WOULD THE IMPLEMENTATION OF AN ALTERNATIVE CONSENT SYSTEM FOR ORGAN DONATION IN ENGLAND, SCOTLAND AND NORTHERN IRELAND BE BENEFICIAL FOR DONATION RATES WHILST SIMULTANEOUSLY PROTECTING THE NEEDS OF DONORS? ©

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INTRODUCTION

Organ donation is a controversial, complicated, and, at times, very sensitive issue to deal with, consequently there are many different opinions on how it works best in practice. Ethical, cultural, and religious norms of different countries have necessitated the development of a variety of consent models to facilitate organ donation. This is most evident across Europe wherein there are a variety of models utilised, some differ subtly, others less so, as Governments seek to implement the one which is most effective for their country and its needs. However, most can be linked to three fundamental models; opt in, opt out and mandated choice. The first of these is used in a majority of States in the United States of America[1] as well as being the system that is currently practiced in England, Scotland and Northern Ireland and is established through the notion of explicit consent. This system is discussed in greater detail through the first chapter as it explains and analyses the current legislation which surrounds organ donation in the UK[2], it will also highlight the events which occurred around the turn of the millennium which acted as a catalyst for the only really significant change to the organ donation system since its inception. Moreover, the first chapter will provide evidence of how the opt in system developed from a paternalistic approach, facilitated by doctors, to the present model, which emphasises consent.[3] Most importantly, it will clarify what is regarded as the fundamental issue with this system; stagnating donor registration numbers leading to a deficiency in procurement.

The opt out model, like its explicit consent counterpart, imposes no obligation upon a person to register their wishes. However, unlike the opt in system, if a person does not opt

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[1] J McIntosh 'Organ Donation: Is an Opt in or Opt out System Better?' (24 September 2014) <http://www.medicalnewstoday.com/articles/282905.php> accessed 1 November 2016

[2] Human Tissue Act 2004.

[3] O O'Neill, 'Paternalism and Partial Autonomy' [1984] 10 Journal of Medical Ethics 173 - 178, 176, D Price, 'The Human Tissue Act 2004' (2005) 68 5 MLR 798 - 821, 805.

out of donation they can have their consent presumed for them after death.[4] Objectors stated that the presumption of consent has a severely detrimental impact upon patient autonomy which makes it possibly the most divisive issue associated with this system.[5] These issues are dealt with in the second chapter through examining the notion of autonomy, with an emphasis towards what it is actually understood to be and, in particular, the validity of the argument behind its prevalence in modern medicine. All of this should enable a conclusion to be drawn as to whether presumed consent truly impacts autonomy.

Furthermore, it is accepted that there are multiple variations of the opt out system, as previously alluded to, which differ in accordance with the national law and societal needs of the country. The two most prominent examples are the 'hard' and 'soft' models. The former referred to all legal removal of organs from all adults that die, providing they have not opted out, as adhered to in Austria whereby relatives' interests can be disregarded in favour of donation.[6] This system, whilst controversial, is proving to be successful as the country boasts donation rates of 25 - 30% higher than countries that operate an explicit consent model. However, it has been heavily criticised for its impact on relational autonomy, which is sometimes perceived as a key component to organ donation, as it essentially removes the family from the situation.[7] The latter, referred to as the 'soft' opt out model, is considered much less intrusive as it affords more respect to the wishes of the patient's relatives, often allowing for the right to veto organ donation if no decision is recorded during life.[8] This process is used to determine what the patient would have wanted, but often it is suggested that the family in fact, impose their own views, which do not always mirror those of the patient,[9] as explained when looking at relational autonomy later in this work. While subtle, there are differences with how this adaptation is interpreted across different countries; the key variation often being how readily the relatives are consulted in the matter. In Belgium,

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[4] G Koffman, I Singh, 'Presumed Consent: The Way Forward for Organ Donation in the UK' [2011] 93 Ann R Coll Surg Engl 268 - 272, 269.

[5] C A Erin, J Harris, 'Presumed Consent or Contracting Out' [1999] 25 Journal of Medical Ethics 365 - 366, 365.

[6] The Organ Donation Taskforce, 'The Potential Impacts of an Opt Out System for Organ Donation in the UK' (November 2008) 10.

[7] A Zúñiga-Fajuri, 'Increasing Organ Donation by Presumed Consent and Allocation Priority: Chile' (December 2014) <http://www.who.int/bulletin/volumes/93/3/14-139535/en/> accessed 30 October 2016, G den Hartogh, 'The Role of Relatives in Opt in Systems of Post mortal Organ Procurement' [2012] 15 Med Health Care and Philos 195 - 205, 195.

[8] V English, A Sommerville, 'Presumed Consent for Transplantation: A Dead Issue after Alder Hey?' [2003] 29 Journal of Medical Ethics 147 - 152, 149.

[9] Families Say No to Donation Results in Missed Opportunity for UK Patients' (15 January 2016) https://<www.organdonation.nhs.uk/news-and-campaigns/news/families-saying-no-to-donation-results-in-missed- transplant-opportunities-for-uk-patients/> accessed 19 November 2016.

for example, the legislation does not require the physician to approach the family but they are able to object, although they have to be proactive to ensure objection is noted.[10] Spain employs a very similar system to the one found in Belgium. The Spanish Organ Transplantation Committee produced "*Good Practice Guidelines*"[11], comparable to that which was published by the Human Tissue Authority in the UK[12], explaining that it is good practice for doctors to consult relatives at the time of death to obtain consent.[13] These systems have been positively received by the public of their respective countries, leading to a marked improvement in donation rates, with Spain considered the world leader in that field[14]. However, there are still questions raised over the inclusion of the family in decisions, particularly emphasised by reports suggesting that, in Belgium, doctors feel obliged to consult the relatives, even though it is unnecessary[15]. In response to this, familial autonomy will also be scrutinised within the second chapter, highlighting that the dependence upon it appears to have had a negative impact on donation rates in the United Kingdom, suggesting that there may now be an over reliance on it, so much that it detracts from the original theory of patient autonomy. In contrast, the argument in favour of familial autonomy will be provided, indicating that there may need to be a balance found for it to work effectively.

The opt out system in its entirety will be examined in the final chapter, taking into consideration everything that has been mentioned throughout the dissertation. The benefits, as well as the potential hurdles to the introduction of the system will be identified in order to provide an idea of how the system works in practice. The aforementioned Spanish model will be contrasted with that which is currently in place in England, Scotland and Northern Ireland, providing an example to underscore how effective the opt out system can be when properly executed. To balance this, the reasoning behind the Organ Donation Taskforce's decision against the recommendation of a presumed consent model will be explained to offer further analysis of the system[16]. Similarly, the recently enforced legislation in Wales[17], which saw a switch to a presumed consent system introduced, will

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[10] P Michielsen, 'Presumed Consent to Organ Donation: 10 Years' Experience in Belgium' [1996] 89 J R Soc Med 663 - 666, 663.
[11] Organización Nacional de Transplantes, 'Good Practice Guidelines in the Process of Organ Donation' (2011).
[12] Human Tissue Authority, 'Codes of Practice' https://www.hta.gov.uk/guidance-professionals/codes-practice accessed 2 October 2016.
[13] (n11) 49.
[14] (n11) 5.
[15] (n10) 666.
[16] The Organ Donation Taskforce, "The Potential Impact of an Opt Out System for Organ Donation in the UK (November 2008)
[17] Human Transplantation (Wales) Act 2013.

allow for a closer examination of how a different system might impact organ donation in a more closely related country.

The third model, 'mandated choice', imposes a requirement on every adult to make a decision about their donation wishes, however it has become less relevant over recent years, with it being considered by many as more of an adjunct to a broader consent system, as opposed to one itself.[18] Even supporters of the model have accepted that it would need to be drastically modified to conform to modern day standards and live up to current healthcare requirements[19]. As a result, it will not be considered any further in this work.

Ultimately, the current organ donation model is in dire need of a change. There is a sizeable disparity between the number of patients waiting for an organ transplant and the number of donations each year, resulting in exceedingly long waiting times, unnecessary pressure on the healthcare system and an increase in deaths whilst waiting. It is plausible that smaller alterations to the system could have a modest impact, such as suggestions for better training of doctors or an increase in staffing to have more on-site specialists to obtain appropriate consent[20]. Such submissions will be considered. However, this dissertation will focus on the possible impact that the implementation of an alternative consent system might have upon organ donation in this country. Finally, it will offer a suggestion as to the best course of action based on all the information discussed and considering all the possibilities, but, most prominently, it will establish whether a change in system will protect the needs of donors, such as consent and autonomy, whilst still being beneficial to donation rates and therefore the needs of patients waiting for transplants.

