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Mental capacity and 'opt out' for organ donation: Principled presumptions?

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Abstract

In recent years, Wales and England have introduced so-called 'opt out' organ donation systems with the passing of the Human Transplantation (Wales) Act 2013 and Organ Donation (Deemed Consent) Act 2019, respectively. Both Acts stipulate various excepted persons, including based on age, residency, and mental capacity. The mental capacity exception raises concerns as it is, we argue, at odds with our ordinary understanding of mental capacity per the Mental Capacity Act 2005. Whilst the Mental Capacity Act 2005 commits to a functionalist approach, the same cannot be said for the opt out legislation. Rather, both the opt out Acts create mental capacity exceptions that tacitly require the adoption of a status-based approach, which is reinforced by the accompanying Codes of Practice. This article therefore contributes to a body of literature that questions the supposed legal commitment to functionalism and to an aspect of the organ donation debate that has been neglected. We argue that the move to a status-based approach is a significant deviation and requires a clear supporting argument that remains absent. There is a short-term need, then, for the Codes of Practice relating to both the Mental Capacity Act 2005 and both opt out Acts to be revised and reduce the risk of confusion and error.

Keywords
Human Transplantation (Wales) Act 2013, mental capacity, Mental Capacity Act 2005, opt out, organ donation, Organ Donation (Deemed Consent) Act 2019

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Introduction

In recent years, Wales and England[1] have both moved to so-called ‘opt out’ systems of organ donation by way of the Human Transplantation (Wales) Act 2013 (HTWA 2013) and Organ Donation (Deemed Consent) Act 2019 (DCA 2019),[2] respectively[3] – moves which have been subject to significant debate.[4] Within the framing of the new statutes are various exceptions, preventing opt out applying to certain groups, including children,[5] those not ordinarily resident for a sufficient period,[6] and those lacking capacity.[7] In general, the groups excluded comprise those less likely to be aware of the change in law and its consequences for them. Their exemption from the remit of opt out, then, is a protective measure, removing (or minimising) the risk of them being exploited or having their autonomy violated. This is rooted in the strong public awareness justification associated with opt out systems, grounded in respect for autonomy per ordinary conceptions of informed consent.[8]

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1. Whilst some readers may find ordering the nations in this way slightly jarring to read, we do so in recognition of the chronology of the changes to organ donation policy.
2. It is important to note that the DCA 2019 does not introduce a new statutory regime. Rather, it acts to amend the Human Tissue Act 2004.
3. As have the other UK nations, which will be considered later. For now, our focus is on Wales and England.
4. Even before either system was introduced, there had been debate as to the need for such a system. See Constantinos Simillis, ‘Do We Need to Change the Legislation to a System of Presumed Consent to Address Organ Shortage?’, *Medicine, Science and the Law* 50 (2010), pp. 84–94; Adnan Sharif, ‘Presumed Consent Will Not Automatically Lead to Increased Organ Donation’, *Kidney International* 94 (2018), pp. 249–251. Since implementation, the beginnings of evaluation can be seen. See Andreas Albertsen, ‘Deemed Consent: Assessing the New Opt-Out Approach to Organ Procurement in Wales’, *Journal of Medical Ethics* 44 (2018), pp. 314–318; Jordan Alexander Parsons, ‘Ensuring Appropriate Assessment of Deemed Consent in Wales’, *Journal of Medical Ethics* 45 (2019), p. 210; Jane Noyes, Leah McLaughlin, Karen Morgan, Philip Walton, Rebecca Curtis, Susanna Madden, Abigail Roberts, and Michael Stephens, ‘Short-Term Impact of Introducing a Soft Opt-Out Organ Donation System in Wales: Before and After Study’, *BMJ Open* 9 (2019), e025159; Lead McLaughlin, Nicholas Mays, Mustafa Al-Haboubi, Lorraine Williams, Jennifer Bostock, Paul Boadu, and Jane Noyes, ‘Potential Donor Family Behaviours, Experiences and Decisions Following Implementation of the Organ Donation (Deemed Consent) Act 2019 in England: A Qualitative Study’, *Intensive and Critical Care Nursing* 86 (2025), 103816. There is, however, a question as to how long we must wait to be in a position to make a fair assessment of any impact. For a general overview, see Jordan A. Parsons, *‘Opt Out’ Organ Donation: An Ethico-Legal Policy Analysis* (Oxford: Oxford University Press, 2025).
5. Section 6(2) Human Transplantation (Wales) Act 2013; section 1 Organ Donation (Deemed Consent) Act 2019 concerns only adults, thereby excluding children by making no related amendments to the Human Tissue Act 2004.
6. Section 5(3)(a) Human Transplantation (Wales) Act 2013; section 3(9)(a) Human Tissue Act 2004, as amended by section 1(5) Organ Donation (Deemed Consent) Act 2019.
7. Section 5(3)(b) Human Transplantation (Wales) Act 2013; section 3(9)(b) Human Tissue Act 2004, as amended by section 1(5) Organ Donation (Deemed Consent) Act 2019.
8. See, for example, Robert M. Veatch and Lainie F. Ross, *Transplantation Ethics* (Washington, DC: Georgetown University Press, 2015).

The group with which we are concerned is those with cognitive impairments, who would not have understood the notion of opt out. This exception essentially introduced a capacity requirement for one to become 'eligible' for opt out.[9] Whilst it may seem appropriate not to apply opt out to those who lack capacity to understand, there are problems in the construction of this exception that, we argue, amount to a diversion from the established understanding of capacity under the Mental Capacity Act 2005 (MCA 2005). The MCA 2005 commits to a functional approach to the determination of capacity, requiring evidence of an individual being unable to make a decision in respect of a specific matter at the relevant time because of 'an impairment of, or disturbance in the functioning of, the mind or brain'.[10] This approach was adopted alongside an explicit rejection of a status-based approach, which determines capacity on a diagnostic basis.[11] The opt out systems of Wales and England, however, tacitly endorse a status-based approach to capacity – that is, determination of incapacity on the basis of an individual's diagnosis (e.g., a neurodegenerative disease). The framing of the capacity requirements under each system is such that, in practice, they can be applied only by treating medical records that are indicative of a cognitive impairment as a reason to exclude that individual from opt out.

