights of those in a vulnerable position from state interference – especially when those rights relate to particularly important aspects of the individual’s private and/or family life.

¹²² K. Moller, ‘Proportionality: Challenging the Critics’ (2012) 10(3) *In J Constitutional Law* 709-731, 713, [‘Challenging the Critics’].

¹²³ Kyritsis, ‘Proportionality as a Constitutional Doctrine’ as above, 396

¹²⁴ A. Legg, *The Margin of Appreciation in International Human Rights Law* (OUP 2012) 178-179, [‘Margin of Appreciation’].

¹²⁵ See eg. *Christine Goodwin v United Kingdom* (App no. 28957/95) (2002) 35 EHRR 18 [93]

¹²⁶ *Young, James and Webster v United Kingdom* (App no. 7601/76) (1983) 5 EHRR 201 [63].

¹²⁷ *SH v Austria* (App no. 57813/00) (2011) 52 EHRR 6 [93] citing *Evans v United Kingdom* (App no. 6339/05) (2008) 46 EHRR. 34 [77]; *X and Y v Netherlands* (App no. 8978/80) (1986) 8 EHRR 235 [24 & 27]; *Dudgeon v United Kingdom* (App no. 7525/76) (1982) 4 EHRR 149 [52]; *Goodwin v United Kingdom* as above [90].

In assessing whether a “reasonable relationship of proportionality”¹²⁸ exists between the state interference and the public interest aim, the court doesn’t just balance individual interests against the public interest. It also takes into account how effective the interference would be in achieving the public interest goal.¹²⁹ In some circumstances, despite the ECtHR’s statement indicating that the margin of appreciation should be restricted in relation to particularly important facets of rights, the effectiveness of achieving a public interest aim could influence the Court’s reasoning. However, the wording of Article 8(2) requires that any interference is necessary, implying that rights can only be restricted if there is no other effective means of achieving a public interest goal. This suggests that, in order to ensure compatibility with Article 8, the judiciary – both domestic and European – should ensure they have considered the effectiveness of other means of achieving the public interest.¹³⁰

Article 8 is an imperfect means of protecting individual autonomy, but it does allow for a process of consideration as to how to best balance autonomy against public interest goals. This is in contrast with the Article 3 right not be subjected to inhuman or degrading treatment, which is also of relevance to non-consensual medical interventions at the end of life.¹³¹ This right is framed within ECtHR jurisprudence as an absolute right, which “does not allow for any exceptions or justifying factors or balancing of interests,”¹³² irrespective of the state’s goals.¹³³ The protection offered by Article 3 is supposed to extend to all ill-treatment that reaches a “minimum level of severity”,¹³⁴ with considerations of proportionality and

¹²⁸ See eg. *SH v Austria* as above, [92].

¹²⁹ Ibid [92]; see also *Nunez v Norway* (App no. 55597/09) (2014) 58 EHRR 17 [OII-1]; *Folgerø v Norway* (App no. 15472/02) (2008) 46 EHRR 47 [100].

¹³⁰ This is considered in more detail in the final section of this chapter.

¹³¹ See discussion in Chapter 1.

¹³² *Gafgen v Germany* (App no. 22978/05) (2011) 52 EHRR 1 [107]

¹³³ Ibid.

¹³⁴ *Ireland v United Kingdom* (App no. 5310/71) (1979-80) 2 EHRR 25 [162]

balancing being entirely excluded from the Court's reasoning.¹³⁵ This framing of Article 3 as an absolute right is based on a textual reading of the Convention right, which unlike Article 8, "makes no provision for exceptions".¹³⁶ In addition, the ECtHR has clarified that the absolute prohibition of torture and inhuman or degrading treatment "enshrines one of the fundamental values of the democratic societies making up the Council of Europe" and is a "generally recognized as an internationally accepted standard".¹³⁷ This all strongly implies that external considerations, such as state interests, do not affect the ECtHR's reasoning in relation to Article 3, yet there is some limited case-law to suggest that this is not always the case.¹³⁸

Although Article 3 is worded as an absolute right, and this is consistent with its recognition as an internationally recognised standard, the ECtHR has on occasion appeared to adopt a balancing test.¹³⁹ For example, in *Soering v United Kingdom*, a case involving a proposed extradition to face a possible death penalty in the USA, the ECtHR – in considering what amounts to inhuman or degrading treatment – refer to the search for a fair balance "inherent in the whole of the Convention" between the interests of the community and individual rights.¹⁴⁰ They then comment that potential danger to a state providing a safe haven for fugitives "must also be included among the factors to be taken into account in the interpretation and application of the notions of inhuman and degrading treatment or punishment in extradition cases".¹⁴¹ Encompassing state interests within the interpretation of

¹³⁵ S. Smet, 'The 'Absolute' Prohibition of Torture and Inhuman or Degrading Treatment in Article 3 ECHR: Truly a Question of Scope Only?', Chapter 13 in E. Brems & J. Gerards, *Shaping Rights in the ECHR: The Role of the European Court of Human Rights in Determining the Scope of Human Rights* (CUP, 2014) 273-293, 274, ['Question of Scope only?].

¹³⁶ *Ireland v United Kingdom* as above, [163]; H. Battjes, 'In Search of a Fair Balance: The Absolute Character of the Prohibition of *Refoulement* under Article 3 ECHR Reassessed' (2009) 22 *Leiden Journal of International Law*, 583–621, 587 ['Article 3 ECHR Reassessed'].

¹³⁷ *Soering v United Kingdom* (App no. 14038/88) (1989) 11 EHRR 439 [88].

¹³⁸ For detailed analysis of case-law see Smet, 'Question of Scope Only?' as above & Battjes, 'Article 3 ECHR Reassessed' as above.

¹³⁹ S. Palmer, 'A Wrong Turning: Article 3 ECHR And Proportionality' (2006) 65(2) *Camb Law J* 438–452, 447 ['Wrong Turning'] citing *Soering v United Kingdom* as above.

¹⁴⁰ Citation as earlier, [89].

¹⁴¹ *Ibid.*

the notion of inhuman and degrading treatment suggests that, in some circumstances, the textual interpretation of Article 3 as absolute is not followed by the ECtHR. However, the ECtHR has rejected such suggestions and in later cases, such as *Chahal v United Kingdom*,¹⁴² has refused to enter into a balancing process between Article 3 rights and public interest grounds for interfering with them.¹⁴³

The severity threshold for ill-treatment to come within the scope of Article 3 might, depending on how it is interpreted, provide a means of restricting this right in what is deemed to be the public interest. The ECtHR has held that this threshold varies according to the circumstances of the case, including “the nature and context of treatment , the manner and method of its execution, its duration, its physical or mental effects and, in some instances, the sex, age and state of health of the victim “. ¹⁴⁴ This suggests, for example, that the context of organ donation and the fact that the potential organ donor is near to death could influence whether a non-consensual medical intervention was deemed to be inhuman and/or degrading treatment. Although the application of Article 3 should “live up to its standard of an absolute prohibitionthe Court does not always comply with the principle in this manner”¹⁴⁵ and public interest concerns can creep in. The collective interests of society in maintaining a supply of organs could therefore potentially result in a higher threshold being required for ill-treatment of potential organ donors to be upheld as an Article 3 violation than for other groups of patients.

Public interest concerns relating to donor optimisation procedures could potentially influence the way that these procedures are viewed in both domestic and ECtHR law. As I have found in my exploration of the law, it is not always clear what the legal rules are with

¹⁴² (App no. 22414/93)(1997) 23 EHRR 413.

¹⁴³ Ibid, [80-82]; *Palmer* as above, ‘Wrong Turning’, 448.

¹⁴⁴ *Kudła v Poland* (App no. 30210/96) (2002) 35 EHRR 11 [91].

¹⁴⁵ See *Smet* as earlier, ‘Question of Scope only?’, 278.

regard to this often unstated principle. Although the Human Rights Act 1998 does place a number of obligations on the state to act in a manner compatible with the interpretation of Convention rights by the ECtHR,¹⁴⁶ the European Court has retained a degree of flexibility in its interpretation of both qualified and unqualified rights. This flexibility means it is difficult to be certain how the relationship between the individual rights of the potential organ donor and public interest concerns would be treated in ECtHR jurisprudence. In the final section of this chapter I nevertheless attempt to apply the pronouncements of the ECtHR, as well as the domestic jurisprudence, to my question of whether the public interest in donor optimisation procedures requires the inclusion of autonomy.