CHAPTER 1 - THE LAW SURROUNDING ORGAN DONATION

The landscape of organ donation in the United Kingdom has evolved significantly, particularly since the millennium. The former legislation was marred in criticism and controversy, ultimately leading to numerous repeals, reforms and new legislation being put in place[21]. As previously explained, the legislation within the UK has changed since the

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[18] (n16) 13.

[19] P Chouhan, H Draper, 'Modified Mandated Choice for Organ Procurement' (2003) 29 3 Journal of Medical Ethics 157 - 162, 161.

[20] PJ Simpson, 'What are the Issues in Organ Donation in 2012?' (2012) 108, British Journal of Anaesthesia i3-i6, i5, NHS, 'Organ Donation Debate' (January2008) <http://www.nhs.uk/news/2007/January08/Pages/Organdonationdebate.aspx> accessed 28 December 2016.

[21] Explanatory Notes to the Human Tissue Act 2004, para 6.

implementation of the Human Transplantation (Wales) Act[22]. Prior to this, all countries in the United Kingdom followed the same 'opt in' system for organ donation; whilst there are minor differences for the application of it in Northern Ireland[23], and it is regulated by a different piece of legislation in Scotland[24], they entail the same fundamental framework[25] that formulates the Human Tissue Act[26].

The Human Tissue Bill[27] was proposed as a direct result of prominent scandals which were uncovered between 1999 and 2000 at the Bristol Royal Infirmary and the Royal Liverpool Children's Hospital (Alder Hey)[28]. Subsequent reports filed by the Kennedy and Redfern Inquiries exposed improper conduct within both hospitals with regards to retention and use of tissue and organs of children, without proper consent from the parents[29]. Further investigations ensued, during which time the Chief Medical Officer produced a report: "*The Removal, Retention and use of Human Organs and Tissue from Post-mortem Examination*", which highlighted and explained the issues that had recently come to the forefront in the media and also offered recommendations as to where changes to the legislation could be made[30]. In 2003, the Isaacs Report uncovered the kind of practices at Alder Hey and Bristol were common and widespread across the country, with some 54,000 organs and body parts of children being retained without obtaining proper consent.[31] During this time, the overriding legislation on tissue removal and use was the Human Tissue Act 1961[32] which, particularly after the release of the reports, received a huge amount of criticism due to the wording of the Act, as it focused primarily on a lack of objection from patients, as opposed to obtaining proper consent, for the removal and storage of their tissue.[33] In many ways it was considered that the law was outdated given the evolution of the medical profession and how they were using cadaveric body parts, alluded to by Gage J in *AB v Leeds Teaching Hospitals NHS Trust*[34], whereby he concluded that, whilst accepting that wrongs were

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[22] Human Transplantation (Wales) Act 2013.

[23] D Price, 'The Human Tissue Act 2004' (2005) 68 5 MLR798 - 821.

[24] Human Tissue (Scotland) Act 2006.

[25] Human Tissue Authority, 'Human Tissue Act 2004', (January 2016) <https://www.hta.gov.uk/policies/human- tissue-act-2004> accessed 4 October 2016.

[26] (n2).

[27] Human Tissue HC Bill (2003-04) [9].

[28] (n21) para 5.

[29] Ibid.

[30] (n21).

[31] Department of Health, 'Human Bodies, Human Choices' (Department of Health, July 2002) 3<http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_

[32] Human Tissue Act 1961.

[33] David Price, 'From Cosmos and Damian to Van Velzen: The Human Tissue Saga Continues' (2003, 11, 1) MedLaw <http://medlaw.oxfordjournals.org/content/11/1/1.long> accessed 27 September 2016.

[34] *AB v Leeds Teaching Hospitals NHS Trust* [2005] QB 506, [2005] 2 WLR 358.

committed on a societal level, the law, as it stood, did not provide any civil or criminal remedy for the case[35]. Clearly the scope for change was being highlighted in the courts, even going back as far as 1972, it was apparent that the 1961 Act was a somewhat flawed piece of legislation that was out of sync with some fundamental principles of English law, particularly autonomy. As Lord Reid commented in *S v McC*[36], "English law goes to great lengths to protect a person of full age and capacity from interference with his personal liberty"[37]. Conversely, the Act revolved more around the notion of medical paternalism, which by definition interfered with a patient's autonomy [38], consequently affecting their liberties.

In response to the issues pertaining to Alder Hey and Bristol, as well as all the controversy, which followed, a consultation paper was issued by the government that accepted the reform recommendations suggested by the Chief Medical Officer in his earlier report. The paper, *"Human Bodies, Human Choices"*[39], as explained in the Human Tissue Bill, "sought issues on a wide range of issues regarding human tissue and what balance might be struck between the needs of research and teaching on one hand and the concerns of families on the other"[40]. Within this, the Department of Health identified eight guiding principles that should underline the new legislation; most notably the propositions of respect, understanding and informed consent [41]. The Bill was not without objection as it was passed through Parliament, as many reports claimed that a change to the system would discourage a progression in medical research[42], this resulted in some concessions being made at the report stage and it is now deemed that these diluted the coherence of the new Act[43].

The Act received Royal Assent in November 2004 and went on to full implementation in 2006. As a result of it coming into force, the Human Tissue Act 1961 along with other laws previously governing tissue use in the United Kingdom were repealed, including the

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[35] Ibid, 752.
[36] *S v McC (Formerly S)* [1972] AC 24, [1970] 3 WLR 366.
[37] Ibid, 43.
[38] O'Neill O, 'Paternalism and Partial Autonomy' [1984] 10 Journal of Medical Ethics 173 - 178, 174.
[39] (n31).
[40] (n27).
[41] (n31) 8.
[42] A Alghrani, R Bennett, S Ost (eds) *Bioethics, Medicine and the Criminal Law* (Cambridge University Press, (2013) 135.
[43] (n23)

Anatomy Act[44], Human Organs Transplants Act[45] and several laws specific to Northern Ireland.[46]

Consequently, the scope of the new legislation was significant, as it aimed to create an overarching authority, which was intended to rationalise the existing regulation of activities like transplantation and anatomical examination.[47] The change from the 1961 Act [48] to the 2004 Act was significant. It has been noted that the 'golden thread'[49] of the new legislation is the notion of consent, which quashed the previous theories of medical paternalism as it put the power of decision back into the hands of the patient. This is emphasised within the opening part of the act, which focused heavily on consent, [50] in particular sections 2 and 3, which set out the new standard of requirement being "appropriate consent" and how it should be obtained from either children[51] or adults.[52] Further explanation of when it is necessary to secure consent follows in schedule 1[53]; outlining the 'scheduled purposes', highlighting situations such as determining the cause of death[54] and transplantation[55]. Part 2 of the Act additionally enforces the latter by establishing a regulatory body; the Human Tissue Authority[56], which is tasked with overseeing and moderating all activities set out under the Human Tissue Act[57], whilst also offering various forms of guidance to physicians[58] and the public[59].