We argue that this unacknowledged divergence from the MCA 2005 is problematic but straightforwardly solved. Problematic because for healthcare professionals, there is a risk of confusion, which ultimately could result in harm. This is a particular risk for those whose work encompasses both organ donation and other forms of care and treatment, conscious that all healthcare professionals dealing with adult patients work within the MCA 2005's framework. This confusion may exacerbate existing issues of misunderstanding related to the MCA 2005,[12] worsening the risk of a status-based approach creeping into wider healthcare practice. To prevent this, we argue that, at the very least, there needs to be acknowledgement of the differing approaches to capacity in the MCA 2005 and opt out. If this difference is intended – and we suggest that such an intention could be justified – then it must be made explicit, with that being reflected in revised Codes of Practice both of the MCA 2005[13] and the opt out systems following consultation and debate.

Whilst our focus is on Wales and England, we also reflect on the applicability of our critique to the opt out systems of Scotland and Northern Ireland to align with growing

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[9] See section 5(3)(b) Human Transplantation (Wales) Act 2013; section 3(9)(b) Human Tissue Act 2004, as amended by section 1(5) Organ Donation (Deemed Consent) Act 2019.

[10] Sections 2 and 3 Mental Capacity Act 2005; *A Local Authority v JB* (Rev1) [2021] UKSC 52.

[11] The Law Commission, Mentally Incapacitated Adults and Decision Making – An Overview available at https://www.lawcom.gov.uk/document/mentally-incapacitated-adults-and-decision-making-an-overview/ (accessed 25 August 2023) at [2.43–2.44].

[12] See, for example, Mary Donnelly, 'Capacity Assessment under the Mental Capacity Act 2005: Delivering on the Functional Approach?', *Legal Studies* 29 (2009), pp. 464–491.

[13] A draft of the updated Code of Practice for the Mental Capacity Act 2005 has been produced which, unsurprisingly, does not address the concerns we will raise in this article.

interest in intra-UK comparative discussion of opt out.[14] Noting significant similarities, we suggest that the same issues arise, albeit slightly less so in the case of Scotland.

We will use the language of 'opt out' throughout this article because it is more widely recognised.[15] However, it should be noted that the systems of Wales and England (with which we are primarily concerned) use the language of 'deemed consent' instead. The descriptor 'consent' for such systems is contentious due to the procurement of the deceased's organs following *in*action – thus in contrast to more familiar notions of consent to something so invasive needing to be active. The Scottish system, however, departs from the rest of the UK in using the language of 'deemed authorisation'[16] – in keeping with its longer-term use of such language. We will also refer to the 'donor', again because it is most commonly used. However, it may be similarly problematic as a means of describing someone whose tissue is used by default with no active agreement from them. This is not the place for a detailed consideration of the language used in this area, but it is worthy of note.

In this article, we begin by outlining pertinent aspects of organ donation, including the organ shortage, common features of opt out systems, and the rationale often employed in defence of opt out. The next two sections detail the approaches of Wales and England to mental capacity and opt out, respectively. Following that, we highlight the disparities with which we are concerned and their potential consequences. Then, before concluding, we consider the same issue in the context of Scotland and Northern Ireland, questioning the applicability of our critique in light of different but largely similar legislation.

Organ donation

The organ shortage

Whilst organ transplants can save lives, they rely on a supply of donor organs of suitable quality and compatibility with recipients. Increased system-level capability for performing transplants is irrelevant if demand outstrips the supply of donor organs.[17] Unfortunately,

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[14] Ruby Reed-Berendt, Anne-Maree Farrell, Matthew Watkins, and John Harrington, 'The Connection-Friction Axis in Devolved Health Policy and Law-Making in the UK: A Case Study of Organ Donation', *Modern Law Review* 87 (2024), pp. 1542–1571; Jordan A. Parsons, 'Breaking Down Organ Donation Borders: Revisiting "Opt Out" Residency Requirements in the UK', *Clinical Ethics* 19(3) (2024), pp. 237–242.

[15] Organ Donation Taskforce, 'The Potential Impact of an Opt Out System for Organ Donation in the UK: An Independent Report From the Organ Donation Taskforce' available at https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4250/thepotentialimpactofanoptoutsystemfororgandonationintheuk.pdf (accessed 28 October 2024), at [5.1].

[16] Section 7 Human Tissue (Authorisation) (Scotland) Act 2019.

[17] System-level capability is, of course, of equal importance. Some commentators on the recent moves to opt out have highlighted the need for adequate focus on ensuring relevant NHS capabilities grow simultaneously. After all, even an unlimited supply of organs for transplantation is useless if the healthcare system does not have the capacity to perform the operations and provide the necessary aftercare. See, for example, Thakshayene Mahenthran, 'The New 'Opt-Out' Organ Donation English Law: Is the NHS Ready for This?', *Clinical Medicine* 21 (2021), pp. e92–e93.

that is the reality we are currently in. There is a widely recognised shortage of organs for transplantation, both in the UK[18] and globally.[19] The result is many patients dying each year awaiting a transplant. For example, the UK saw 439 deaths on the transplant waiting list in the financial year 2022/23, an increase of 2% on the previous year.[20] Further, the real figure will undoubtedly be higher because of the distortion caused by the way in which patients are added to the waiting list. That is, some of those who will die without a transplant are not added to the waiting list due to the low likelihood of finding a suitable donor – transplant organs being so scarce a resource that allocation of those available is based on various criteria. In addition, those with particularly poor health may be ineligible for a transplant, with some (732 in 2022/23[21]) removed from the waiting list after which most will soon die.

For some, there are interim – although generally less desirable – options. Patients awaiting a kidney transplant, for example, may receive dialysis to artificially perform the role of the organ.[22] Those with end-stage heart failure may benefit from a left ventricular assist device (LVAD).[23] But for many, the only hope is to receive a transplant before their native organ entirely stops functioning.

There are other contributors to lower rates of transplantation, such as quality thresholds for donated organs that could arguably be lowered.[24] These issues are similarly in need of discussion, but the core problem is the organ shortage. That is because the shortage problem is not as easily addressed by the provision of additional resources.

In recognition of this global shortage of organs for transplantation, myriad proposals have come about in an attempt to address the issue. These range from the lighter, nudge-based suggestions like mandated choice to the more controversial thought experiment of

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[18] NHS Blood and Transplant, ‘Organ and Tissue Donation and Transplantation Activity Report 2022/23’ available at https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/30188/activity-report-2022-2023-final.pdf (accessed 25 August 2023).