The Public Interest in Donor Optimisation Procedures

The multi-faceted nature of the public interest becomes apparent when attempting to determine where the public interest in donor optimisation procedures lies at a conceptual level. These facets are not limited to the collective interests of society in achieving an adequate supply of transplantable organs. They also include the interests of two particularly important groups within society: patients waiting for organs and patients who might be subject to donor optimisation procedures. All of these interests contribute to the public interest overall and determining the direction of that public interest can be difficult. This is particularly apparent with respect to one crucial influence on the overall public interest, that being the consent of the potential organ donor to donor optimisation procedures. On one hand, asking for this consent in advance might seem to risk a drop in the number of people willing to sign up to and/or leave their names on the NHS Organ Donor Register (ODR). On the other hand, that consent itself is an important contribution to the public interest and

¹⁴⁶ S. 2, 3 & 6.

proceeding without that consent risks triggering an outbreak of public distrust and a transplantation crisis.¹⁴⁷

The vagueness of public interest at a conceptual level doesn't seem to lend itself to resolving the problem of determining the relationship between the different contributing factors to the public interest in donor optimisation procedures. Nevertheless, it is clear that the public interest is not a simple aggregate of these factors, as there is no easy formula for combining seemingly disparate factors to produce one overarching interest shared by all. Also, some of these factors may have more influence on the overall public interest than others. Neither is the public interest a notion that inevitably trumps individual interests, such as individual autonomy. The public do have an interest in the inclusion of autonomy within healthcare policies, including organ procurement policy and end-of-life care policy. All society members could potentially be identified as organ donors at the end-of-life and many would consider it against their individual interests to undergo non-consensual non-therapeutic – and potentially harmful – procedures. However, all society members are also at risk of organ failure and many would benefit from the achievement of an adequate supply of transplantable organs. Determining what the relationship is between these different factors is a conundrum, but is not helped by a narrow view of the public interest as inevitably in conflict with individual interests.

There is a public interest in according each individual member of the public the right to determine in advance whether or not they would wish to undergo donor optimisation procedures. There is a public interest in maintaining the right to bodily integrity and the dignity of all brain-injured patients. This self-determination, bodily integrity, and dignity are important components of the public interest in donor optimisation procedures. If these factors are acknowledged as contributing to rather than being in opposition to the public

¹⁴⁷ See Chapter 2 on the relationship between autonomy, trust and the supply of organs.

interest, they could form the basis of a system which maintains the functioning and integrity of the organ donation programme by the introduction of informed consent.¹⁴⁸ It should not be beyond the wit of policy-makers to design a system which successfully promotes both autonomy and trust in organ donation, being in both the individual interests of the potential organ donor and the public interest overall.

The public interest in donor optimisation procedures, to the extent that it has been considered at all by policy-makers, seems to have been assumed to lie in the direction of avoiding the potential upset caused by the introduction of a system of informed consent.¹⁴⁹ This approach has resulted in, as I set out in Chapter 3, a failure to reach the information disclosure standards required by the tort of negligence and by the civil and criminal law on battery. Although an alternative defence to battery, namely best interests, is relied upon by policy-makers to encompass donor optimisation procedures performed on incapacitated patients within the law, as I set out in Chapter 4, there are many problems encompassing these procedures within best interests and they mostly revolve around the lack of consent. However, as I have explored within the current chapter, the law does sometimes accommodate public interest justifications within medical law, raising the question as to whether the law could accommodate public interest concerns relating to donor optimisation procedures, and if so, what direction it would take.

Best interests is, as I argued in Chapter 4, supposed to be primarily concerned with the individual affected by the proposed medical intervention. However, healthcare professionals' concerns to ensure they fulfil their perceived duty to organ recipients¹⁵⁰ may

¹⁴⁸ The impact on the supply of organs of a system of informed consent is considered in Chapter 6.

¹⁴⁹ See Murphy's comments on the risks of introducing informed consent in P. Murphy 'Optimizing Donor Potential in the UK' (2011) 6 *Clin Ethics* 127–133, 128.

¹⁵⁰ See responses of healthcare professionals in A.Gathani, G.Moorlock & H.Draper, 'Pre-mortem Interventions for Donation after Circulatory Death and Overall Benefit: A Qualitative Study' (2016) 11(4) *Clin Ethics* 149-158, 153.

influence their decision-making as to what optimisation procedures can be encompassed within the best interests of the donor. If so, this is not inconsistent with the apparent encompassment of concerns regarding the delivery of a healthy baby within the best interests of expectant mothers.¹⁵¹ In both of these situations, some healthcare professionals may feel they have a duty to a third party or parties as well as the patient who will be subject to the medical intervention. Some may, like the judiciary did *In re Y (Mental Patient: Bone Marrow Donation)*,¹⁵² feel torn and try and stretch the law on best interests in a way that accommodates their perceived duty to potential organ recipients. If so, this would not sit comfortably with the direction the law has since taken in ensuring that the individual and their interests remain paramount.¹⁵³

When judges are presented with “life-or-death” situations affecting more than one individual, they have on occasion come to a decision that is clearly not in the best interests of a particular individual to be subject to a medical procedure. The Court in *Re A (Children) (Conjoined Twins: Surgical Separation)* was aware that the proposed separation would result in the death of the weaker twin.¹⁵⁴ However, they justified this on the basis that it was necessary to save the stronger twin.¹⁵⁵ The judiciary was prepared to “break the letter of the law”¹⁵⁶ to reach the solution that they deemed to be for the greater good.¹⁵⁷ This was based on a value judgement that they believed the law endorsed,¹⁵⁸ yet – as Wicks recognises – it is immediately obvious that this judgement contains an element of subjectivity.¹⁵⁹ This element

¹⁵¹ *Re AA* as earlier [5] & *Re P* as earlier [17] as discussed earlier.

¹⁵² [1997] Fam 110 as discussed earlier.

¹⁵³ See particularly *Aintree University Hospitals v James* [2013] UKSC 67 as discussed in Chapter 4.

¹⁵⁴ [2000] 4 All ER 961.

¹⁵⁵ *Ibid* [1067]; See E. Wicks, ‘The Greater Good? Issues of Proportionality and Democracy in the Doctrine of Necessity as Applied in *Re A*’ (2003) 32 *Comm L World Rev* 15-34, 19-20, [‘Greater Good?’].

¹⁵⁶ S. Uniacke, ‘Was Mary’s Death Murder?’ (2001) 9(3) *Med Law Rev* 208-220, 215, [‘Mary’s Death’].

¹⁵⁷ Wicks as earlier, ‘Greater Good?’, 20.

¹⁵⁸ Uniacke as earlier, ‘Mary’s Death’, 215.

¹⁵⁹ Wicks as earlier, ‘Greater Good?’, 20.

of subjectivity cannot be easily removed from public interest decisions and breaking the letter of the law leaves decisions without a firm and unequivocal legal foundation.

As I noted in Chapter 3, the MCA encompasses circumstances of necessity within its provisions and, at least on the face of it, decisions always have to accord with the patient's best interests.¹⁶⁰ If treatment is necessary in the patient's best interests, it can lawfully proceed, but if it is only considered necessary in the interests of others – such as patients on the transplant waiting list – there is no apparent legal basis for it. However, there is a degree of flexibility, or even malleability, in determining an individual's best interests and public interest concerns, such as contributing to the supply of organs, can creep in to the factors considered under Section 4(6). Doctors are protected from liability if they “reasonably believe” that procedures to improve the chance of successful organ donation are in a patient's best interests.¹⁶¹ If it is not known what the patient wanted, it is perhaps not unreasonable to presume they would want to be remembered as someone who selflessly saved others' lives. Nevertheless, such an approach may be against the individual interests of the patient and in reality made for a public interest reason.

The Courts are exempted from the reasonable belief proviso.¹⁶² Reasonableness of best interests decisions is not the legal threshold to be met. The judiciary have to demonstrate that they have weighed up all relevant considerations and reached a decision which is to the overall benefit of the patient. Public interest concerns should not, according to the letter of law, have any place in this determination. In cases related to the donation of bodily tissues, the court is primarily concerned with the potential donor's wishes and feelings

¹⁶⁰ S. 1(5) & S. 5.

¹⁶¹ S. 4(9).

¹⁶² S. 4(9).

and with “the benefits, if any, which the donor may derive from being a donor”.¹⁶³ Although these benefits were stretched to accommodate familial interests *In Re Y*,¹⁶⁴ this approach does not sit easily with the current law. The increased emphasis on the individual’s viewpoint, both in statute and jurisprudence,¹⁶⁵ suggests that a court making a best interests decision regarding donor optimisation procedures would consider the individual’s viewpoint paramount to this decision.