Whilst organ donation within the United Kingdom has existed, in some way, for over one hundred years, it was not until 1979 that the UK Transplant Service was established; a consequence of the merger between National Tissue Typing and Reference Laboratory and National Organ Matching and Distribution Service, which had been regulating previously[60]. Furthermore, it was not until 1994 that the NHS Organ Donor Register was set up to

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[44] Anatomy Act 1984
[45] Human Organs Transplant Act 1989
[46] (n21) para 8.
[47] Herring J, *Medical Law and Ethics* (5th edn, Oxford University Press 2014) 433.
[48] Human Tissue Act 1961.
[49] David Price (n23).
[50] Human Tissue Act 2004, part 1.
[51] Human Tissue Act 2004, s2.
[52] Ibid, s3.
[53] Human Tissue Act 2004, Sch 1.
[54] Ibid, sch 1(2).
[55] HTA (n52) sch 1(7).
[56] Human Tissue Act 2004, s13.
[57] Ibid, s14.
[58] Human Tissue Authority "Codes of Practice"
[59] Human Tissue Authority, 'Guidance for the Public'
[60] 'History of Donation' <http://www.nhs.uk/Tools/Documents/transplant.htm> accessed 2 October 2016.

correlate all registered donor information in to one database and also to allow for new ways to 'opt in' for donation, such as registering when applying for a driver's license[61]. However, it was not long before new measures were put into place to further increase registration numbers as the UK Transplant Service absorbed the United Kingdom Transplant Support Service Authority in 2000, and was subsequently afforded a wider remit to increase organ donation rates[62]. Throughout this time, the 'opt in' system was the focal point of the register, nevertheless, it still operated on the same principle as previously explained, acting in line with the 1961 Act[63] and the concept of 'no rejection' in obtaining human tissue. This was reformed and "streamlined" following the inception of the Human Tissue Act in 2006[64]. The change to the legislation, along with the amelioration of the governing bodies, had the intended result; the UK saw a sharp rise in registered donors in line with the predictions that had been made, much to the surprise of many[65]. Since then, there has been a steady increase over the years, with the most recent figures suggesting that the country has now over 23 million people opted in to the Organ Donor Register, equating to 36% of the population; an increase of 1% on last year[66]. On first examination, it would be justifiable to interpret these numbers as a positive. Indeed, any increase in registered donors should be accepted as a good thing. However, despite this, the United Kingdom is still trailing behind many other European countries in relation to donation per million people (pmp)[67]. The data in this area has revealed that the UK has a deceased donation rate of 21 pmp[68], which includes both donation after brain death and donation after circulatory death, which, again, is an increase on five years ago, but it does leave us some way behind countries such as France (26 pmp), Portugal (27.8 pmp) and Spain (35.3 pmp)[69]. Even though the overall numbers of registered organ donors are on the rise, the issue is that a majority of transplants still have to be taken from donors who have passed as a result of circulatory death. As a consequence, on average, only 2.8 transplantable organs can be retrieved in this situation, compared to 3.9 from donors after brain death[70], this is accepted to be

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[61] Ibid.

[62] White T, *A Guide to the NHS* (Radcliffe Publishing, 2010) 24.

[63] Human Tissue Act 1961.

[64] (n60).

[65] J Neuberger, A Keogh, 'Organ Donation in the UK: How General Practice can Help' (2013) 65 British Journal of General Practice 513 - 514.

[66] NHS Blood and Transplant, 'Organ Donation and Transplantation Activity Data: United Kingdom' (January 2016)

[67] (n65).

[68] NHS Blood and Transplant, "Organ Donation Activity" (2016)

[69] European Commission, 'Journalistic Workshop on Organ Donation and Transplantation' (26 November2014)

[70] Organ Donation and Transplantation "Donation After Circulatory Death"

fundamentally a result of ischaemic injury which damages the organs whilst a person is on life support[71].

All of this means that there are actually fewer organs available. Moreover, it has been observed and emphasised that, while the number of donors has increased over the last 10 years, since the implementation of the Human Tissue Act 2004, the characteristics of the donors has similarly developed over that same period. An example of these changes would be that the proportion of clinically obese donors has risen from 18% to 25%[72] and does not show signs of decreasing. Similarly, the number of deceased donors following trauma death has decreased from 16% to 5%, all of which have a highly adverse impact on the quality of the organs, which has a knock-on effect on transplantations.

Whilst there are very apparent issues with securing enough organs to cope with demand, it could be said that the fundamental problem lies within the system for obtaining consent for the organs in the first place; in other words, the opt in system. Although the changes to the legislation that brought about the new structure with the prioritisation of autonomy and patient choice, as previously explained, were timely, necessary and well received, it cannot be denied that it has relatively substantial flaws. The first of which is echoed in the chasmic difference in numbers between those who have actually opted in to the Organ Donor Register and those who merely claim to be 'in favour of organ donation'. The current level of authorisation for donation having stagnated at 57%[73] whilst 80% of people still claim to support it[74] in the UK. There could, potentially, be many reasons for this gap; it is conceivable that not enough people know how to register, wherein a case could be made for better education on the matter, but it does highlight one of the issues that not enough is being done to aid procurement. Secondly, and possibly one of the more predominant issues, is that the United Kingdom currently has the second highest percentage of family refusal rates in Europe; at present, around 45%[75] of families refused to consent to allow donation to occur. Reports have stipulated that between 2010 and the end of 2015, that family refusal rate has led to an estimated 1200 people missing out on a lifesaving transplant. The source of this can, once again, be traced back to the Human Tissue Act 2004, as the primacy of

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[71] Ibid

[72] (n68)

[73] NHS Blood and Transplant, "Taking Organ Tranplantation to 2020" (2013)

[74] (n65)

[75] (n73)

appropriate consent within the Act extends to nominated representatives[76] or those falling in the category of a 'qualifying relationship'[77] which, in practice, can allow for family members to override any consent decision made before the death of the patient. The problem with this is encapsulated by Jonathan Montgomery, as he highlights the issues with the changing legal landscape of the medical profession[78]and consequently reaffirms the point that the Human Tissue Act's "almost unthinking reliance on individual consent makes it more difficult to obtain organs for transplantation, and thus lessens the number available, to the detriment of society as a whole"[79]. Finally, in addition to this point, it is clear that the overriding power afforded to those who fall in to the categories of 'qualifying relationship' or nominated representative is not one that is widely accept as a positive principle, as over 73% of people claim that the decision to donate should not be capable of being overruled. In turn, this brings into question the validity of the prerequisite for "appropriate consent" that is currently operated on within the United Kingdom. The argument could now be made to say that the current system is essentially stagnating and even in some areas, as already highlighted, going backwards. The system put in place by the 2004 Act[80] was appropriate and successful at the time, however now could be the time to start to explore alternatives.

CHAPTER 2 - PRESUMED CONSENT AND AUTONOMY

The effect that the implementation of a presumed consent model has upon a patient's personal autonomy is often cited as one of the most preeminent arguments against an opt out system for organ donation. Autonomy in itself is generally considered to be the cornerstone of medical ethics, as emphasised by the quote from Schneider, highlighted by Stirrat and Gill; "the law and ethics of medicine are dominated by one paradigm - the autonomy of the patient"[81], mirroring the assumption that it is one of the foremost requirements of an organ donor. This principle, and the belief behind it is also echoed in a famous judgment from Cardozo, a highly respected American judge, when speaking during

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[76] Human Tissue Act 2004, s4.

[77]Human Tissue Act 2004, s27

[78] Jonathan Montgomery, 'Law and the Demoralisation of Medicine' (2006) 26 2 LS

[79] C Foster, J Miola, "Who's in Charge? The Relationship between Medical Law, Medical Ethics and Medical Morality (2015) Med Law Rev 23(4): 529 Lexis Library database accessed 3rd Oct 6th Oct 2016.

[80] Human Tissue Act 2004.

[81] G M Stirrat, R Gill, "Autonomy in Medical Ethics after O'Neill" [2005] 31 Journal of Medical Ethics 127 - 130, 127.

the *Schloendorff* case, stated that "every human being of adult years and sound mind has a right to determine what shall be done with his own body"[82].

To better understand why the concept of autonomy is so pivotal in medical ethics, it must be explained what it is commonly understood to mean. First and foremost, it is considered, by some, as the notion of self-determination or self-governance; in other words, the ability to make decisions for oneself and to be able to lead one's life based on those decisions. Moreover, it is the allowance to make mistakes and not be treated negatively as a result[83]. This is followed by the understanding that, under common law, the body can be property, therefore a person should have the right to do with it as they choose, which is the underlying aspect of autonomy according to Cardozo [84]. One of the key cases that reaffirmed this within the United Kingdom was that of *R v Kelly (Anthony Noel)*[85] which followed the judgment of the Australian case, *Doodeward v Spence*[86], principally deciding that possession and ownership of body parts was lawful. Whilst Gage J held and professed the law in this area to be unclear[87]; the judgment from *Doodeward*[88] was later scrutinised in *Yearworth*[89], yet the Court still upheld a similar principle as was decided in *R v Kelly*[90] in that the body could be considered to be property.

Conversely, if it is true, as the case law would suggest, that a person can own their body and consequently has a freedom of choice over what can be done to it. As the notion of autonomy indicates, a person should be able to do anything they wish, unfettered by legislation. As it is, the law prevents a person from undertaking such acts, most notably the commercialisation of human material[91]. This applies to both the selling and buying of 'controlled material'[92] as specified in the act[93], in particular, for the purposes of this work, organs. It should be highlighted that this is contrary to the principles laid down by common

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[82] *Schloendorff v New York Hospital* (1914) 105 NE 92.