[19] Global Observatory on Donation and Transplantation, ‘Global Report on Organ Donation and Transplantation 2020: Activity and Legislative & Organizational Issues’ available at https://www.transplantobservatory.org/wp-content/uploads/2022/07/2020-Global-report-para-web.pdf (accessed 25 August 2023).

[20] NHS Blood and Transplant, ‘Organ and Tissue Donation and Transplantation Activity Report 2022/23’, p. 2. All figures since 2020 must be taken with a pinch of salt due to the significant impact the COVID-19 pandemic had on transplantation activity. Nonetheless, these figures are sufficient to illustrate the shortage.

[21] Op. cit.

[22] Jonathan Himmelfarb, Raymond Vanholder, Rajnish Mehrotra, and Marcello Tonelli, ‘The Current and Future Landscape of Dialysis’, *Nature Review Nephrology* 16 (2020), pp. 573–585.

[23] Eric A. Rose, A. C. Gelijns, A. J. Moskowitz, D. F. Heitjan, L. W. Stevenson, W. Dembitsky, J. W. Long, D. D. Ascheim, A. R. Tierney, R. G. Levitan, J. T. Watson, P. Meier, N. S. Ronan, P. A. Shapiro, R. M. Lazar, L. W. Miller, L. Gupta, O. H. Frazier, P. Desvigne-Nickens, M. C. Oz, and V. L. Poirier, ‘Long-Term Use of a Left Ventricular Assist Device for End-Stage Heart Failure’, *New England Journal of Medicine* 345 (2001), pp. 1435–1443.

[24] Antonia J. Cronin and James F. Douglas, ‘Non-Standard Kidneys for Transplants: Clinical Margins, Medical Morality, and the Law’, *Medical Law Review* 21 (2013), pp. 448–473.

a 'survival lottery'.[25] However, the core debate – at least currently – is very much that of opt in versus opt out. That is, whether the state should, in the absence of a known decision by the deceased, adopt a default of donation. With more and more countries moving to this approach,[26] it has unsurprisingly reached the whole of the UK.

Common features of opt out systems

Even when the debate has narrowed to opt out, there remains variation in how such a system may be constructed. The broad, binary division of such systems is between 'hard' and 'soft' opt out. This distinction rests primarily on the role the deceased's family (and often friends) are afforded in any donation decision. A hard opt out system entirely discards the perspective of the deceased's family, allowing donation to proceed in any scenario where there is not a properly recorded objection (an opt out) from the deceased.[27] In a sense, then, hard opt out is a purer form of opt out – it very much does what it says on the tin.

By contrast, a soft opt out system recognises a role for the deceased's family. This role will generally be to provide healthcare professionals with information pertaining to the views held by the deceased, allowing them to rule out unrecorded, but nonetheless clear, opposition to donation. That is, the family are limited to representing the views of the deceased and *not* to voice their own disposition regarding organ donation. In practice, however, the family may have far more power, to the extent that even their personal objection could prevent donation proceeding.[28] From this point on, we will concern ourselves only with soft opt out systems not only because they are more common, but because that is the approach taken in the UK.[29]

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[25] A survival lottery being a system whereby everyone is allocated a number and, if their number is drawn, must surrender their life to allow the lives of several people to be saved through transplantation. See John Harris, 'The Survival Lottery', *Philosophy* 50 (1975), pp. 81–87.

[26] In the last decade, opt out systems have been introduced in Greece, the Netherlands, and more. There are also several countries currently considering the change, such as Denmark and Switzerland.

[27] Such a system is relatively rare, in part because of public perception of the state infringing upon their bodily rights. Hence the failing of such a system in Brazil. Claudia Csillag, 'Brazil's Law on Organ Donation Passed', *Lancet* 349 (1998), p. 482; Claudia Csillag, 'Brazil Abolishes "Presumed Consent" in Organ Donation', *Lancet* 352 (1998), p. 1367.

[28] See, for example, Human Tissue Authority, 'Code of Practice F (Part Two) Deceased Organ and Tissue Donation' available at https://content.hta.gov.uk/sites/default/files/2023-07/Code%20F%20part%20two%20-%20Deceased%20organ%20and%20tissue%20donation.pdf (accessed 25 August 2023) at [90]. We will revisit the nature of the family's role as it relates to mental capacity in the opt out systems of Wales and England.

[29] Some would argue both Wales and England have introduced *hard* opt out systems because they do not formally incorporate family vetoes. The Human Tissue Authority guidance confirms this. However, the guidance also suggests there is scope for the family to prevent donation through both action and absence in various ways. See, for example, Jordan A. Parsons, 'Deemed Consent for Organ Donation: A Comparison of the English and Scottish Approaches', *Journal of Law and the Biosciences* 8 (2021), lsab003; James F. Douglas and Antonia J. Cronin, 'The Human Transplantation (Wales) Act 2013: An Act of Encouragement, Not Enforcement', *Modern Law Review* 78 (2015), pp. 324–348. As such, they can be considered soft opt out systems.

Soft opt out systems vary across jurisdictions, but there are common features beyond the central concept of the deceased being assumed to have agreed to donation in the absence of a recorded objection. Beginning with remit, it is common for opt out systems to apply only to adults. Whilst the precise age will vary across jurisdictions in line with different legal systems' age of majority,[30] it is the norm that children are not included in an opt out system. It is similarly common for certain groups of adults to be excluded. Such exclusions are based on the extent to which it can be reasonable to think that individuals would be aware of and understand the nature of the system.[31] To that end, we frequently see residency and capacity exclusions – for opt out to apply, the deceased must have lived within the jurisdiction for a minimum period and have had the requisite decision-making capacity to have been able to opt out of organ donation if they so desired. Often, there will also be stipulations as to what organs and tissue can be taken under opt out, with certain materials excluded for reasons of, for example, novel transplants and sensitivity. However, such stipulations are often provided for in supplementary regulations,[32] partly out of a need for them to be (relatively) swiftly reactive to developments in transplantation medicine.[33]

These common features are all to be found in the opt out systems of the UK, albeit with some variations in detail. For example, Scotland stands out by setting the age at which deemed authorisation (in the language of the Scottish system) applies as 16 years rather than 18.[34]

Rationale for opt out organ donation

Opt out systems of organ donation are increasingly popular and have been justified in various ways. Whilst the core rationale is ordinarily an (expected) increase in transplantation activity, this is not the sole basis of such policy decisions. It is also common to see arguments relating to respect for the individual's right to self-determination; with public opinion surveys indicating overwhelming support for organ donation, an opt out system

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[30] For example, Singapore's opt out system applies from the age of 21, whereas those in England and Wales deem someone an adult at 18 years.