There is no statutory or common law public interest justification for ante-mortem donor optimisation procedures, so the UK judiciary seems unlikely to consider the question of whether the public interest requires the inclusion of consent for donor optimisation procedures. However, there is a potential for a human rights challenge to current donor optimisation policy, and one of the key concerns in human rights law is the relationship between individual rights and the public interest. As I have earlier commented, the lack of consent for donor optimisation procedures brings current donor optimisation policy squarely within the scope of Article 8(1). However, due to the structure of Article 8, the issue examined under Article 8(2) is not whether consent is necessary in the public interest, but whether a lack of consent is necessary in the public interest. If a lack of consent is found to be unnecessary in the public interest, the balance of considerations that make up the public interest would be weighted in favour of introducing a system of consent.

In balancing individual autonomy against the public interest, one of the factors that the ECtHR take into account is whether any interference with autonomy is “in accordance

¹⁶³ *In the matter of SW* [2017] EWCOP 7 [24], Sir Munby citing *In Re Y*, as earlier, p.115-116.

¹⁶⁴ *In Re Y* as before; L. Cherkassky, ‘The Interfamilial Principle and the Harvest Festival’ (2016) 23(1) *Eur J Health Law* 61-79.

¹⁶⁵ Refer back to Chapter 4.

with the law”.¹⁶⁶ There is a public interest in ensuring that there is a clear legal basis for any non-consensual medical interventions, that the law is accessible to the individual concerned, and that the consequences of the law are foreseeable.¹⁶⁷ This public interest is not met by the proposed legal basis for current donor optimisation policy, i.e. the best interests of the potential organ donor.¹⁶⁸ As registered organ donors have not been informed that interventions commence before death and there is no system of determining the individual’s viewpoint towards donor optimisation procedures, this basis in law is dubious. It does not meet the qualitative standards required by the ECtHR, which are that the law must be “compatible with the rule of law and accessible to the person concerned, who must, moreover, be able to foresee its consequences for him”.¹⁶⁹ Registered organ donors are not given “an indication that is adequate, in the circumstances, of the legal rules applicable to a given case”.¹⁷⁰ The inaccessibility of information about ante-mortem donor optimisation procedures renders them unable to foresee the consequences of signing up for deceased organ donation. The public interest in ensuring that a clear and accessible legal basis exists for any move away from consent for medical interventions is not met by the absence of a clear and accessible legal framework for current donor optimisation policy.

The onus is on the state to “convincingly establish”¹⁷¹ the need for the current interference with the Article 8 rights of potential organ donors. There is certainly a “pressing social need”¹⁷² for an increase in the supply of transplantable organs, but there are many

¹⁶⁶ Art. 8(2).

¹⁶⁷ *Amann v Switzerland* (App no. 27798/95) (2000) 30 EHRR 843 [50].

¹⁶⁸ See Chapter 4 on the difficulties with best interests providing a clear legal basis for non-consensual donor optimisation procedures; also S-J Brown, ‘The Legal Justification for Donor Optimisation Procedures’ (2016) 11(4) *Clin Ethics* 122-129.

¹⁶⁹ *Liberty v United Kingdom* (App no. 58243/00) (2009) 48 EHRR 1 [59]; *Kruslin v France* (App no. 11801/85) (2009) 12 EHRR 547 [27].

¹⁷⁰ *Sunday Times v United Kingdom* (App no. 6538/74) (1979-1980) 2 EHRR 245 [49].

¹⁷¹ *Funke v France* as earlier [55].

¹⁷² *Handyside v United Kingdom* as earlier [48].

different options for increasing the supply of organs and not all of these require a move away from consent.¹⁷³ Some options, such as preventing family members from overriding the wishes of registered organ donors, could protect rather than override the autonomy of potential organ donors.¹⁷⁴ Others, such as public information and education initiatives, could also be designed to protect and promote the Article 8 rights of potential organ donors. Some policies which are deemed by policy-makers to require a move away from consent, such as current donor optimisation policy, could be rethought and redrafted to include informed consent. The lack of consideration given to informed consent means that the state has not convincingly established that the current policy of non-consensual donor optimisation procedures is the only or least restrictive means of effectively answering the pressing social need for an improved supply of transplantable organs.

The ECtHR has increasingly integrated the “less restrictive means” test into its analysis of the necessity and proportionality of human rights restrictions.¹⁷⁵ This test is worded in *Mouvement Raelien Suisse v Switzerland* as “the authorities are required, when they decide to restrict fundamental rights, to choose the means that cause the least possible prejudice to the rights in question”.¹⁷⁶ In *Nada v Switzerland* the ECtHR framed the test as “for a measure to be regarded as proportionate and as necessary in a democratic society, the possibility of recourse to an alternative measure that would cause less damage to the fundamental right at issue whilst fulfilling the same aim must be ruled out”.¹⁷⁷ This second formulation appears more

¹⁷³ For a review of some of the many options, see *Journal of Medical Ethics* Special Issue on Organ Donation (2003) 29(3). Although this is now more than a decade old, a lot of the suggestions remain pertinent. Also see BMA Medical Ethics Committee, *Building on Progress: Where Next for Organ Donation Policy in the UK?* (2012).

¹⁷⁴ See eg. D. Shaw, D. Georgieva, B. Hasse *et al*, ‘Family Over Rules? An Ethical Analysis of Allowing Families to Override Donation Intentions’ (2017) 101(3) *Transplantation* 482-487. The reasons for the current high rates of family veto will be considered in Chapter 6.

¹⁷⁵ E.Brems & L.Lavrysen, ‘Don’t Use a Sledgehammer to Crack a Nut’: Less Restrictive Means in the Case Law of the European Court of Human Rights’ (2015) 15 *Human Rights Law Review* 139–168, 140 [‘Less Restrictive Means’].

¹⁷⁶ (App no. 16354/06) (2013) 56 EHRR 14 [75].

¹⁷⁷ (App no. 10593/08) (2013) 56 EHRR 18 [183].

useful as it allows for the possibility that no restriction of the right is needed to fulfil the aim and it demands that a search for a less or non-restrictive alternative is conducted. For a policy of non-consensual donor optimisation procedures to meet the requirements of necessity and proportionality, the possibility of recourse to an alternative policy that would cause less or even no damage to autonomy while fulfilling the aim of achieving an adequate supply of organs must be ruled out by state authorities. In some cases, the Court itself contributes to the search for a less restrictive alternative and makes its own proposals as to what that alternative might involve,¹⁷⁸ implying that their approach might extend to suggestions as to how a less restrictive means of meeting the pressing social need for organs might be achievable.

The ECtHR has previously reached findings of violation of the Article 8 right to private life on the basis that alternatives were available which may not have required a move away from consent. For example, in *Avilkina v Russia*,¹⁷⁹ a case involving the non-consensual disclosure of medical information, the Court recognised that there were alternatives available which included asking for consent.¹⁸⁰ Commenting that the state authority nevertheless chose to order the disclosure without giving the applicants “an opportunity to object or to agree”,¹⁸¹ the Court found that their Article 8 rights had been violated.¹⁸² Similarly, NHSBT is choosing to implement donor optimisation procedures without giving ODR registrants an opportunity to object or to agree. Alternatives are available which include asking for consent. Should the ECtHR’s approach in *Avilkina* be followed, the current lack of consent for donor optimisation procedures could be upheld as an Article 8 violation before the balancing stage has even been

¹⁷⁸ Eg. *Glor v Switzerland* (App no. 13444/04) (2009, unreported) [95]; see evaluation by *Brems & Lavrysen*, ‘Less Restrictive Means’ as earlier, 155.

¹⁷⁹ (App no. 1585/09) (2013) ECHR 515.

¹⁸⁰ *Ibid* [48].

¹⁸¹ *Ibid* [48].

¹⁸² *Ibid* [54].

reached. It certainly weakens any claim that the lack of consent in current donor optimisation procedures is necessary and proportionate in the public interest.

The less restrictive means test is now a part of the ECtHR's approach to qualified rights but it does not replace the balancing exercise nor eliminate concerns about overriding human rights in what is deemed to be the public interest. The wide margin of appreciation afforded to the state in determining where to "str[ike] a fair balance" between competing interests in other cases relating to medical technologies could be to the detriment of patients identified as potential organ donors.¹⁸³ However, as patients dying from brain injuries are vulnerable, being unable to protect themselves from exploitation by those in a dominant position, the ECtHR's pronouncements in other cases demand that any balancing exercise should prioritise their fair and proper treatment.¹⁸⁴ Although the ECtHR do not always clarify what the balancing exercise should entail, autonomy at the end of life is an important facet of an individual's identity and it should be afforded significant weight. However, how this should be balanced against the aim of achieving an adequate supply of transplantable organs is a troublesome question, particularly as these two factors have not been demonstrated to be in opposition.