[83] R Gillon, "Ethics Needs Principles – Four can Encompass the Rest and Respect for Autonomy should be " First Among Equals" [2003] 29 Journal of Medical Ethics 307 -312, 310, Mental Capacity act 2005 s1 (4)

[84] (n82)

[85] *R v Kelly (Anthony Noel)* [1999] QB 621, [1999] 2 WLR 384.

[86] *Doodeward v Spence* (1908) 6 CLR 406.

[87] *AB v Leeds Teaching Hospital NHS Trust* [2005] QB 506, [2005] 2 WLR 358, 135.

[88] Ibid.

[89] *Yearworth v North Bristol NHS Trust* [2009] EWCA Civ 37, [2009] 3 WLR 118.

[90] (n85)

[91] Human Tissue Act 2004, s32.

[92] Ibid, s32(1)(a).

[93] (n91) s32(8).

law, particularly in the cases of *Kelly*[94] and *Dobson*[95] wherein it was concluded that, if work and skill had been applied in the removal or retention of a body part, then ownership could be attributed to that body part, therefore a person should be free to act with it as they see fit. Given that the legislation prohibits this, it could be seen as a constraint upon absolute autonomy as it prevents a person from having total freedom over their body, with some critics going so far as to call the notion that we have actual autonomy, under such constraints, "patriarchy's great lie"[96]. The most prominent argument in favour of this constraint is that the reasoning behind it is ethically defensible, given that the commodification of organs is seen as incompatible with human dignity, therefore the limitations are in line with regulations provided by the Council of Europe[97]. Prohibiting it allows for the altruistic element of organ donation to be untainted and subsequently prevents any unconscionable dealings, but if it can be ethically defensible to restrict a living person's autonomy for the sake of unconscionability, in turn it could be proposed that it would be ethically defensible to restrict a person's autonomy after death, when many argue that they no longer have it, in the pursuit of obtaining life-saving organs[98]. Therefore, regardless of the actual impacts a presumed consent model has upon autonomy, which are examined later in this chapter, it could be argued that the reasoning behind the model; to increase the procurement of organs and help save lives, could very well be justified. Irrespective of how 'ethically defensible' the current legislation may be, it is evidence of the constraints which are already attached to a person's freedom over their own body which could invalidate any suggestion that we have absolute autonomy over our bodies. In spite of this, the relevant case law, as previously highlighted, when considered alongside the theory that a person should be free to choose what they do with their body, appears to endorse the concept of autonomy within the scope of medical ethics; the consequence of this being that there is a much greater emphasis placed on consent in the medical profession.

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[94] (n85)

[95] *Dobson v North Tyneside HA* [1997] 1 WLR 596, [1996] 4 All ER 474.

[96] Allan G Johnson, The Gender Knot: Unravelling our Patriarchal Legacy (2edn, Temple University Press 2005) 56

[97] Council of Europe Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine 1997 (Convention on Human Rights and Biomedicine), Chapter VII.

[98] B Hippen, L Friedman Ross, R M Sade, 'Saving Lives Is More Important Than Abstract Moral Concerns: Financial Incentives Should Be Used to Increase Organ Donation' (2009) 88 4, 3, S Giordano, 'Is The Body a Republic?' (2005) 39 470 - 475, 471.

As explained in the first chapter, this has not always been the case, particularly within the United Kingdom. Prior to the current legislation, the Human Tissue Act 1961[99], which governed the removal and donation of human tissue for over forty years, was heavily criticised for facilitating what was considered to be a paternalistic style of medical care[100]. Interference with the actions of the patient, even when it is considered in their best interests, is generally understood to be the characterisation of medical paternalism[101]. However, using this as a defence does not hide the fact that it might be acting contrary to the will of the patient. The scandals mentioned in the first chapter highlighted that the paternalistic style of medical care which became synonymous with the 1961 legislation was damaging the reputation of the medical system[102], particularly tissue transplantation. It was also evident that the drafting of the original Act did not prioritise patient autonomy in line with the development of societal expectations of the concept over time[103]. Consequently, the issues which occurred were the result of out-dated legislation which did not afford enough fastidiousness to the ideals of consent and autonomy. The outcome of which was a seismic shift in legislation that saw the old act repealed and the Human Tissue Act 2004[104] introduced, enforcing the opt in system for donation and what was considered the "golden thread"[105] of the new law; informed consent. This allowed for a restructure in the healthcare process and required physicians to ensure that their patients had all the prerequisite information to be able to make a fully informed decision regarding their treatment[106]. It has been depicted as the "antidote to counter medical paternalism"[107], and thus reviving the long sought after theory of autonomy, putting the decision-making powers back into the hands of the patient. As a result, this principle has been backed up in judgments from the courts, particularly when considering if a patient had been sufficiently informed before making a decision[108] and also providing that a patient has the right to refuse treatment[109].

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[99] Human Tissue Act 1961.
[100] O O'Neill, 'Paternalism and Partial Autonomy' [1984] 10 Journal of Medical Ethics 173 - 178, 176.
[101] A Buchanan, 'Medical Paternalism' (1978) 7 4 Philosophy and Public Affairs 370 - 390, 371.
[102] (n100)
[103] V English, A Sommerville, "Presumed Consent for Transplantation: A Dead Issue after Alder Hey?" [2003] 29 Journal of Medical Ethics 147 – 152, 147.
[104] Human Tissue Act 2004.
[105] D Price, 'The Human Tissue Act 2004' (2005) 68 5 Modern Law Review 798 - 821, 803.
[106] O Corrigan, " Empty Ethics: The Problem with Informed Consent" (2003) 25 3 Sociology of Health and Illness 768 – 792, 768.
[107] Ibid, 769.
[108] *Chester v Afshar* [2004] UKHL 41, [2004] 3 WLR 927.
[109] *Montgomery v Lanarkshire Health Board* [2015] AC 1430, [2015] 2 WLR 768.

However, there are criticisms of this system, in particular the theory that the patient, even when fully informed, may not truly understand what the most appropriate course of action is to take. Chin makes the comment that "an exercise of autonomy may fulfil the patient's expressed desire, but that may not necessarily translate to serving the patient's best interests, if at all"[110], taking a broadly instrumentalist view towards autonomy, but suggesting the importance of it has reached a point where it appears to take priority over the basic principle underlying healthcare. This idea is echoed in the comments made by Lord Diplock in *Sidaway*[111], advocating that an excess of information presented to a patient may, in actual fact, deter them from undergoing the treatment recommended to them[112]. In turn, this can have serious ramifications upon societal needs, most notably in this case, the need for more transplantable organs. It is proposed that these issues could be rectified through the application of better education on the subject, not just when people are contemplating and enquiring about donation, but at a more rudimentary level; in schools and universities, to help pre-empt any misinformation[113]. Such systems have been in place in various other countries, particularly Spain and New Zealand, and have proven to be beneficial, but what is more, it has shown to encourage a more responsible exercise of autonomy[114]. The donation system currently utilised in the UK has already been shown to be stagnating. Therefore, there is a crucial imbalance between the demand for organs and the rate of supply, which subsequently has a significant impact on the lives of those who are currently waiting for donations[115]. Moreover, if the reliance upon absolute patient autonomy was to remain, then it seems unlikely that there will be much change in this approach to organ procurement and donation.

In contrast, as already mentioned, one of the foremost arguments in opposition of a presumed consent model is the negative impact that it appears to have upon autonomy[116]. Commonly, the idea of presumed consent is viewed as a reversion back to the days of paternalistic medical care, wherein a patient must "succumb" to the expertise of the doctor. In some cases, critics of the concept have equated it to a violation of basic personal integrity,

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[110] JJ Chin, "Doctor- Patient Relationship:From Medical Patermalism to Enchanced Autonomy" (2002) 43 3 Singapore Medical Journal 152-155, 154.

[111] *Sidaway v Board of Governors of the Bethlem Royal Hospital* [1985] AC 871, [1985] 2 WLR 480.

[112] Ibid 895

[113] S Giordano, 'Is The Body a Republic?' (2005) 39 470 - 475, 474.

[114] Ibid, 475.