[31] Parsons, 'Deemed Consent for Organ Donation'.

[32] Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015; Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020; Human Tissue (Excepted Body Parts) (Scotland) Regulations 2020; Human Tissue (Permitted Material) Regulations (Northern Ireland) 2023.

[33] Wales, for example, launched a public consultation in 2020 to amend the Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015, in part to 'take account of advancements in medical science'. See Welsh Government, 'Human Transplantation (Excluded Relevant Material) (Wales) (Amendment) Regulations: Consultation on Draft Regulations' available at https://www.gov.wales/sites/default/files/consultations/2020-02/consultation-document_0.pdf (accessed 2 October 2023).

[34] Section 60(1) Human Tissue (Scotland) Act 2006. This was in line with Scotland's existing approach in considering someone an adult at 16 for the purposes of organ donation – it was the case when the Human Tissue (Scotland) Act 2006 was passed.

is said to facilitate the actioning of this feeling where an individual has not actively joined an organ donation register.[35]

The matter of increasing transplantation activity through the implementation of an opt out system is contentious. Whilst examples of countries, such as Spain, where there is an opt out system and high transplantation figures are often highlighted in support of such a policy move, there are reasons to question whether it was the legislative change that led to this success.[36] For example, the Spanish system's success has been recognised as down to its efficient protocols for engaging with families rather than the legislative change *per se*.[37] As such, others argue that it would be more beneficial to focus energies on changing organ donation practices on the ground (such as the protocol for when and how the deceased's family is approached), as well as on boosting public awareness and debate.[38]

Regardless of rationale, public awareness is recognised as a key element to any opt out system that is to be considered ethically and legally justified.[39] Price, for example, proposed four criteria for a defensible system:

(1) People are aware of the system and the implications of (in)action;
(2) Ways of opting out of donation are straightforward and accessible;
(3) People are afforded reasonable time to reach a decision; and
(4) No consequences are associated with opting out.[40]

Public awareness is the running theme in criteria (1) to (3), centring the importance of people knowing about the change of system and being able to respond as they desire. Criterion (4) is also concerned with autonomy in avoiding any sense of coercion but is less so related to public awareness. Price is not alone in this view, with other scholars writing similarly of the importance of protecting individual liberty in this way.[41] It is this prioritisation of public awareness that can be identified in all the exceptions to the opt out policies in Wales and England – including capacity – that we will shortly discuss.

That being said, one might argue that neither system satisfies Price's criteria. Indeed, opt out as an approach to organ procurement has been critiqued for years. Some focus on

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[35] Veronica English and Ann Sommerville, 'Presumed Consent for Transplantation: A Dead Issue After Alder Hey?', *Journal of Medical Ethics* 29 (2003), pp. 147–152.

[36] Adam Arshad, Benjamin Anderson, and Adnan Sharif, 'Comparison of Organ Donation and Transplantation Rates Between Opt-Out and Opt-in Systems', *Kidney International* 95 (2019), pp. 1453–1460.

[37] Rafael Matesanz, 'Factors That Influence the Development of an Organ Donation Program', *Transplantation Proceedings* 36 (2004), pp. 739–741.

[38] Rafael Matesanz and Beatriz Dominguez-Gil, 'Opt-Out Legislations: The Mysterious Viability of the False', *Kidney International* 95 (2019), pp. 1301–1303.

[39] Although some maintain fundamental ethical objections to opt out systems notwithstanding the kind of safeguards found in English law.

[40] David Price, *Human Tissue in Transplantation and Research: A Model Legal and Ethical Donation Framework* (Cambridge: Cambridge University Press, 2009), pp. 137–138.

[41] Ben Saunders, 'Opt-Out Organ Donation Without Presumptions', *Journal of Medical Ethics* 38 (2012), pp. 69–72.

the ‘unavoidable degree of uncertainty’ as to the deceased’s preferences where inaction is relied upon.[42] Others look to the lack of clear evidence that such systems improve donation and transplantation rates.[43] By no means is there consensus as to whether opt out systems are truly ethically justified.

Mental capacity

Given our focus on the capacity safeguards in the opt out legislation under consideration, an examination of mental capacity law is needed. In this section, we set out the law on mental capacity and its assessment, with a focus on Wales and England, highlighting some of the difficulties that can arise in making mental capacity assessments. From this, we will consider how the capacity safeguards that implicitly rely on this law may operate.

Informed consent is normally required to render medical procedures, including organ transplantation, lawful.[44] However, the law recognises that adults cannot provide informed consent where they lack the requisite decision-making capacity.[45] In such circumstances, treatment may be provided during that person’s lifetime without consent, provided that the treatment is in that person’s ‘best interests’.[46] This remains true even where the person who lacks the decision-making capacity strongly objects to the treatment.[47] Consequently, distinguishing those decisions made by adults with mental capacity and decisions made without mental capacity is of fundamental importance in Welsh and English law.

A core principle of the MCA 2005 is that before an adult can be determined to lack requisite decision-making capacity, they must be assessed as being unable to make the *specific decision* at hand at the *specific time* of the assessment.[48] It may be that a person with some manner of cognitive impairment is able to make some decisions but not others, and/or can make decisions at some times but not others.[49] The starting point is the presumption of mental capacity.[50]

The first section of the MCA 2005 sets out its own guiding principles,[51] and such is the significance of the presumption of capacity that it is first among them.[52] That the

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[42] Shahla Siddiqui, Ng Ee Ling, and Voo Teck Chuan, ‘Delays in Brain Death Certification in an Opt-Out Deceased Organ Donation System: Causes, Ethical Problems, and Avoidance’, *Asian Bioethics Review* 10 (2018), pp. 189–198, pp. 194–195.

[43] Matesanz, ‘Factors That Influence the Development of an Organ Donation Program’.

[44] Mental Health Act 1983.

[45] Section 3 Mental Capacity Act 2005.

[46] Sections 4–5 Mental Capacity Act 2005.