Although references to balancing within the ECtHR jurisprudence seem to suggest that individual rights are to be viewed in opposition to public interest aims, it may be that the doctrine of proportionality is flexible enough to accommodate a view of individual rights as contributing to the public interest. A conception of proportionality appears to be emerging in ECtHR jurisprudence which treats human rights as an important component of the collective

¹⁸³ See eg. *Evans v United Kingdom* (App no 6339/05) (2008) 46 EHRR 34 [91].

¹⁸⁴ *Young, James and Webster v United Kingdom* as earlier [63].

values of the international community.¹⁸⁵ Establishing whether or not an interference is proportionate, under this conception, involves a process of consideration of the relationship between the individual's rights, the interests of others in the community, the collective interests of society, and the collective values of the international community.¹⁸⁶ This is more in line with the liberal conception of the public interest outlined towards the start of this chapter and may reduce the risk of state interests quashing what are alleged to be universal and inalienable rights.

Individual autonomy and achieving an adequate supply of organs seem, on the face of it, to be factors that can't be balanced because they are incommensurable. However, a common point of comparison does exist and that is the social importance of each consideration.¹⁸⁷ It is of importance to society that the human right to autonomy is protected and it is also of importance to society that an adequate supply of organs is achieved. Both of these contribute to the public interest and, because of the relationship between autonomy and trust,¹⁸⁸ the social importance of including autonomy in donor optimisation policy may be so great as to determine the overall direction of the public interest. The inclusion of autonomy may contribute to the achievement of the supply of organs, and the social importance of the latter may only be achievable with the recognition of the social importance of the former. Not only should alternatives to the current policy of a lack of consent for donor optimisation procedures be actively considered to avoid unnecessary and disproportionate restrictions on

¹⁸⁵ See E. Cannizzaro & F. De Vittor, 'Proportionality in the European Convention on Human Rights' in R. Kolb & G. Gaggioli, *Research Handbook on Human Rights and Humanitarian Law* (Edgar Elgar Publishing, Cheltenham UK, 2013) 125-145 for a thorough review of the ECtHR jurisprudence.

¹⁸⁶ Ibid.

¹⁸⁷ A. Barak, "Proportionality and Principled Balancing," (2010) 4 *Law & Ethics of Human Rights* 1-16, 7-8; T. Endicott, 'Proportionality and Incommensurability', Chapter 14 in G. Huscroft, B. Miller, G. Webber, *Proportionality and the Rule of Law: Rights, Justification, Reasoning* (CUP 2014) 311-342, 317-318.

¹⁸⁸ Refer back to Chapter 2 on the relationship between autonomy, trust and the supply of organs.

autonomy, but they may also be the most effective means of achieving the public interest aim sought.

My exploration of the concept of the public interest and the doctrine of proportionality in this chapter leads me to the conclusion that the state is under a positive obligation to investigate less restrictive alternatives to the current policy of non-consensual donor optimisation procedures and, if at all feasible, to incorporate autonomy into donor optimisation policy. This is necessary not only to protect the interests of potential organ donors but crucially also those of the many patients whose lives are curtailed by the currently inadequate supply of transplantable organs. I argue in the final chapter of this thesis that the uncertainty regarding the impact of policy change should not prevent the state from fulfilling their ethical and legal obligation to incorporate autonomy into donor optimisation policy.

6. Incorporating Autonomy into Donor Optimisation Policy

Introduction

Throughout this thesis, I have made one overarching claim. This claim is that a system of specific advance consent to ante-mortem donor optimisation procedures should be introduced. I have argued this on several different grounds. First, it is required to promote the autonomy of individuals registering on the NHS Organ Donor Register (ODR) and the dignity and integrity of patients identified as potential organ donors.¹ Second, it is needed to safeguard and promote trust in the organ donation programme and secure the supply of organs for transplantation.² Third, autonomy is an important contributing factor to the public interest in donor optimisation procedures.³ In addition to these ethical arguments, I have argued that a system of specific advance consent is required as part of the duty of care owed to potential ODR registrants⁴ and to enable best interests to take on its ascribed role as the legal justification for donor optimisation procedures.⁵ Finally, I have argued that human rights law places the state under an obligation to avoid placing a disproportionate burden on potential organ donors by assessing alternatives to the current policy of non-consensual donor optimisation procedures and implementing the option that is the least restrictive means of meeting transplantation needs.⁶

¹ Chapter 2 on Autonomy, Trust and the Supply of Organs.

² Ibid.

³ Chapter 5 on The Public Interest in Donor Optimisation Procedures.

⁴ Chapter 3 on Autonomy, Informed Consent, and Advance Decision-Making.

⁵ Chapter 4 on The Best Interests of the Potential Organ Donor; also see S-J. Brown, 'The Legal Justification for Donor Optimisation Procedures' (2016) 11(4) *Clin Ethics* 122-129 ['Legal Justification'].

⁶ Final two sections of Chapter 5.

In this final chapter, I aim to address the concern that my proposed system of specific advance consent could put people off from registering as organ donors and reduce the supply of organs.⁷ I argue that, on the contrary, this system is needed to encourage people to trust in the organ donation programme and to secure the adequate supply of organs that is so desperately needed. I support the ethical and legal arguments I have presented throughout this thesis with empirical evidence of a positive correlation between knowledge of the organ donation process and willingness to donate organs. I further argue that the principle of democratic presumption⁸ demands that the autonomy of ODR registrants should not be restricted in the absence of evidence as to the necessity of this restriction.

In the latter part of this chapter, I argue that the uncertainty regarding the impact on the supply of organs of my proposed system of specific advance consent is just one example of a problem inherent to any change in healthcare policy. The impact of any policy change cannot be definitively determined in advance, yet this should not prevent policies promoting patient rights from being introduced. I consider what role health impact assessments may have in informing policy-makers of the likely impact of my proposed system of specific advance consent and in refining the system to secure both patient rights and societal interests.⁹ I argue that the acceptability of incorporating autonomy into donor optimisation policy is probably greater than might be supposed by policy-makers and that the ill-informed

⁷ This concern is expressed by P. Murphy in 'Optimizing Donor Potential in the UK' (2011) 6 *Clin Ethics* 127-133, 128 ['Optimizing Donor Potential']; the UK Donation Ethics Committee (UKDEC) also expressed concerns that a system of informed consent could put people off registration, see UKDEC, *An Ethical Framework for Controlled Donation after Circulatory Death* (2011) p.55, [3.1.1.] & Recommendation 31 ['An Ethical Framework']..

⁸ As explicated by J. Harris in 'Sex Selection and Regulated Hatred' (2005) 31 *J Med Ethics* 286-288, 287 ['Regulated Hatred'] & 'No Sex Selection Please, We're British' (2005) 31 *J Med Ethics* 291-294, 292 ['No Sex Selection'].

⁹ See WHO European Centre for Health Policy, 'Health Impact Assessment: Main Concepts and Suggested Approach – Gothenburg Consensus Paper' (Brussels, European Centre for Health policy, 1999) p.1 & 4 ['Gothenburg paper']; also J. Kemm, 'Origins and Outline of Health Impact Assessment' Chapter 1 in J. Kemm, *Health Impact Assessment: Past Achievement, Current Understanding, and Future Progress* (OUP, 2012) p. 3-13, 3 ['Origins and Outline'].

fear that it will damage the supply of organs should not prevent informed consent standards from being introduced.

Trust, Knowledge, and Willingness to Donate

Trust in the organ donation programme is crucial to securing the supply of organs for transplantation.¹⁰ In the UK, that supply of organs remains inadequate for the needs of the thousands of patients waiting for a transplantable organ.¹¹ Contributing factors to the inadequacy of the supply of organs are the low levels of registration on the ODR (36%) and the high levels of family refusal of organ donation (37%).¹² Both of these factors are at least partially caused by a lack of public trust in the organ donation programme. People are not registering as organ donors as they are concerned about the way they may be treated as a result, with the most common concern being that healthcare professionals might not do everything they can to save their life.¹³ This concern regarding the standard of care provided to donors, together with a lack of trust in the organ donation process, has also been reported by relatives approached for their consent to deceased organ donation.¹⁴ The high levels of trust that are necessary to secure an adequate supply of organs do not currently exist in the UK. This needs rectifying if the supply of organs is to increase, and an important part of this is

¹⁰ For empirical evidence supporting this claim see L. Boulware, L. Ratner, J. Sosa, L. Cooper *et al*, 'Determinants of Willingness to Donate Living Related and Cadaveric Organs: Identifying Opportunities for Intervention' (2002) 73 *Transplantation*, 1683–1691, 1684 & 1687–1689; also D. McGlade, C. McClenahan, B. Pierscionek, 'Pro-Donation Behaviours of Nursing Students from the Four Countries of the UK' (2014) 9(3) *PLOS ONE* e91405, 1–6,4.