[115]M D D Bell, 'The Human Tissue Act and Consent: Surrendering a Fundamental Principle to Transplantation

[116] C A Erin, J Harris, ' Presumed Consent or Contracting Out' [1999] 25 Journal of Medical Ethics 365 - 366, 365.

almost akin to theft, as it is argued that the State should not presume ownership of an individual's body after death[117]. This idea echoes the common law, whereby it provides that there can be no property in a corpse[118]. Similarly, a further established principle within common law is that if a person is unable to consent to treatment, then it is an offence to act upon them[119], therefore any act carried out under a presumption of consent would be in contravention of this. This principle also appears to reaffirm the concept of autonomy and the importance of it in healthcare, as it seeks to ensure that the patient has been able to take control of what is done to them; again, this is reaffirmed in the case of *X NHS Trust v T*[120] where it was reiterated that a patient should always be given the opportunity to consent. However, this argument is predicated on the theory that a deceased person maintains autonomy after death, which is often a contentious topic. If it is correct that a person no longer exists after death, as is consistent with the government Code of Practice[121] and subsequently reiterated at common law[122], there can no longer be a claim of autonomy over their body therefore it cannot be violated[123]. The standard procedure in post death situations is comparable to that of a will; the wishes of a person must be respected when they are known, reaffirming their autonomy[124]. Conversely when they are not, the family is essentially arguing for the right of survivorship, much like the residue of an estate left undecided, which is afforded to them through legislation and relational autonomy which is based on the belief that a person's wishes can only be understood by reference to their relationships[125]. Setting this aside, as relational autonomy is dealt with at length later, the notion that relatives can claim a right over the deceased's body should be halted by the previous argument that there is no property in a corpse, therefore, as Giordano suggests, the body could become a 'republic'; a public thing for which consent can be assumed as the

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[117] M S V Kumar, S Valsangkar, 'Ethical and Legal Issues of Presumed Consent' (2014) 36 4 Journal of Indian Forensic Medicine 404-406, 405.

[118] (n85)

[119] *Re T (Adult: Refusal of Treatment)* [1993] Fam 95, [1992] 3 WLR 782.

[120] *X NHS Trust v T (Adult Patient: Refusal of Medical Treatment)* [2004] EWHC 1279 (Fam), [2005] 1 All ER 386.

[121] Department of Health "A Code of Practice for the Diagnosis of Brain Stem Death" (1998) <http://webarchive.nationalarchives.gov.uk/20130107105354/http:/www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4035462.pdf> accessed 10 February 2017, T Woodcock, R Wheeler, 'Law and Medical Ethics in Organ Transplantation Surgery' (2010) 92 Ann R Col Surg Engl 282 - 285, 282

[122] *Re A* [1992] 3 Med LR 303.

[123] S Giordano, 'Is The Body a Republic?' (2005) 39 Journal of Medical Ethics 470 - 475, 471, A R Maclean, 'Advance Directives, Future Selves and Decision-Making' (2006) 14 Med Law Review 291 - 320, 292.

[124] Ibid

[125] M A Verkerk, 'The Care Perspective and Autonomy' (2001) 4 Medicine, Healthcare and Philosophy 289 - 294,
292.

procurement of organs is in the public interest[126]. Whilst this seems like a particularly drastic concept as it leans towards the 'hard' opt out by removing the family from the scenario, the issues with relational autonomy, highlighted later, suggest that such an idea could be effective. In practice the opt out model, utilising presumed consent, does not affect autonomy in the way it is often criticised for. The system itself still affords individuals every chance to have their say by removing themselves from the organ donation register, therefore they still have autonomy over the donation of their organs. Whilst it is noted that it adheres to the concept of complete autonomy during life[127], this does lend itself to suggest that the inherent issues are concerned with autonomy after death. This is a particularly complicated and divisive issue as there can be many views, noted by English and Sommerville, as it can be heavily dependent on religious beliefs or particular societal understandings[128] as to what happens when we die. However, the success of it in countries such as Singapore and Spain, both countries with rich religious heritage and vastly different societal norms, implies that this is not an issue once implemented. Similarly, as already discussed, the idea that autonomy continues after death is technically quashed by common law and governmental provisions, which state that a person no longer exists after death[129].

Possibly a more tangible issue that accompanies the presumed consent model is the detrimental impact it has upon relational autonomy[130]. This is generally regarded as an 'umbrella term', but it is premised on the idea that convictions are socially embedded, so relationships form part of our identity, therefore such relationships can be used to understand a person's beliefs or intentions[131]. These worries are predominantly synonymous with the 'hard' opt out system[132], as seen in Austria, wherein the doctors are permitted to remove organs from deceased patients irrespective of the consent of the family[133]. Conversely, less reliance upon relational autonomy in cases such as organ donation could be viewed to be a positive step for medical care. The case of *CM v EJ's Executor*[134] is an example of how expansive the law relating to consent from a nominated

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[126] (n123).
[127] V English, A Sommerville, 'Presumed Consent for Transplantation: A Dead Issue after Alder Hey?' [2003] 29 Journal of Medical Ethics 147 - 152, 149.
Journal of Medical Ethics 147 - 152, 149.
[128] Ibid.
[129] (121).
[130] G Koffman, I Signh, 'Presumed Consent: The Way Forward for Organ Donation in the UK' [2011] 93 Ann R Coll Surg Engl 268 - 272, 269.
[131] C Mackenzie and N Stoljar (eds), *Relational Autonomy* (Oxford University Press 2000) 4.
[132] Ibid.
[133] The Organ Donation Taskforce, 'The Potential Impacts of an Opt Out System for Organ Donation in the
[134] *CM v EJ's Executor* [2013] EWHC 1680 (Fam), [2013] 2 FLR 1410.

representative[135] can be, as it can fall to someone who is not in fact related in any way. As a result of this, it could be argued that a nominated representative may not always act in a way consistent with the will of the patient. Similarly, as organ donation can be a sensitive topic, there is a possibility that some individuals may come under duress from family members to opt one way or the other, suggesting a need for provisions to prevent or invalidate decisions made if they show signs of duress, much like with wills. Moreover, it is highlighted by the NHS that more than 500 families have actually objected to organ donation taking place, despite knowing or being informed their relative was on the NHS Organ Donor Register and wanted to donate[136]. Furthermore, arguments have been made to suggest that if the family is able to object to the donation, against the wishes of the patient, then it allows for it to happen the opposite way and want to have their relation's organs donated in spite of what they may have wanted[137]. Whilst this reversal would, clearly, be beneficial to anyone awaiting organs, it does call into question the strength and legitimacy of the argument behind relational autonomy as it can clearly have a similarly detrimental impact upon a person's absolute autonomy.

This is an issue that would be evident in either of the donation models as both make concessions for relational autonomy when necessary, however the current legislation assumes that an individual and their family share the same views on the topic, which may not always be true. Consequently, it might be that the current legislation goes too far to establish the "golden thread"[138] of consent in medical treatment and, in doing so, it provides for more grave violations of autonomy than the presumed consent system[139]. Moreover, the argument could be made that the 'hard' presumed consent model partially disregards the notion of relational autonomy, replacing it with presumption on behalf of the patient when it is practicable to do so.

The presumption of consent would only become applicable to any medical situation when a person, who has not made an advance decision, lacks capacity to give consent, as legislated

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[135] Human Tissue Act 2004, s4.

[136] 'Families Say No to Donation Results in Missed Opportunity for UK Patients' (15 January 2016) https://<www.organdonation.nhs.uk/news-and-campaigns/news/families-saying-no-to-donation-results-in-missed- transplant-opportunities-for-uk-patients/> accessed 19 November 2016.

[137] T M Wilkinson, 'Individual and Family Consent to Organ and Tissue Donation: Is the Current Position Coherent?' [2005] 31 Med Ethics 587 – 590, 588

[138] (n105).