[47] *Re T (Adult: Refusal of Treatment)* [1993] Fam 95 (CA); *Re E (Medical treatment: Anorexia) (Rev 1)* [2012] EWHC 1639 (COP).

[48] Section 2(1) Mental Capacity Act 2005; *Kings College Hospital NHS Foundation Trust v C and V* [2015] EWCOP 80.

[49] *Guys and St Thomas’ NHS Foundation Trust v R* [2020] EWCOP 4, [35].

[50] Section 1(2) Mental Capacity Act 2005.

[51] See Alex Ruck Keene, Nuala B. Kane, Scott Y. H. Kim, and Gareth S. Owen, ‘Taking Capacity Seriously? Ten Years of Mental Capacity Disputes Before England’s Court of Protection’, *International Journal of Law and Psychiatry* 62 (2019), pp. 56–76, p. 58.

[52] It is found in section 1(2), but section 1(1) merely states that the principles apply to the Act.

determination of mental incapacity cannot be based on assumptions made from the person's appearance or diagnosis is central to the law's commitment to functionalism.[53] That is, the question of mental capacity only pertains to whether a person is *capable of making a decision*. This approach can be contrasted with a status-based approach wherein mental capacity is determined on the basis of a person's diagnostic status.[54] In such a system, a person could be found to lack mental capacity without necessarily assessing their ability to make a specific decision at a specific time. Rather, their mental capacity could be determined as a result of their diagnosis alone.

Whilst still distinguishable from a status-based approach, the MCA 2005's approach to capacity controversially[55] incorporates a diagnostic element. The difference being that within the MCA 2005's approach, diagnosis itself is insufficient to establish a lack of capacity. Instead, a causal relationship must be established between the underlying impairment and the evidence of an inability to make a decision.[56] Moreover, the MCA 2005 requires all practicable steps to be taken to assist a person in making a decision, and assessors are encouraged to consider the possibility that the person may later regain capacity to make the decision.[57]

In its 1991 review of the law on decision making for those who lack mental capacity, the Law Commission acknowledged that the status-based approach was probably more convenient for healthcare providers, and indeed may have been used in practice prior to the MCA 2005.[58] However, it clearly preferred the functional approach, which was subsequently firmly incorporated into the MCA 2005.[59] It is also noteworthy that despite being a signatory to the Convention on the Rights of Persons with Disabilities (CRPD), which prohibits the framing of legal rights or 'legal capacity' as being contingent on mental capacity[60] and the use of 'substitute decision-making' rather than 'supported decision-making',[61] Welsh and English laws maintain that certain rights (e.g., the right to refuse treatment) *are* dependent on mental capacity.[62]

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[53] Section 2(3) Mental Capacity Act 2005.

[54] See The Law Commission, 'Mentally Incapacitated Adults and Decision Making', at [2.43–2.44].

[55] See Beverley Clough, *The Spaces of Mental Capacity Law: Moving Beyond Binaries* (New York: Routledge, 2023), pp. 41–43.

[56] Section 2(1) Mental Capacity Act 2005; *PC & Anor v City of York Council* [2013] EWCA Civ 478, [58].

[57] Section 1(3) Mental Capacity Act 2005; Department for Constitutional Affairs, 'Mental Capacity Act 2005: Code of Practice' available at https://www.gov.uk/government/publications/mental-capacity-act-code-of-practice (accessed 25 August 2023), at [4.26 - 4.27].

[58] See The Law Commission, 'Mentally Incapacitated Adults and Decision Making', at [2.43 - 2.44]; section 3 Mental Capacity Act 2005.

[59] Op. cit.

[60] Article 12 CRPD.

[61] Article 12 CRPD; see also Anna Arstein-Kerslake and Eilionóir Flynn, 'The General Comment on Article 12 of the Convention on the Rights of Persons with Disabilities: A Roadmap for Equality before the Law', *The International Journal of Human Rights* 20 (2016), pp. 475–480.

[62] Keene et al., 'Taking Capacity Seriously'. See also Alex Ruck Keene, Nuala B. Kane, Scott Y. H. Kim, and Gareth S. Owen, 'Mental Capacity—Why Look for a Paradigm Shift?', *Medical Law Review* 1 (2023), pp. 340–357; Peter Bartlett, 'At the Interface Between Paradigms: English Mental Capacity Law and the CRPD', *Frontiers in Psychiatry* 11 (2020), p. 570735.

As for the application of the functional test, the MCA 2005 sets out four criteria that an individual must meet, demonstrating that they can:

- Understand relevant information[63]
- Retain that relevant information[64]
- Use or weigh that relevant information in making a decision[65]
- Communicate that decision[66]

Failure to satisfy any one of the four may result in a determination of incapacity. The current test requires 'the matter' to be decided to be ascertained, and then P's ability to make a decision on that matter is tested with reference to the aforementioned criteria. If P is found to be unable to make a decision on that basis, the next step is to consider whether there is a 'causative nexus'[67] between the inability to decide and 'an impairment of, or disturbance in the functioning of, the mind or brain'.[68] Of note, however, this order of tests – that is, functional before diagnostic – was not confirmed by the Supreme Court until *JB* in 2021.[69]

Functionalism was well-established in the common law prior to the MCA 2005,[70] but one of the respects in which the MCA 2005 goes further is in its efforts to provide greater support and protection for the person subject to an assessment. An example of this is the addition of a further principle that no one is to be assessed as lacking capacity before all practicable steps have been taken to assist them to make a decision.[71] Various steps that might be taken are outlined in the MCA 2005 Code of Practice, to which healthcare providers are required to have regard.[72] Provision was also made for a group of professionals called independent mental capacity advocates (IMCAs) who can support their clients to receive adequate decision-making support.[73] These provisions and guidance are of general applicability, but as we will discuss, it is difficult to see how they can be honoured in respect of the opt out legislation. Before this, we consider some of the problems associated with assessing mental capacity in practice generally.