¹¹ NHS Blood and Transplant, *Organ Donation and Transplantation Activity Report 2016/2017*, preface and p.2, available at <https://www.organdonation.nhs.uk/supporting-my-decision/statistics-about-organ-donation/transplant-activity-report/> (accessed 11/09/17) ['Activity Report'].

¹² *Ibid*, p.114 & p.126, table 13.1.

¹³ Optimisa Research, *Understanding Current Attitudes and Behaviours Towards Organ Donation Within England* (NHSBT research report, 2013) p.30 Figure 8 ['Understanding Current Attitudes'].

¹⁴ See eg. A. Ralph, J. Chapman, J. Gillis, J. Craig *et al*, 'Family Perspectives on Deceased Organ Donation: Thematic Synthesis of Qualitative Studies' (2014) 14 *Am J Transplant* 923–935, 927 ['Thematic Synthesis'].

addressing the misconceptions that people hold about the organ donation process.¹⁵

However, the provision of accurate factual information about the organ donation process will only improve trust if it improves the public's confidence that they will only be treated in ways that they have agreed to. To achieve this, organ procurement policy has to be based on individual choice.

Amongst the most common reasons given by people who support organ donation for not registering on the ODR are a lack of information (15%), a lack of trust (9%), and concern about being viewed as an organ donor rather than a patient (7%).¹⁶ The first two reasons are unsurprising considering the lack of readily available information on the consequences of registration and the limited understanding of the UK population of the ODR's function.¹⁷ As 14% of the population believe that signing up on the ODR covers the use of their bodies for medical testing, and 11% believe it covers live donations,¹⁸ there is a clear need for public education about the consequences of registration on the ODR. This includes information on how registration may impact on their care whilst still alive. In addition, there is a need to re-evaluate the ODR's role in determining end-of-life care. The concern that an ODR registrant may be viewed as an organ donor rather than a patient does, since the introduction of policies that identify and treat patients as potential organ donors before death, have a basis in reality and should not be viewed as a misconception. Instead, policy-makers should pay heed to the reasons people are not registering as organ donors and re-evaluate their policy of not requiring specific consent for interventions before death.

¹⁵ See Optimisa Research as above, *Understanding Current Attitudes*, p.32.

¹⁶ Optimisa research as above, *Understanding Current Attitudes* p.44 Figure 14 (all statistics cited from this report are based on 2013 research).

¹⁷ *Ibid*, p.42 Figure 13.

¹⁸ *Ibid*, p.42.

Accurate factual knowledge about organ donation, including the process that it involves, has been found to be positively correlated with willingness to become an organ donor.¹⁹ For example, the majority of respondents in a study of the awareness of and attitudes towards organ donation in the black community in London, a population with a significant degree of mistrust towards organ donation, stated that if information were available about organ donation it could change their attitudes because they would be in a position to make an informed decision.²⁰ One of the fears expressed was that people could be kept alive just “so they can whip their organs out”.²¹ Being in a position to make an informed decision about life-sustaining but non-therapeutic procedures could allay the fear that people will be kept alive regardless of their wishes.

Research demonstrates not only a link between knowledge and stated attitudes, but also a positive association between accurate knowledge about organ donation and actual donor registration rates.²² For example, one study found that respondents who had mostly correct knowledge regarding different aspects of organ donation and transplantation were more likely to be either registered donors or state that they wanted to become donors than

¹⁹ M. Hyde & S. Chambers, ‘Information Sources, Donation Knowledge, and Attitudes Toward Transplant Recipients in Australia’ (2014) 2 *Prog Transplant* 169-177, 169 [‘Information Sources’]; see also J. Falomir-Pichastor, J. Berent & A. Pereira, ‘Social Psychological Factors of Post-Mortem Organ Donation: A Theoretical Review of Determinants and Promotion Strategies’ (2013) 7(2) *Health Psychology Review*, 202-247; S.V. Haustein, M.T. Sellers, ‘Factors Associated With (Un)Willingness to be an Organ Donor: Importance of Public Exposure and Knowledge’ (2004) 18(2) *Clin Transplant* 193-200; R.L. Horton, P.J. Horton, ‘Knowledge Regarding Organ Donation: Identifying and Overcoming Barriers to Organ Donation’ (1990) 31(7) *Soc Sci Med* 791-800 [‘Knowledge Regarding Organ Donation’]; M.J. Irving, A. Tong, S. Jan *et al*, ‘Factors That Influence the Decision to be an Organ Donor: A Systematic Review Of The Qualitative Literature’ (2012) 27(6) *Nephrol Dial Transplant* 2526-2533 [‘Systematic Review of Literature’].

²⁰ C. Davis, G. Randhawa, ‘“Don't Know Enough About It!": Awareness and Attitudes Toward Organ Donation and Transplantation Among the Black Caribbean and Black African Population in Lambeth, Southwark, and Lewisham, United Kingdom’ (2004) 78(3) *Transplantation* 420-5, 423-424 [‘Don't Know Enough’].

²¹ *Ibid*, 423.

²² Hyde & Chambers, ‘Information Sources’ as above, 169; see also Horton and Horton, ‘Knowledge Regarding Organ Donation’ as above .

those with mostly incorrect knowledge.²³ This confirms the results of an earlier study that found positive correlations between knowledge of organ donation and both carrying and requesting an organ donor card.²⁴ The generality of the finding to different aspects of knowledge about organ donation is implied by the repeated finding in different studies of a positive correlation between factual knowledge about organ donation and registration as a deceased organ donor, despite the fact that these studies are assessing different aspects of knowledge.²⁵ However, this may depend on whether the knowledge being assessed is that of a policy that is viewed negatively or positively.

Knowledge that patients identified as potential organ donors undergo non-therapeutic interventions at the end of life, even though they have not agreed to this, is likely to be viewed negatively and be associated a decreased willingness to donate. It reinforces the fears expressed by some individuals that they will be treated merely as a source of organs at the end of life if they register as an organ donor.²⁶ In contrast, knowledge that registered organ donors will only undergo procedures to optimise their chances of successful organ donation if that is what they have chosen in advance is likely to be viewed more positively and increase willingness to donate. The positive association between knowledge of the organ donation process and willingness to donate is reliant, in the circumstances of ante-mortem donor optimisation policy, on that policy being based on individual choice.

Although the physical risks of ante-mortem donor optimisation procedures differentiate them from other aspects of the organ donation process, knowledge of these risks

²³ H. Pham, C. Spigner, 'Knowledge and Opinions About Organ Donation and Transplantation Among Vietnamese Americans in Seattle, Washington: A Pilot Study' (2004) 18 *Clin Transplant* 707–715, 711.

²⁴ Horton and Horton, 'Knowledge Regarding Organ Donation' as above .

²⁵ R. Ryckman, V. Van den Borne, B. Thornton, J. Gold, 'Value Priorities and Organ Donation in Young Adults' (2005)35(11) *J App Soc Psychol* 2421-2435, 2432.

²⁶ See eg. Davis & Randhawa as earlier, 'Don't Know Enough', 423.

is not likely to cause a drop in registration numbers if members of the public are afforded the option whether or not to take these risks. Those who are not willing to take these risks could still be afforded the option to register for deceased organ donation itself.²⁷ Increased public awareness of the organ donation process and an emphasis on individual choice, including options to consent to or refuse changes to end-of-life care, is likely to encourage more people to visit the ODR website and register their informed decision regarding deceased organ donation itself and the steps they would be willing to undergo to become a deceased organ donor. Those who are only willing to begin the organ donation process after death can have confidence that their end-of-life care will not be altered by the act of registration. This is not currently the case, and although the public has not been informed about ante-mortem donor optimisation procedures, there are trust issues surrounding the end-of-life care of ODR registrants.²⁸ These trust issues are likely to be resolved rather than exacerbated by the provision of accurate information and the opportunity to record an autonomous decision regarding ante-mortem donor optimisation procedures.

Lack of knowledge about the organ donation process and a lack of trust in the organ donation programme are modifiable barriers to organ donation.²⁹ A systematic review of the effectiveness of interventions designed to improve registration rates, intention/willingness to donate or knowledge about organ donation in ethnic minority groups concluded that educational interventions are effective in increasing donor registration rates.³⁰ For example, one study assessing the effectiveness of an educational intervention found a significant

²⁷ As I suggested in Chapter 3, the information provided to ODR registrants should include the chances of successful organ transplantation if the organ donation process is not initiated until death is diagnosed.