[139] G den Hartogh, 'The Role of Relatives in Opt in Systems of Postmortal Organ Procurement' [2012] 15 Med Health Care and Philos 195 - 205, 202.

by the Mental Capacity Act[140], stating that a person is lacking capacity when they are unable to make decisions due to an impairment or disturbance in the functioning of the brain[141]. Under these circumstances, the Act presupposes that the doctor should act in the best interests of the patient[142] and in doing so must consider their past or present wishes and any beliefs or values that may influence a decision[143]. The consequence of this is usually that the clinician will turn to a nominated representative, or a family member for guidance. However, as already highlighted by NHS reports and similar independent investigations[144], the evidence suggests that there is a strong possibility that the family will still object, because they are usually acting in accordance with their own beliefs. Some cases, such as *HE*[145], even suggest that a divide in a family will lead to contention regarding which values should be applicable. Scenarios such as this can also raise ethical dilemmas, such as how a doctor can know that a relationship is sufficiently strong enough to be able to take their consent as being appropriate and adequate[146]. Ultimately this could make it difficult for doctors to act, which may make some reluctant to involve themselves with organ donation as a whole[147]. In theory, removing this as a factor of consideration, or at least diluting the dependency upon it, could increase donation rates as it takes away the chance for a patient's consent to be overridden. Therefore, perhaps the presumption of consent would be, in reality, less damaging to individual autonomy than the assumption of relational autonomy.

A final point to be made, somewhat expands on the idea that presumed consent is too similar to the previous legislation[148], but also includes the possibility that clinicians may not approve of it; there is a real worry that enforcing presumed consent might damage the relationship between doctors and patients[149]. Subsequently, it might lead to doctors opting out of donation programmes[150] which would have a drastically adverse impact on donation

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[140] Mental Capacity Act 2005.

[141] Ibid, s2(1).

[142] (n140) s4.

[143] Ibid, s4(6).

[144] K Barber, S Falvey, C Hamilton, D Collett, C Rudge, 'Potential for Organ Donation in the United Kingdom: Audit of Intensive Care Records' (2006) 332 BMJ 1 - 4, 3.

[145] *HE v A Hospital NHS Trust* [2003] EWHC 1017 (Fam), [2003] 2 FLR 408.

[146] B J Walton, L Taylor, M T Nolan, 'Ethical Analysis of Living Organ Donation' (2005) 15 3 Progress in Transplantation 303 - 309, 307.

[147] J K Walter, L Friedman Ross, 'Relational Autonomy: Moving Beyond the Limits of Isolated Individualism' [2014] 133 Pediatrics s16 - s23, s22.

[148] Human Tissue Act 1961.

[149] S Bramhall, 'Presumed Consent for Organ Donation: A Case Against' [2011] 93 Ann R Col Surg Eng 270 - 272, 271.

[150] Ibid

rates, as evidence from the Spanish system, which will be examined further in the next chapter, implies; the greater number of hospitals and doctors involved, the greater the donation rates can be. It would appear that, on the evidence provided, any concerns over the impact of a presumed consent system on autonomy are misguided. Seemingly, there are issues that follow it, such as the ethical implications it carries for doctors, however the obstacles that accompany relational autonomy are evidently more detrimental to patient autonomy. Therefore, it could be suggested that a reform to the relational autonomy concept would be more beneficial to donation rates and more protective of donors and their autonomy.

CHAPTER 3 – THE OPT OUT SYSTEMS

Irrespective of the different impacts upon autonomy, it is apparent, from all the data that is available, that there is a material difference between donation rates when comparing states that operate an opt in system as compared to those with an opt out system[151]. The most preeminent benefit of presumed consent can be derived from these facts; as already briefly mentioned, when directly comparing the figures associated with two organ donation structures, the evidence suggests that operating an opt out system will facilitate a much higher donation rate, often a variance as high as 30%[152], depending on the countries being compared. The obvious merits of this are that a greater number of cadaveric organs are available for transplants, therefore it is common for waiting lists in these countries to be much shorter, leading to more lives being saved. Consequently, this can alleviate significant financial stress from national health services as the cost of supporting a person who is on the waiting list for organ donation is substantially higher per annum than the cost of the transplantation and after care. In some circumstances it can be as much as £21,000 saving per patient, per year[153]. A further advantage of the presumed consent system is the notion that it would alleviate a certain amount of stress on the relatives of donors, as it is recognised that it would likely be a particularly sensitive period for the family, therefore, removing the need to be consulted about organ retention and donation would offer some

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[151] A Zúñiga-Fajuri, 'Increasing Organ Donation by Presumed Consent and Allocation Priority: Chile' (December 2014) <http://www.who.int/bulletin/volumes/93/3/14-139535/en/> accessed 30 October 2016.

[152] Koffman, I Signh, 'Presumed Consent: The Way Forward for Organ Donation in the UK' [2011] 93 Ann R Coll Surg Engl 268 - 272, 269.

[153] S Van der Spiegel, 'Economic Costs and Benefits of Transplantation' (7 October 2013) <http://ec.europa.eu/health/blood_tissues_organs/docs/ev_20131007_co03_en.pdf> accessed 2 November 2016.

relief during this time[154]. Moreover, in the United Kingdom, there is a notable gap between the percentage of people who are registered donors, currently stagnating at around 34% of the population[155], and those that have claimed to be in favour of donation, which stands at about 80%[156]. This could suggest that there are flaws in the current system that are not attracting people to sign up to the donor register, in spite of supporting the practice of donation; an opt out policy would offer the opportunity to bring these figures more into line with each other, as the latter indicates that the public would be, for the most part, receptive of the revitalisation of the system. Similarly, research done by the Organ Donation Taskforce found that 60% of the public would be in support of a presumed consent system[157]. The Taskforce, which was set up to investigate the issues surrounding organ donation in the UK and subsequently create an advisory report to the Government on their findings[158]. It produced unequivocal data to show that an opt out system can work by including donation statistics from countries such as Spain[159], which will be examined later, that is considered to be the world leader in the field of organ procurement and donation[160] and coincidentally utilises a soft opt out model.

However, the conclusion that was made in the advisory report from the Organ Donation Taskforce recommended against the adoption of a system of presumed consent under any guise, rejecting the evidence that they had already set out[161]. Multiple reasons were provided within the report as to why a change in system was not endorsed such as the potential legal issues, as it could "create difficulties clinically and might be open to successful legal challenge under the European Convention on Human Rights"[162], also highlighting concern over the potential monetary impact that might result from the need to inform the public and also record all the prerequisite information[163]. The idea that a change

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[154] Consent / Authorisation Best Practice Development Group, 'Approaching the Families of Potential OrganDonors' (Best Practice Guidance, March 2015) 5.

[155] NHS Blood and Transplant, 'Organ Donation and Transplantation Activity Data: United Kingdom' (January 2016) <https://nhsbtdbe.blob.core.windows.net/umbraco-assets/1067/united_kingdom.pdf> accessed 22 September 2016.

[156] J Neuberger, A Keogh, 'Organ Donation in the UK: How General Practice can Help' (2013) 65 British Journal of General Practice 513 - 514, 513.

[157] (n151) 4.

[158] P G Murphy, M Smith, 'Towards a Framework for Organ Donation in the UK' [2012] 108 British Journal of Anaesthesia i56 - i67, i58.

[159] The Organ Donation Taskforce, 'The Potential Impacts of an Opt Out System for Organ Donation in the UK' (November 2008) 22.

[160] Organización Nacional de Transplantes, 'Good Practice Guidelines in the Process of Organ Donation' (2011).

[161] (n152).

[162] (n159) 13.

[163] (n159) 20.

in the legislation could open the door to potential claims for breach of human rights is a sizeable issue. Whilst there is no direct violation under either the Human Rights Act[164] or the European Convention on Human Rights[165] (ECHR), as neither contain any provisions relating to healthcare, there could be an argument made that it is in contravention of article 8 of the ECHR[166], the right to respect for private and family life[167], which is also incorporated in the Human Rights Act[168]. There have been cases brought for similar reasons, for example in *R v Chief Constable of South Yorkshire*[169] it was contested that the retention of DNA, in this case fingerprints, without knowledge or consent was a breach of the appellant's article 8 rights. This case was unsuccessful, nevertheless a successful but controversial verdict was given in an identical case through the European Court of Human Rights[170]. These judgments, whilst circumstantially different, could imply that the European courts do not act favourably in scenarios where consent has not been prioritised, therefore reinforcing the concerns proposed by the Organ Donation Taskforce[171] the consequence of which being that the Government would appear to be more vulnerable to successful legal proceedings if a claim was brought after the implementation of a presumed consent model. Whilst there is no firm evidence from the courts to suggest that a claim under Article 8 against a presumed consent system would be accepted, the cases mentioned, and others like it, may act as a platform for potential claims to be made, consequently opening the proverbial floodgates. It seems that the Organ Donation Taskforce is implying that the application of an opt out model might facilitate more litigation, particularly if the new system was not universally approved of, conversely this is an issue that is not readily apparent with the current system.