Problems with mental capacity and its assessment

For all the well-intentioned functionalist provisions of the MCA 2005, commentators have questioned whether the functional approach is truly respected in practice. First, there is a question over whether healthcare professionals always follow the law, or

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[63] Section 3(1)(a) Mental Capacity Act 2005.
[64] Section 3(1)(b) Mental Capacity Act 2005.
[65] Section 3(1)(c) Mental Capacity Act 2005.
[66] Section 3(1)(d) Mental Capacity Act 2005.
[67] *PC & Anor v City of York Council* [2013] EWCA Civ 478, [58].
[68] *A Local Authority v JB (Rev 1)* [2021] UKSC 52; Section 2(1) Mental Capacity Act 2005.
[69] *A Local Authority v JB (Rev 1)* [2021] UKSC 52.
[70] See, for example, *Re C (Adult: Refusal of Medical Treatment)* [1994] WLR 290, 295.
[71] Department for Constitutional Affairs, 'Code of Practice'.
[72] Section 42(4) Mental Capacity Act 2005.
[73] Department for Constitutional Affairs, 'Code of Practice'.

whether they occasionally fall back to a more pragmatic (generally status-based) approach. Doing so would not imply bad intent but may be due to a lack of knowledge and training. Donnelly highlights that capacity assessments are often made by those who are not legally trained as being a significant problem, given her view that these assessments are a 'legal task'.[74] These concerns appear to be supported by evidence of variance in adherence to legal requirements in respect of the assessment of capacity.[75] Worryingly, there are reports that assessments are influenced by the characteristics of the person being assessed, in direct contravention of the MCA 2005.[76] The true scale of deviation from the requirements of the MCA 2005 in practice is difficult to gauge, given the breadth of application of the MCA 2005 and the fact that there is no strict requirement to record assessment decisions (although to do so is recognised as best practice[77]). Moreover, very few personal welfare decisions ever reach the Court of Protection,[78] meaning there is a low likelihood of capacity assessments being scrutinised by the Court.

Second, there is the question of the reliability of assessments. A large-scale survey of healthcare professionals has suggested a lack of self-reported confidence in making capacity assessments, which highlights a need for training.[79] Even for those who are confident in being able to conduct assessments, the complex interpersonal nature of capacity assessments, as well as the values of the assessor, may impose themselves on assessment itself,[80] meaning there is potential for different outcomes to be arrived at even by those who apply the legal tests accurately. Indeed, outside of those small number of decisions thought to be so serious or contentious as to require judicial scrutiny, there is little to prevent extraneous factors and biases from influencing capacity assessments.[81] In the event of bias or other interpersonal factors entering into the assessment, it becomes less likely that mental capacity will be assessed perfectly in line with the functional approach.

Third, a significant practical problem may arise in the frequency of need for assessment. A by-product of the functional test is that it is possible for a person to have mental capacity in respect of some decisions, but not in respect of others. It is also possible for a person's capacity to fluctuate.[82] This has the potential to invite numerous capacity

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[74] Donnelly, 'Capacity assessment under the Mental Capacity Act 2005', p. 464.

[75] Mark Jayes, Rebecca Palmer, Pamela Enderby, and Anthea Sutton, 'How Do Health and Social Care Professionals in England and Wales Assess Mental Capacity? A Literature Review', *Disability and Rehabilitation* 42 (2020), pp. 2797–2808.

[76] Op. cit., p. 2803. See also section 2 Mental Capacity Act 2005.

[77] Capacity Guide. 'Recording my Assessment' available at https://capacityguide.org.uk/practical-legal-guidelines/recording-my-assessment/ (accessed 25 August 2023). Whilst this is not official guidance, it is linked to by the General Medical Council as an appropriate resource.

[78] See Keene et al., 'Taking Capacity Seriously', p. 60.

[79] Kevin Ariyo, Andrew McWilliams, Anthony S. David, and Gareth S. Owen, 'Experiences of Assessing Mental Capacity in England and Wales: A Large-Scale Survey of Professionals', *Wellcome Open Research* 6 (2021), p. 144.

[80] Donnelly, 'Capacity Assessment Under the Mental Capacity Act 2005'.

[81] Op. cit., pp. 474–480.

[82] *Guys and St Thomas' NHS Foundation Trust v R* [2020] EWCOP 4, [35]; Department for Constitutional Affairs, 'Code of Practice', [4.26–4.27].

assessments to be made in respect of the same kind of decisions and has been identified as a particular challenge for the MCA 2005.[83] Recent jurisprudence on this point has sought to distinguish recurrent decisions from isolated decisions, with a presumption that if someone has been assessed as lacking capacity for a decision that is likely to recur, they can be treated as continuing to lack mental capacity unless there is evidence to suggest they may have capacity.[84] This solution is pragmatic but extends greater power to healthcare professionals at the expense of the rights of those in their care. In the process, it strains the principle of functionalism.

Fourth, the court has the power to pronounce on mental capacity through making declarations.[85] These declarations may relate current decisions but may also apply to anticipatory declarations in ‘exceptional circumstances’.[86] There has recently been critical interest in the use of such anticipatory declarations in obstetrics cases.[87] However, this power can also operate in retrospect. The case of *Re E* is instructive on this point.[88] The Court determined that E did not have the capacity to create an advance decision in the past despite having been assessed as having the capacity shortly before creating the decision and having received professional assistance in its creation. This sits uneasily with the presumption of capacity and the obligation for those performing the assessment to take all practicable steps to assist the person making the decision.[89] In the more recent case of *JH*, the importance of the presumption of capacity was emphasised when retrospectively interrogating the capacity to create advance decisions.[90] Nevertheless, it is impossible for decision-making assistance to be rendered in retrospect, and consequently those being assessed in this way are at a disadvantage. As will be discussed, similar concerns may be raised in respect of making retrospective assessments of mental capacity for the purposes of organ donation.

All considered, the operation of the MCA 2005 appears to have developed a rather looser adherence to the principle of functionalism than might have been expected from the letter of the law. Formally, functionalism remains its core, and healthcare professionals have no discretion to deviate from it, however expedient that may be. However, the willingness of the Court of Protection to interpret the MCA 2005 and its principles in a pragmatic manner has elevated the role of status in the law.

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[83] Clough, *The Spaces of Mental Capacity Law*, p. 63.

[84] *Cheshire West and Chester Council v PWK* [2019] EWCOP 57; see also Clough, The Spaces of Mental Capacity Law, pp. 63–67.

[85] Section 15 Mental Capacity Act 2005.

[86] *United Lincolnshire Hospitals v CD* [2019] EWCOP 24.

[87] See, for example, Aimee V. Hulme, ‘Anticipatory Declarations in Obstetric Care: A Relational and Spatial Examination of Patient Empowerment, Institutional Impacts and Temporal Challenges’, *Medical Law Review* 32 (2024), 530–548.