²⁸ See Optimisa Research, *Understanding Current Attitudes*, p.30 Figure 8 as discussed earlier in this section.

²⁹ S. Deedat, C. Kenten, M. Morgan, 'What are Effective Approaches to Increasing Rates of Organ Donor Registration Among Ethnic Minority Populations: A Systematic Review' (2013) 3 *BMJ Open* 2013 e003453, 1-13,1 ['Systematic Review'].

³⁰ Deedat et al , 'Systematic Review' as above, 1-2 & 7.

improvement in several different aspects of knowledge, including the knowledge that doctors would not make less effort to keep them alive if they were a registered donor, as well as increased willingness to donate one's own or one's relatives' organs after death.³¹ African Americans had a significantly greater increase in trust following the intervention than other ethnic groups.³² The authors of this study and the systematic reviewers both identified that for an increase in knowledge to result in actual registration, some sections of the population may require multiple educational interventions that reinforce and build on each other over time.³³ It is important, however, that these educational interventions are targeted towards accurate factual knowledge of organ donation policy. People can remove their names from the ODR at any time, and "educating" people with a view to increasing registration rather than improving the accuracy of their knowledge could potentially backfire if that education constrains rather than develops their autonomy.

As current policy is to seek the relatives' consent regardless of registration status,³⁴ their trust is also crucial to achieving an adequate supply of organs.³⁵ The fact that 100 families in 2016-2017 overruled a known decision to become an organ donor, including 89

³¹ C. Callender, M. Hall, D. Branch, 'An Assessment of the Effectiveness of the MOTTEP Model for Increasing Donation Rates and Preventing the Need for Transplantation – Adult Findings: Program Years 1998 and 1999 (2001) 21(4) *Semin Nephrol* 419-428, 424-425, tables 2& 4.

³² *Ibid*, 425.

³³ *Ibid*, 426; *Deedat et al*, 'Systematic Review' as above, 11.

³⁴ G. Webb, N. Phillips, S. Reddiford, & J. Neuberger, 'Factors Affecting the Decision to Grant Consent for Organ Donation: A Survey of Adults in England' (2015) 99 *Transplantation* 1396–1402, 1397; see also D. Shaw, D. Georgieva, B. Haase, D. Gardiner *et al*, 'Family Over Rules? An Ethical Analysis of Allowing Families to Overrule Donation Intentions' (2017) 101(3) *Transplantation* 482-487 ['Family Over Rules?']; N.B. The Code of Practice on the Human Transplantation (Wales) Act 2013 (Human Tissue Authority, May 2014) clarifies that although there is no legal right of veto in Wales, the Specialist Nurse on Organ Donation is not obliged to proceed with donation if the family object [116 & 121].

³⁵ Abolishing the family veto is one potential means of improving the supply of organs. However, such a change in policy and practice would not mean that relatives' trust is no longer relevant as being removed from the decision could cause distress and generate distrust, which could become more widespread within society. See *Shaw et al* 'Family Over Rules' as above; J. Wispelaere & L. Stirton, 'Advance Commitment: An Alternative Approach to the Family Veto Problem in Organ Procurement' (2010) 36(3) *J Med Ethics* 180-183.

decisions registered on the ODR,³⁶ and a further 1072 families refused consent in the absence of a known decision to donate,³⁷ suggests that relatives also harbour low levels of trust in the organ donation programme. This may be compounded by emotional exhaustion and concerns about bodily mutilation.³⁸ Some relatives reportedly want more information, for example about brain death, but are afraid to ask.³⁹ This contributes to the high rates of refusal and to the subsequent regret of refusal that affects approximately one third of refusing relatives.⁴⁰ Receiving adequate and understandable information about organ donation is reported to be the strongest predictor of family consent, with one study finding that consenting relatives were over twice as likely as refusing relatives to report that information had been adequate and understandable.⁴¹ Information is crucial to securing the sense of security in their expectations that is needed to give informed consent to organ donation.

Prior knowledge of an expressed wish to become an organ donor is significantly associated with family consent to organ donation.⁴² The outcome of nondonation is more likely in the absence of ODR registration and in families who lack knowledge or are uncertain

³⁶ NHSBT, *Activity Report* as earlier, p.126, table 13.1.

³⁷ The NHSBT, *Activity Report* as above, page 125, figures 13.1 & 13.2, records a total of 1172 cases of family refusal out of 3144 approaches. This includes 13 families who did not support deemed consent, out of 33 cases where deemed consent applied, see p.126, table 13.1.

³⁸ L. Siminoff, M.B. Mercer, G. Graham *et al*, 'The Reasons Families Donate Organs for Transplantation: Implications for Policy and Practice' (2007) 62(4) *J Trauma* 969- 978.

³⁹ J. de Groot, M. Vernooij-Dassen, C. Hoedemaekers, A. Hoitsma *et al*, 'Decision Making by Relatives About Brain Death Organ Donation: An Integrative Review' (2012) 93(12) *Transplantation* 1196-1211, 1197 ['Integrative Review']; M. Sque, T. Long, S. Payne, 'Organ Donation: Key Factors Influencing Families' Decision-Making' (2005) 37(2) *Transplant Proc* 543- 546; A. Aldridge, B.S. Guy, 'Deal Breakers in the Organ Donation Request Process' (2008) 23(4) *Health Mark Q* 17-31.

⁴⁰ De Groot *et al*, 'An Integrative Review' as above, 1196-1197; J.R. Rodrigue, D.L. Cornell, R.J. Howard, 'The Instability of Organ Donation Decisions by Next-of-Kin and Factors That Predict it' (2008) 8(12) *Am J Transplant* 2661-2667; L. Jacoby, J. Jaccard, 'Perceived Support Among Families Deciding About Organ Donation for Their Loved Ones: Donor vs Nondonor Next of Kin' (2010) 19(5) *Am J Crit Care* e52-e61, e56['Perceived Support'].

⁴¹ Jacoby & Jaccard, 'Perceived Support' as above, e57.

⁴² W. Walker, A. Broderick, M. Sque, 'Factors Influencing Bereaved Families' Decisions About Organ Donation: An Integrative Literature Review' (2013) 35(10) *West J Nurs Res* 1339-1359, 1346 ['Integrative Literature Review'].

of donation wishes.⁴³ In addition, prior knowledge about organ donation itself is positively correlated with family consent to organ donation.⁴⁴ Conversely, lack of knowledge or the holding of incorrect beliefs about organ donation is associated with family refusal.⁴⁵ Family decisions are also influenced by relatives' own views towards organ donation, with relatives who intend to become an organ donor themselves being more likely to consent to the donation of their loved ones' organs.⁴⁶ People are more likely to agree to donate either their own or their relative's organs if they have prior knowledge of organ donation.⁴⁷ Raising public knowledge of organ donation is critical to overcome the fears and concerns of grieving relatives and to address the problem of continued high rates of family refusal.⁴⁸

The empirical research demonstrating a positive correlation between knowledge of organ donation, trust in organ donation, registration on the ODR, and family consent to organ donation appears robust. The chain of factors that leads to an adequate supply of organs starts with information. Information generates knowledge, understanding and trust. Trust increases willingness to donate and registration numbers on the ODR. Knowledge of donation wishes and of organ donation itself increases family consent to organ donation. The empirical evidence supporting each of these claims, including that provided by several good quality reviews of the research literature,⁴⁹ negates any claim that telling people about donor optimisation procedures will cause organ donation rates to plummet. On the contrary, it supports my ethical and legal arguments that NHSBT is under an obligation to introduce informed consent standards for the organ donation process. These informed consent

⁴³ *Walker et al* as above, 'Integrative Literature Review' 1348.

⁴⁴ *Ibid*, 1348.

⁴⁵ *Ibid*.

⁴⁶ *Ibid*.

⁴⁷ See sources given earlier in this section, including *Hyde & Chambers*, 'Information sources'; *Horton & Horton*, 'Knowledge Regarding Organ Donation'.

⁴⁸ *Walker et al* as earlier, 'Integrative Literature Review', 1354.

⁴⁹ *Craig et al* as earlier, 'Thematic Synthesis'; *Irving et al* as earlier 'Systematic Review of Literature'; *Deedat et al* as earlier, 'Systematic Review'; *Walker et al* as earlier, 'Integrative Literature Review'.

standards are critical to securing improved rates of registration on the ODR and improved rates of family consent.