Possibly the foremost reason opposing the change which is offered by the Organ Donation Taskforce, is the idea that the introduction of opt out legislation for organ donation may not lead to an increase in donation numbers[172]. Once again, this argument is made in spite of the large number of statistics put forward in the report which indicate to the contrary, such as the success of it in Spain, Portugal and Belgium[173], all of which have donation rates

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[164] Human Rights Act 1998.
[165] European Convention on Human Rights 1950.
[166] European Convention on Human Rights 1950, art 8.
[167] J M Cartwright-Shamoon, 'Human Rights and Presumed Consent or Organ Donation in the UK' (2008) 77 3 Ulster Medical Journal 206, 206.
[168] (n163) Sch 1, part 1, art 8.
[169] *R (on the application of S) v Chief Constable of South Yorkshire* [2004] UKHL 39, [2004] 1 WLR 2196.
[170] Case 30563/04 *S v United Kingdom* (2009) 48 EHRR 50.
[171] (n159).
[172] (n159) 23
[173] Ibid.

significantly over 25 per million people (PMP) compared to the UK which is barely over 20 pmp[174]. The basis for their argument is grounded in the examples where the implementation of an opt out system has not been as successful. One focus is on the issues which occurred in Brazil, wherein the law was enforced in 1997 but subsequently abolished in 1998, although the opt in legislation was not officially in place until 2001[175], citing the mistrust of physicians as the main reason for the reversion back to an opt in system, however in this case it was a 'hard' opt out system which was put in place[176]. The main problems were that doctors in Brazil were not providing adequate discussion with patients regarding how the process of donation will occur and often they would be reluctant to operate within 'hard' law imposed; refusing to act unless family consent was obtained. Furthermore, given a majority of the country resides in a state of poverty, they could not afford the forms of personal identification; passports or drivers licenses, which were relied upon to make their wishes known[177]. This is evidence of how hard systems may not actually be beneficial as it substantiates that it can have a negative impact on the ethics of the practitioners. In contrast, in Sweden a softer approach to the same system was adopted, but still they have one of the lowest donation rates per million people in the world, and the lowest of the opt out models in Europe[178]. The suggestion from these examples, and the conclusion that the Organ Donation Taskforce has attempted to submit, is that a change in organ donation legislation from the current opt in model to one which entails opting out, would not be beneficial in any way to either the patients or society and the medical profession as whole as it may not provide a higher yield of organs and may inspire distrust in the healthcare system. However, whilst this could be seen as a logical conclusion to come to, it must be noted that those two examples offer something of an anomaly in respects to how the implementation of an opt out system for organ donation is usually received. Most countries that have adopted any type of presumed consent model for organ procurement and donation have witnessed an increase in donation numbers, as all the facts available

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[174] European Commission, 'Journalistic Workshop on Organ Donation and Transplantation' (26 November 2014) <http://ec.europa.eu/health/blood_tissues_organs/docs/ev_20141126_factsfigures_en.pdf> accessed 1 October 2016

[175] L Shepherd, R E O'Carrol, E Ferguson, 'An International Comparison of Deceased and Living Organ Donation/Transplant Rates in Opt in and Opt out Systems: A Panel Study' (2014) 12 131 BMC Medicine 1 - 14, 4.

[176] A Rithalia, C McDaid, S Suekarran, L Myers, A Snowden, 'Impact of Presumed Consent for Organ Donation Rates: A Systematic Review' (2009) 338 British Medical Journal, 7.

[177] G B Neto, A K Campelo, E N da Silva, 'The Impact of Presumed Consent Law on Organ Donation: An Empirical Analysis from Quantile Regression for Longitudinal Data' (2007) Latin American and Caribbean Law and Economics Association Annual Papers, 10.

[178] (n174).

suggest[179]. Conversely, the figures that are commonly associated with the studies conducted could be manipulated to appear more favourable by omitting certain details. Not mentioning the type of population a country has alongside the figures, for example, can be misleading, as this can have a direct effect on the suitability of the organs available. For example, the UK has an ageing population, with nearly 20% over the age of 65[180] and a relatively low mortality rate, both of which are factors that can drastically reduce the suitability of the organs retrieved[181]. As a result of this, it can seem as though the organ donor and transplant rates are low because of other extenuating factors, such as low registration numbers, when the reality could be that the healthcare system is, in essence, too effective. This is implied by research conducted by the Netherlands Institute or Health Services Research, which has shown that there is a distinct correlation between countries with high mortality rates having high donation rates and low donation rates in those areas with low mortality rates[182]. It is unlikely that the numbers are being twisted in such a way, however this does provide a potential reason for why some developed countries with strong healthcare systems, such as Sweden, may have lower comparative donation rates than its comparators. Finally, the advice from the Organ Donation Taskforce suggested that steps should be taken to introduce a similar framework to that seen in Spain, however with the need for a change in legislation; focussing on incentives and targets with a need for additional budgeting.

It is well documented that Spain is the world leader in organ donation[183] with a current donation rate of 35.3 donations per million people[184]. The success that Spain has developed in this area is accredited to two tributaries of the Spanish Health Department, the first of which is the Organización Nacional de Trasplantes (ONT); having been set up in 1989[185], ten years after the initial legislation to institute the opt out system was introduced, it

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[179] (n176).

[180] Office for National Statistics, 'Overview of the UK Population: February 2016' (26 February 2016) <http://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/articles/overviewoftheukpopulation/february2016> accessed 6 November 2016.

[181] (n156).

[182] R Coppen, R D Friele, R L Marquet, S K M Gevers, 'Opting-Out Systems: No Guarantee for Higher Donation Rates' (2005, 18, 11) Transplant International 1275, 1277.

[183] (n161).

[184] European Commission, 'Journalistic Workshop on Organ Donation and Transplantation' (26 November 2014) <http://ec.europa.eu/health/blood_tissues_organs/docs/ev_20141126_factsfigures_en.pdf> accessed 1 October 2016.

[185] B Miranda, M Fernández Lucas, C de Felipe, M Naya, J M González Posada, R Matesanz, 'Organ Donation in Spain' Nephrology Dialysis Transplantation (1999) 14 3, 15.

developed a three tiered, hierarchical management structure within the network of recognised donation hospitals which become responsible for the procurement of organs, operating regionally and then having to report nationally. The coordinators that oversee each area are also responsible for internal audits, whilst external audits are carried out by experts from different regions[186], all of which is imposed to ensure quality assurance is maintained throughout the donation process, in turn garnering public acceptance and approval. The second health department which is often commended in relation to organ donation within Spain is the medical training programme. Once again accepted as the world leader, the University of Barcelona is considered as 'the international benchmark' for training in transplantation and donation[187]. A final contributing factor to be highlighted is the budgeting that is afforded to organ donation within Spain. As it acts as an entity separate from the Health Department, a consequence of the three levels of coordination, it has separate funding which is divided differently depending on the regional areas, however for the most part it is paid in accordance with organ procurement activity for the previous year; essentially acting as an incentive.

Possibly the best example to highlight is that of Wales; having recently passed new legislation[188] to implement soft opt out model for organ donation. Application of the Act meant that many aspects of the Human Tissue Act[189] which, until that point, governed the donation and transplantation of human tissue throughout the UK, were repealed. A consequence of the drastic change meant that there was a necessary period of campaigning to ensure that everyone who would be affected by the legislation was aware and sufficiently informed, mirroring one of the issues highlighted by the Organ Donation Taskforce report[190]. Thus far it has proved successful, with a nearly 45% increase in organs donated since the legislation was first introduced; between 1st December 2015 and 31st May 2016, over half the organs donated were from cadaveric patients that had their consent presumed as they neither opted in or out. Furthermore, the number of people on the transplant

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[186] Organ and Tissue Authority, 'International Approaches to Organ Donation Reform' (November 2013) <http://www.donatelife.gov.au/sites/default/files/OTA_Fact_Sheets_-_International_approaches_to_organ_donation_reform_November_2013.pdf> accessed 4 November 2016

[187] Ibid.

[188] Human Transplantation (Wales) Act 2013.

[189] Human Tissue Act 2004.

[190] (n163).

waiting list has reduced by nearly 38%[191]. Most importantly, there have yet to be any cases against the government as a result of the new act.