[88] *Re E (Medical treatment: Anorexia)*.

[89] Section 1 Mental Capacity Act 2005.

[90] *NHS Surrey Heartlands Integrated Care Board v JH* [2023] EWCOP 2.

Opt out legislation

Following the general direction of this area of public policy, the four UK nations have introduced opt out[91] legislation to replace the previous express consent system (or opt in) of organ donation.[92] However, owing to devolution, it took a decade for the four nations to realign on this matter. Wales took the lead in passing the HTWA 2013, which introduced the first opt out system of the UK in December 2015. Then came England in 2020,[93] Scotland in 2021,[94] and, finally, Northern Ireland in 2023.[95]

Given our focus on mental capacity, we will here outline only the opt out systems of Wales and England in detail. This is to match the jurisdiction of the MCA 2005, as Scotland and Northern Ireland operate within alternative mental capacity frameworks. Nonetheless, we will consider Scotland and Northern Ireland in a later section. Whilst we will briefly note the overall construction of the Welsh and English opt out systems, our focus will be on how they frame mental capacity.[96]

Wales

Adults[97] who die in Wales and have not recorded a formal objection to organ donation can have their consent deemed,[98] subject to two excepted groups. The first is based on residency, permitting the application of opt out only to those who have been ordinarily resident in Wales for at least 12 months immediately prior to their death.[99] The second concerns the mental capacity of the individual and will be discussed further shortly.

The Welsh system is one of ‘soft’ opt out, meaning the deceased’s family[100] are afforded a role in donation decisions. This was very much the intention long before the

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[91] As earlier noted, not all four of the systems use the language of ‘deemed consent’, with Scotland instead opting for ‘deemed authorisation’.

[92] As have the neighbouring Crown Dependencies, in chronological order, of Jersey, Guernsey, and the Isle of Man. Jersey’s opt out system came into force in July 2019, detailed in the Human Transplantation and Anatomy (Jersey) Law 2018. Guernsey was next, with the Human Tissue and Transplantation (Bailiwick of Guernsey) Law 2020 coming into force in January 2023. The Isle of Man has not yet implemented its opt out system, but the Human Tissue and Organ Donation Act 2021 received Royal Assent in July 2021 and practical arrangements ahead of a confirmed implementation date are underway.

[93] Organ Donation (Deemed Consent) Act 2019.

[94] Human Tissue (Authorisation) (Scotland) Act 2019. Scotland was originally due to introduce its system at the same time as England, in 2020, but delayed this in light of the COVID-19 pandemic. See Parsons, ‘Deemed Consent for Organ Donation’.

[95] Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022.

[96] Further detail on both systems can be found elsewhere. See Douglas and Cronin, ‘The Human Transplantation (Wales) Act’; Parsons, ‘Deemed Consent for Organ Donation’.

[97] Meaning those aged 18 years or older. Section 19(1) Human Transplantation (Wales) Act 2013.

[98] Section 4(2) Human Transplantation (Wales) Act 2013.

[99] Section 5(3)(a) Human Transplantation (Wales) Act 2013.

[100] The language used by the HTWA 2013 is ‘relative or friend of long standing’. Section 4(4)(a) Human Transplantation (Wales) Act 2013. It is not only members of the deceased’s family who may contribute to a decision, but we will continue to use ‘family’ for ease.

HTWA 2013 was passed, with the Health, Wellbeing, and Local Government Committee of the National Assembly for Wales[101] recommending this back in 2008 based on the nature of public support.[102] The role afforded to the family is, on the face of it, consultative. Donation may be stopped by the family presenting an objection ‘on the basis of views held by the deceased’.[103] It is not, then, the family’s decision as to whether to donate the deceased’s organs, but they may represent the deceased’s own views. In practice, however, donation is unlikely to proceed where the family object on the basis of their own views, but we will not consider that here.

Another – and somewhat defining – feature of the Welsh system concerns the duties placed on Welsh Ministers in relation to public awareness. In recognition of the importance of widespread public understanding to the justification of an opt out system, the HTWA 2013 explicitly requires Welsh Ministers to ‘inform the public of the circumstances in which consent to transplantation activities is deemed to be given in the absence of express consent’.[104] To carry out this duty, it is further required that a public information campaign be undertaken at least once a year.[105] Such campaigns being conducted annually aligns with the 12-month residency exception, meaning that anyone whose consent might be deemed has (at least theoretically) been present for at least one of the campaigns. These duties in relation to public awareness were supplemented by reporting requirements, introducing some level of accountability. However, this requirement was only for an annual report on public awareness activities to be produced for the first five years after the HTWA 2013 was enacted.[106] Now that this period has passed, there is seemingly no formal accountability.

Regarding the capacity exception, the precise wording of the HTWA 2013 is to exclude from opt out:

> an adult who has died and who for a significant period before dying lacked capacity to understand the notion that consent to transplantation activities can be deemed to be given.[107]

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[101] The National Assembly for Wales was renamed in 2020 to become the Welsh Parliament (or Senedd Cymru). Nonetheless, as it was the National Assembly for Wales when the HTWA 2013 was debated, passed, and implemented, we will continue to refer to it as such in this article.

[102] Health, Wellbeing, and Local Government Committee of the National Assembly for Wales, ‘Inquiry into Presumed Consent for Organ Donation’ available at https://senedd.wales/media/4kaffrkb/cr-ld7192-e-english.pdf (accessed 25 August 2023). The Committee did not recommend that an opt out system be implemented at the time, but that any future decision to introduce such a policy ought only to consider soft opt out. This report came shortly after that of the UK-wide Organ Donation Taskforce, which similarly did not recommend moving to opt out. Organ Donation Taskforce, ‘Organs for Transplants: A Report From the Organ Donation Taskforce’ available at https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4245/organsfortransplantstheorgandonortaskforce1streport.pdf (accessed 25 August 2023).

[103] Sections 4(2)(b) and 4(4)(a) Human Transplantation (Wales) Act 2013.

[104] Section 2(1)(c) Human Transplantation (Wales) Act 2013.

[105] Section 2(2) Human Transplantation (Wales) Act 2013.

[106] Section 2(3) Human Transplantation (Wales) Act 2013.

[107] Section 5(3)(b) Human Transplantation (Wales) Act 2013.