Democratic Presumption

As Harris asserts, “what is fundamental to liberal democracy is that the liberty of citizens should not be abridged unless good and sufficient cause can be shown as to why this is required”.⁵⁰ This “democratic presumption” demands that the state should not restrict the freedom of citizens “to make their own choices in light of their own values” unless they can produce these “good and sufficient justifications”.⁵¹ In line with my interpretation of human rights law,⁵² this principle which is at the core of liberal democracies places the burden of proof on those restricting the freedom of individuals to make their own choices.⁵³ The state and its authorities are aware that current organ procurement policy does not meet informed consent standards and that this is a restriction on the autonomy of ODR registrants.⁵⁴ NHSBT has not provided good and sufficient justifications for restricting the autonomy of ODR registrants and potential organ donors, and is acting out of fear of the consequences rather than on the basis of empirical, ethical, or legal evidence.

Following the democratic presumption, ODR registrants who wish to make an autonomous decision about donor optimisation procedures should not be made to “qualify for this freedom by showing that its exercise provides substantial demonstrable benefits”.⁵⁵ The impact on the supply of organs of an autonomy-based framework for donor optimisation

⁵⁰ J. Harris, ‘No Sex Selection Please, We’re British’ (2005) 31 *J Med Ethics* 286-288, 287, [‘No Sex Selection’].

⁵¹ J. Harris, ‘Sex Selection and Regulated Hatred’ (2005) 31 *J Med Ethics* 291–294, 291 & 292, [‘Regulated Hatred’].

⁵² See section on Human Rights in Chapter 5.

⁵³ Harris, ‘No Sex Selection’ as earlier, 287.

⁵⁴ Murphy, ‘Optimizing Donor Potential’ as earlier, 128; UKDEC, *An Ethical Framework* as earlier, p. 55 [3.1.1].

⁵⁵ Harris, ‘Regulated Hatred’ as earlier, 294.

procedures cannot, like any other changes to healthcare policy, be definitively determined in advance but that should not prevent it being introduced. As I argued in Chapter 5, organ procurement policy-makers have not established that the policy of non-consensual donor optimisation procedures is necessary to secure the supply of organs.⁵⁶ In the absence of this evidence as to its necessity, the democratic presumption demands that autonomy is incorporated into donor optimisation policy – even if the impact on the supply of organs is uncertain.

Harris argues in relation to embryonic sex selection, “the way forward for a tolerant society respectful of autonomy, and mindful of the democratic presumption, would surely be to license the activity with regular monitoring and follow up studies”.⁵⁷ Although affording individuals the freedom to make their own choices about sex selection would have different consequences to affording individuals that freedom in relation to donor optimisation procedures, the democratic presumption is defined broadly to cover all healthcare policies that could potentially restrict that freedom. Under current policy, sex selection is not allowed whereas donor optimisation procedures are being implemented without consent. Donor optimisation procedures are going to occur whether or not autonomy is introduced into healthcare policy. However, good and sufficient reasons for not incorporating autonomy into donor optimisation policy have not been produced. Fear or inertia, in the absence of evidence that introducing autonomy would reduce the supply of organs, does not provide an adequate defence to the current policy of non-consensual donor optimisation procedures. Harris’s argument that the way forward is to introduce a policy based on self-determination, with regular monitoring and follow-up, applies equally to donor optimisation policy.

⁵⁶ See particularly final section of Chapter 5.

⁵⁷ Harris, ‘No Sex Selection’ as earlier, 288. Quote adapted for clarity.

Under the democratic presumption, it is presumed that both individual rights and societal interests can be met. In the absence of evidence to the contrary, individual rights take precedence. This principle of precedence of individual interests⁵⁸ is the basis for allowing individuals to determine for themselves whether or not to become deceased organ donors. The opt-in system for organ donation, despite its many flaws in practice,⁵⁹ is based on the premise that individual autonomy takes precedence over the supply of organs. Likewise, the law on how potential organ donors can be treated at the end-of-life, if not always practice and policy, is based on the premise that what that patient would have wanted takes precedence over societal interests.⁶⁰ Unless the state intends to enact prohibitive legislation removing potential organ donors from the group of patients to whom the principle of precedence of individual interests applies, it is obliged to plan policy change to promote individual autonomy first and foremost. Societal interests can still be taken into account, but only after the primary justification of patient rights has been met.

The Impact of Policy Change

A problem inherent to introducing any changes to healthcare policy is that it is only after the policy change has been implemented that its factual consequences become apparent, and only with the passage of time that it is possible to determine its impact on the interests of those affected by that policy change.⁶¹ The concern that the impact on the supply of organs of a system of specific advance consent cannot be known in advance is just one example of this inherent problem. The existence of similar concerns regarding other policy changes does not prevent any changes to healthcare policy from ever being made. The underlying justification for making that policy change, whether that be to promote patient rights and/or to protect

⁵⁸ This principle is discussed in section on Social and Psychological Interests in Chapter 4.

⁵⁹ Refer back to section on Organ Donation System in Chapter 1.

⁶⁰ See section on Social and Psychological Interests in Chapter 4.

⁶¹ This is the same with legislative change, see J. Gerards, 'How to Improve the Necessity Test of the European Court of Human Rights' (2013) 11(2) *I.CON* 466-490, 476-477.

societal interests, means that new healthcare policies are introduced on the basis of their likely effectiveness in meeting these justifications.

Ex ante evaluations such as health impact assessments may be useful to inform policy-makers of the potential impact of a healthcare policy change and to facilitate adaptation of the proposed policy to meet the justifications for the policy, maximise the positive impacts, and mitigate the potentially negative consequences.⁶² These evaluations may include consideration of the available evidence of the anticipated impact of the policy on people's health,⁶³ together with the opinions and expectations of people who may be affected by the policy.⁶⁴ They may include the provision of information to decision-makers and affected people, which may result in more understanding of the likely effects of the policy on healthcare outcomes.⁶⁵ Perhaps most importantly for my question of the likely effect on the supply of organs of a system of informed consent, this informed and evidence-based understanding allows the policy to be adapted to maximise the positive impact on individual autonomy whilst minimising the risk to the supply of organs.

Health impact assessments lend themselves to the situation in which NHS Blood and Transplant (NHSBT) could either continue with the *status quo* or introduce a policy of specific advance consent, as it allows for the comparison of the health impacts of two or more options.⁶⁶ This comparison is what is required under the doctrine of proportionality to

⁶² WHO European Centre for Health Policy, 'Health Impact Assessment: Main concepts and Suggested Approach – Gothenburg Consensus Paper' (Brussels, European Centre for Health policy, 1999)p.1 &4 ['Gothenburg paper']; See *Gerards*, 476-477 as above for an analysis of how such evaluations may be treated within ECtHR jurisprudence; see also J. Kemm, 'Origins and Outline of Health Impact Assessment' Chapter 1 in J. Kemm, *Health Impact Assessment: Past Achievement, Current Understanding, and Future Progress* (OUP, 2012) p. 3-13, 3 ['Origins and Outline'].

⁶³ *Gothenburg paper* as above, 5; *Kemm*, 'Origins and Outline' as above, 3.

⁶⁴ *Gothenburg paper* as above, 5.

⁶⁵ *Ibid.*

⁶⁶ *Kemm* as earlier, 'Origins and Outline' p.5.

determine whether there are any less restrictive means of securing the supply of organs.⁶⁷

Because the less restrictive means test is concerned with alternatives that are less restrictive of autonomy, prohibitive legislation authorising non-consensual donor optimisation policy can be excluded as an option. It is clearly deficient in meeting the justification of individual autonomy, and the health impact assessment process allows it to be ruled out on this basis at an early stage.⁶⁸ The remaining options, continuing without an unequivocal legal justification for current policy or introducing a system of specific advance consent, are both of uncertain effectiveness in terms of securing the supply of organs. A health impact assessment would acknowledge this uncertainty and provide a best judgement assessment as to the likelihood of each option achieving this desired outcome.⁶⁹ The process could help refine and improve the proposed system⁷⁰ of specific advance consent in order to meet both the primary justification of autonomy and the secondary justification of securing the supply of organs.

The fear that introducing a system of specific advance consent will reduce the supply of organs is not based on any empirical evidence. In reality, the UK population is probably more willing to accept policy change, particularly which furthers their own rights, than might be supposed by organ procurement policy-makers. One way of determining this would be to conduct empirical research into the acceptability of the proposed policy change to members of the public. Although looking into different organ donation policy options, an Australian study concluded that “the public have a stronger attitude for change than policy-makers, advocates, and experts in this area”.⁷¹ As in the UK, there is broad public support for organ

⁶⁷ See final section of Chapter 5.

⁶⁸ *Kemm* as earlier, ‘Origins and Outline’ p.5.