In contrast, it has already been explained how the donation rates within the UK are stagnating and, in spite of the efforts by the government to enforce basic changes as recommended to them, it appears that organ donation rates are starting to hit a ceiling, with the trend of donation figures appearing to slow to almost a halt[192]. The initial attempts to increase donation which followed the recommendations by the Organ Donation Taskforce saw positive results[193]. However, given the recent statistics that have been released in regards to Wales[194], as it is about the closest comparator, the rest of the UK could get to see how a change of the donation system might be received. Also, given how promising the numbers have been to this point and how successful similar systems have been in the past, it may be time to accept that the opt out system is the most logical step towards higher rates of organ procurement and, subsequently, donation. This has been further echoed in the increase in national Governments actively switching to an opt out system over recent years, most notably Wales in 2015 and even more recently France, which switched to this this type of system at the beginning of 2017[195]. Similar to the Welsh system, the recentness of the switch in France has not afforded much in the way of reliable statistics, nevertheless it is interesting to see that the Government is attempting to enforce the system for a second time, after having substantial issues the first time[196]. This is a clear statement from the French Government that drastic action needed to be taken in order to rectify the issues that are occurring in the donation sector, also suggesting that any negative connotations that followed the system previously can be countered or explained to garner public support. It is possible that the same could be said for the rest of the United

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[191] Health in Wales, 'We Must Continue to Improve Rates of Organ Donation in Wales, says Vaughan Gething' (17 October 2016) <http://www.wales.nhs.uk/news/42956> accessed 28 October 2016.

[192] NHS Blood and Transplant, 'Organ Donation and Transplantation Activity Data: United Kingdom' (January2016) <https://nhsbtdbe.blob.core.windows.net/umbraco-assets/1067/united_kingdom.pdf> accessed 22 September 2016.

[193] NHS Blood and Transplant, 'Taking Organ Transplantation to 2020' <http://www.nhsbt.nhs.uk/to2020/resources/nhsbt_organ_donor_strategy_long.pdf> accessed 13 November 2016, 5.

[194] (n191).

[195] K Willsher, 'France Introduces Opt out Policy on Organ Donation' (2 January 2017) <https://www.theguardian.com/society/2017/jan/02/france-organ-donation-law> accessed 13 January 2017.

[196] S Bramhall, "Presumed Consent for Organ Donation: A Case Against" [2011] 93 Ann R Col Surg Eng 270 - 272, 271.

Kingdom, especially considering that France, with donation rates of 26 pmp[197], significantly higher than the UK, saw and acted on the issue in the same way that Wales did, meanwhile England, Scotland and Northern Ireland remain stagnant.

CONCLUSION

The opening of this dissertation proposed that the subject of organ donation is at times contentious, complicated and often very emotive and therefore sensitive to deal with. This was emphasised immediately in the first chapter as it highlighted the reaction to the Alder Hey and Bristol Hospital scandals. Such a reaction that it started a change in the landscape of organ donation across the United Kingdom. The first chapter explored this change to identify the key developments that occurred; one of the most preeminent being a switch to an explicit consent model, which has been referred to as the "golden thread" of the legislation[198] which subsequently quashed any notion of medical paternalism that remained after the previous issues. Similarly, new strategies enforced in an attempt to improve donation rates, such as being able to register when applying for a driver's license which worked initially. However, the current situation is a different picture, with registration rates stagnating, an increase in clinically obese donors and more families refusing to allow donation, the struggle to meet the demand for organ transplants is becoming a sizeable problem.

The right to autonomy, and subsequently consent, has been recognised as one of the most fundamental needs for potential donors which makes it key to, and therefore a significantly contested part of, any debate concerning alternative consent systems. The second chapter dealt with this issue in detail, highlighting that the change in system in the United Kingdom was a direct result of the previous legislation not affording enough respect to the personal autonomy of the patient[199]. What is also made clear is how imperative autonomy is to the healthcare system and medical law as a whole, reaffirmed through a variety of common law judgments, particularly the claim that a patient should always be given the

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[197] (n174).

[198] D Price, 'The Human Tissue Act 2004' (2005) 68 5 MLR 798 - 821, 801.

[199] Human Tissue Act 1961, David Price, 'From Cosmos and Damian to Van Velzen: The Human Tissue Saga Continues' (2003, 11, 1) MedLaw <http://medlaw.oxfordjournals.org/content/11/1/1.long> accessed 27 September
2016.

opportunity to consent[200]. Nevertheless, the second chapter also provides the argument that the concept of absolute autonomy might, in fact, be misguided as a result of the restrictions imposed on what a person can do with their body and the controversy which surrounds ownership of the body. Furthermore, it is explained that there is a common misconception regarding the actual impact of a presumed consent system upon the general understanding of patient autonomy and that the only real issue follows after a person has passed away without making their wishes known whereby autonomy should cease to exist and therefore relational autonomy takes over. Although, the argument is made that relational autonomy is not wholly beneficial and can, in fact, lead to many controversial issues and, in practice, seems to favour the protection of doctors and their ethics as opposed to patient autonomy.

The final chapter noted the benefits of the introduction of an alternative consent system for organ donation. What comes to be most apparent is the sizeable variance between the success of opt in and opt out models, as it is shown that the majority of countries, particularly developed countries, have superior donation rates when utilising the opt out system[201]. Moreover, it appears that the majority of the British public would be in favour of the switch[202]. This is by no means a conclusive argument, however the final chapter also highlights countries that have recently made the change to an opt out system: Wales and France in particular, both of which seem to have had positive receptions to the new system.

Fundamentally, the issue inherent in the system is not the number of registered donors the government has at any one time. Under this condition, the current system could be considered a success with over 23 million people signed up to the organ donor register. The issue is procurement. A higher procurement rate leads to more donations, therefore more transplantations, which leads to more lives saved. Even with the registration numbers, England, Scotland and Northern Ireland have cumulatively one of the lowest donation rates in Europe, significantly behind the leaders such as Spain and Portugal[203]. What has been highlighted in this dissertation is that there are notable barriers to donation in this country,

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[200] *X NHS Trust v T (Adult Patient: Refusal of Medical Treatment)* [2004] EWHC 1279 (Fam), [2005] 1 All ER 386.

[201] G Koffman, I Singh, 'Presumed Consent: The Way Forward for Organ Donation in the UK' [2011] 93 Ann R Coll Surg Engl 268 - 272, 269.

[202] A Zúñiga-Fajuri, 'Increasing Organ Donation by Presumed Consent and Allocation Priority: Chile' (December 2014) <http://www.who.int/bulletin/volumes/93/3/14-139535/en/> accessed 30 October 2016.

[203] The Organ Donation Taskforce, 'The Potential Impacts of an Opt Out System for Organ Donation in the UK' (November 2008) 23.

one of the most prominent being relational autonomy, with misconceptions about donation through other systems also an underlying issue.

A lot of this work details how these barriers are presenting a problem to donation, but by no means does this mean they should be removed or ignored. The introduction provided two distinctly different approaches to the 'opt out' system for organ donation; the first of which, the 'hard' model, would essentially remove all of these barriers and, the statistics suggest, would greatly increase donation rates. However, this is likely to be at the expense of the needs of the donors as it deprives them and their families of seemingly all liberties. In contrast, the 'soft' model appears to provide all the benefits of presumed consent, whilst still paying adequate respect to the requirements of the donor. What needs to be understood is that, even though there is an unquestionable need for more donated organs, the act of donation is a noble and wholly altruistic one. Consequently, any change to the system would have to balance the needs of the donors as well as the interests of patients waiting for donations, to ensure it remains to be trusted.

The implementation of an opt out system, based on all the facts and evidence provided throughout this piece of work, would seemingly be very beneficial to donation rates and if it were to be operated properly, with the utmost care and attention, the prerequisite needs of donors could be protected. Consequently, it would seem like the most logical course of action. Nevertheless, there are still efforts that could be put in place to bolster the current system, as seen in the Spanish model, such as more investment, both time and money, providing more information and even setting procurement targets for hospitals. Similarly, one of the most overlooked assets the Government currently has is the changes happening around them; some may argue that they are falling behind by not making changes similar to those recently seen in Wales and France. Nonetheless, what this allows them to do is make a more informed decision as to the viability of an alternative consent system by identifying the success of those systems closer to home.

To conclude; yes, an alternative consent system would be beneficial to donation rates whilst still protecting the needs of donors. However, whilst there are still other options available to explore within the current system, it is unlikely that a change will take place. Although, if those options prove successful, there would be no need for a change.