⁶⁹ J. Kemm, ‘Health Impact Assessment of Policy’, Chapter 8 in J. Kemm, *Health Impact Assessment: Past Achievement, Current Understanding, and Future Progress* (OUP, 2012) 81-89, 83 [‘HIA of Policy’];

⁷⁰ *Kemm* as earlier, ‘Origins and Outline’ p.5.

⁷¹ K. Howard, S. Jan, J. Rose, G. Wong *et al*, ‘Preferences for Policy Options for Deceased Organ Donation for Transplantation: A Discrete Choice Experiment’ (2016) 100(5) *Transplantation* 1136-1148, 1147.

donation in Australia but a shortage of deceased donor organs.⁷² As the authors of the Australian study comment, “future policy discussions and options should not be limited by preconceived notions about what is acceptable to the community, rather active and meaningful engagement should be informed by actual community values and preferences”.⁷³ The ill-informed fear that incorporating autonomy into donor optimisation policy will prove unacceptable to the UK population should not prevent a system of specific advance consent from being introduced. However, the actual viewpoints of the UK population may be helpful in designing a system that both promotes individual autonomy and is acceptable to members of the public.

Conclusion

In this chapter, I have addressed a potential problem with my proposed system of specific advance consent to donor optimisation procedures. This is that, despite having a firm ethical and legal foundation in autonomy, it rests on less certain grounds in terms of its likely impact on the supply of organs. I have argued that this uncertainty should not prevent autonomy being incorporated into donor optimisation policy. Furthermore, I have argued that autonomy needs to be introduced to improve trust in the organ donation programme and I have presented empirical arguments to support my claim that information about the organ donation process is likely to have a positive impact on the supply of organs.

The onus is on the state to establish the necessity of their current policy of non-consensual donor optimisation procedures, and it has not done so. Under the democratic presumption, an autonomy-based framework should therefore be introduced. This framework can be planned to minimise any potential risks to the supply of organs, but individual autonomy demands that it is introduced even if these risks cannot be entirely eliminated.

⁷² Ibid, 1136.

⁷³ Ibid, 1147.

Empirical research into the acceptability of a system of specific advance consent for donor optimisation procedures may help policy-makers overcome their fear of detrimental impact. However, the ethical and legal arguments I have presented throughout this thesis are robust enough, even without this specific data on the viewpoints of the UK population, to support my claim that autonomy needs to be introduced as a matter of some urgency into UK donor optimisation policy.

Although it appears axiomatic that autonomy needs to be incorporated into donor optimisation policy, there has been surprisingly little in the academic literature on the subject. Few authors have recognised the consequences of the limited information provided to ODR registrants on the interests of the potential organ donor.⁷⁴ Although one article concludes that it “may... help to have more precise options in terms of what people can register for”,⁷⁵ there has been no detailed examination of what demands the ethical and legal principle of autonomy places on NHSBT. The original arguments I have presented within this thesis are the first to provide this detailed examination and also the first to address the complex relationship between the autonomy of ODR registrants, the interests of potential organ donors, and the interests of potential organ recipients.

The originality of my arguments on the value of incorporating self-determination into donor optimisation policy lies first in my recognition of the correlation between the autonomy of ODR registrants and the dignity and integrity of patients identified as potential organ donors.⁷⁶ Second, it lies in my exploration of the relationship between the autonomy of ODR registrants and the long-term maintenance of trust in the organ donation programme. My

⁷⁴ Some of the few to do so are A. Gathani, G. Moorlock & H. Draper, ‘Pre-mortem Interventions for Donation After Circulatory Death and Overall Benefit: A Qualitative Study’ (2016) 11(4) *Clin Ethics* 149-158, 157 [‘Pre-mortem Interventions’] (published concurrently with my arguments in S-J Brown, ‘Legal Justification’ as earlier).

⁷⁵ Gathani *et al*, ‘Pre-mortem Interventions’ as above, 157.

⁷⁶ As discussed in section on Self-determination, Dignity, and Integrity in Chapter 2.

distinction between blind trust and informed trust, and the consequences of the type of trust relied on by the organ donation programme on the supply of organs, highlights the importance of openness and transparency to the supply of organs.⁷⁷ Although trust is recognised as a factor of importance to organ donation,⁷⁸ my thesis is the first to consider in detail what this means for donor optimisation policy.

NHSBT is under a duty of care towards ODR registrants and this duty of care includes providing them with the information that is needed for autonomous decision-making. Again, there is little recognition in the literature that NHSBT is currently failing in its duty of care and no detailed examination of the content of their duty of care. My arguments on the demands placed by this duty of care provide this much-needed examination.⁷⁹ My examination of the attributes distinguishing ante-mortem donor optimisation procedures from deceased organ donation⁸⁰ rejects any claim that these procedures can be dismissed as mere ancillary procedures. My proposed system of specific advance consent is built on the legal recognition of autonomy as the rationale behind obtaining informed consent.⁸¹ Like the information-withholding consultant in *Montgomery*,⁸² NHSBT needs to recognise that it is in an informed consent situation and that this demands they disclose information on the nature, timing, and risks of donor optimisation procedures to allow people to make their own autonomous decisions about their future medical care.

Much of what has been written on the best interests of the potential organ donor is from the perspective of how this legal concept can be interpreted in such a way as to facilitate

⁷⁷ Refer back to last 2 sections of Chapter 2.

⁷⁸ See particularly B. Almassi, 'Trust and the Duty of Organ Donation' (2014) 28(6) *Bioethics* 275-283.

⁷⁹ See particularly section on Informed Consent and the Law in Chapter 3.

⁸⁰ Refer back to section on Realising the Autonomy of Organ Donor Registrants in Chapter 3.

⁸¹ This proposed system is outlined in final section of Chapter 3.

⁸² *Montgomery v Lanarkshire Health Board* [2015] UKSC 11, as discussed in Chapter 3.

organ donation,⁸³ rather than how the system should be changed to provide doctors with the information they need to determine their individual patient's specific wishes in the circumstances. This, as I argued in my examination of the legal concept of best interests, is what is required if organ procurement policy-makers intend to rely on this concept as a legal defence to battery.⁸⁴ My proposed system of specific advance consent thus acts to remedy two legal problems at different points on the temporal trajectory of the potential organ donor. It rights the wrong of NHSBT's failure to fulfil its legal duty of care and it enables the individual determination – as required by law – of the best interests of each patient identified as a potential organ donor.

The original arguments I have presented in this thesis are aimed not only at meeting the individual interests of potential organ donors, but also at meeting the public interest in donor optimisation procedures.⁸⁵ This is a concept that does not appear to have been previously looked at in relation to donor optimisation policy. My evaluation of the role of autonomy in meeting this public interest aims to fill this gap in the literature,⁸⁶ but also to determine whether a system could be designed that incorporates the autonomy of the potential organ donor whilst also meeting transplantation needs. As I argued in Chapter 5, human rights law places the onus on the state to establish the need for the current interference with the Article 8 rights of potential organ donors, which it has failed to do so. The increased emphasis on the less restrictive means test in ECtHR jurisprudence⁸⁷ demands

⁸³ See particularly J. Coggon, M. Brazier, P. Murphy, D. Price *et al*, 'Best Interests and Potential Organ Donors' (2008) 336 *BMJ* 1346-1347 & J. Coggon, 'Elective Ventilation for Organ Donation: Law, Policy and Public Ethics' (2013) 39 *J Med Ethics* 130-134.

⁸⁴ See Chapter 4. Also S-J Brown, 'The Legal Justification for Donor Optimisation Procedures' (2016) 11(4) *Clin Ethics* 122-129.

⁸⁵ See Chapter 5.

⁸⁶ See particularly 2nd & final sections of Chapter 5.

⁸⁷ *Nada v Switzerland* (App no. 10593/08) (2013) 56 EHRR 18 [183]; *Mouvement Raelien Suisse v Switzerland* (App no. 16354/06) (2012) 56 EHRR 14 [75]; E. Brems & L. Lavrysen, 'Don't Use a Sledgehammer to Crack a Nut': Less Restrictive Means in the Case Law of the European Court of Human Rights' (2015) 15 *Human Rights Law Review* 139-168, 140.

that the alternative policy of introducing informed consent standards for potential ODR registrants is scrutinised with a view to determining its potential impact on the supply of organs. The state has not established the necessity of the current policy of non-consensual donor optimisation procedures. In the absence of evidence as to the necessity of abandoning informed consent, my proposed autonomy-based framework should be introduced to secure the rights of potential organ donors and to safeguard the supply of organs from the detrimental consequences of public distrust.

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