This first presents an issue as to the interpretation of 'significant period'. It is notable that the legislation does not, as with the residency exception, stipulate a specific timeframe. Rather, it adds that 'for this purpose, a significant period means a sufficiently long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed to be given'.[108] Ultimately, the Code of Practice issued by the Human Tissue Authority clarifies that this should, in practice, be taken to mean 12 months[109] – so, much like the residency requirement. This is not, however, the time to ponder on why the fixed period for the capacity exception was not included in the legislation itself.[110]

In determining whether the deceased ought to be excluded from opt out on the basis of incapacity, specialist nurses in organ donation (SNODs) are advised, as part of their broader assessment, to look for evidence of 'a condition or illness which may have impacted the person's capacity to understand deemed consent [opt out]'.[111] Identification of such a condition or illness then triggers a process of confirmation, involving discussion with the deceased's family, to better understand the likelihood that they would have been aware of and understood the opt out system and how it would affect them. In effect, then, this is the application of some manner of status-based test for capacity. The deceased having had, for example, a neurodegenerative disease will be taken as prima facie evidence of (possible, likely, or definite, depending on how one interprets the guidance) lack of requisite capacity.

England

The opt out system that was introduced into English law in 2020 closely resembles its Welsh counterpart. Most significant among the DCA 2019's effects is its amendment to section 3 of the Human Tissue Act 2004 to provide for deceased organ donation to take through opt out.[112] Like the law in Wales, opt out in England cannot be relied on for certain forms of tissue transplantation.[113] In respect of the kinds of tissue that can be subject to opt out, the DCA 2019 provides for multiple excepted categories of person whose consent may not be deemed. The main such categories are children,[114] those who

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[108] Section 5(3) Human Transplantation (Wales) Act 2013.

[109] Human Tissue Authority, 'Code of Practice on the Human Transplantation (Wales) Act 2013' available at https://content.hta.gov.uk/sites/default/files/2020-11/Code%20of%20Practice%20on%20the%20Human%20Transplantation%20%28Wales%29%20Act%202013.pdf (accessed 25 August 2023), at [69].

[110] Incidentally, lawmakers have been a little indecisive in what constitutes a reasonable period even in relation to the residency exception. When first drafted, the Bill noted six months for the residency exception, before it was later changed to 12.

[111] Human Tissue Authority, 'Code of Practice on the Human Transplantation (Wales) Act 2013', at [66b].

[112] Section 3 Human Tissue Act 2004, as amended by section 1 Organ Donation (Deemed Consent) Act 2019.

[113] Section 3(6A)(b) Human Tissue Act 2004, as amended by section 1(4) Organ Donation (Deemed Consent) Act 2019.

[114] As with the Welsh system, a child is taken to be an individual under the age of 18 years. See Explanatory Notes to the Organ Donation (Deemed Consent) Act 2019, at [2].

have given express consent or have expressed refusal of consent,[115] those who have appointed a representative to offer consent on their behalf,[116] those who have not been ordinarily resident *in England* for a period of 12 months or more immediately prior to their death,[117] and those who have lacked mental capacity with respect to the question of organ donation for a significant period.[118]

In respect of the latter category, with which we are concerned, the DCA 2019 frames its capacity requirement in much the same way as the HTWA 2013:

> an adult who has died and who for a significant period before dying lacked capacity to understand the effect of subsection (6)(ba)[119]

Subsection (6)(ba) outlines the change to opt out.

The same issue is thus present in relation to the meaning of 'significant period', with the DCA 2019 similarly going on to state that:

> For the purposes of the definition of 'excepted adult' in subsection (9), a significant period means a sufficiently long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed to be given.[120]

The Code of Practice relevant to the DCA 2019, like that of the HTWA 2013, offers more concrete guidance in suggesting that 12 months would suffice.[121] That provides some assistance but leaves open the possibility that shorter periods could be considered significant too. It also does not prevent lengthier periods of time failing to be recognised as significant. Thus, as with the question of assessing mental capacity for the purposes of this Act (which we will come to explore further shortly), the way the law is written with respect to a 'significant period' offers room for interpretation.[122]

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[115] Section 6(a) Human Tissue Act 2004.

[116] Section 3(b)(ba) Human Tissue Act 2004, as amended by section 1(2) Organ Donation (Deemed Consent) Act 2019.

[117] Section 3(9)(a) Human Tissue Act 2004, as amended by section 1(5) Organ Donation (Deemed Consent) Act 2019.

[118] Section 3(9)(b) Human Tissue Act 2004, as amended by section 1(5) Organ Donation (Deemed Consent) Act 2019.

[119] Op. cit.

[120] Section 3(10) Human Tissue Act 2004, as amended by section 1(5) Organ Donation (Deemed Consent) Act 2019.

[121] Human Tissue Authority, 'Code of Practice F (Part Two)', at [183].

[122] The explanatory notes offer little on this point aside from a curious reference to 'people who lack the capacity to *fully* understand the consequences of deemed consent for a significant period before dying' [emphasis added]. Explanatory Notes to the Organ Donation (Deemed Consent) Act 2019, at [2]. It seems unlikely that understanding's descriptor is legally substantive, given its absence from the legislation itself and the Code of Practice's reference to the MCA 2005. That, however, leaves the question open as to why it was included at all. Even supposing 'fully' holds no significance, it is questionable why the provision specifies a 'capacity to understand', given that the MCA 2005 holds 'understanding' (without qualification) to be constituent of mental capacity, but not its sole requirement. A more direct reference to the MCA 2005 might have been helpful here.

As we discuss in the next section, the challenges with the law on mental capacity and its implementation discussed earlier are magnified in respect to the HTWA 2013 and the DCA 2019. Despite this, and somewhat surprisingly, little attention was paid to the mental capacity exception in DCA 2019 during its passage through Parliament.[123]

Organ donation and a departure from functionalism?

Having outlined the framing of mental capacity within the MCA 2005 and the respective opt out systems of Wales and England, it remains to consider the interaction between them. We are here concerned with whether the capacity requirements of the new organ donation laws of Wales and England align with the MCA 2005's emphasis on a functional approach to mental capacity.

Disparate framings of capacity

As discussed earlier, the MCA 2005 requires a functional approach to capacity assessment. The HTWA 2013 and DCA 2019 seemingly rely on the MCA 2005 for their definition of mental capacity, and yet their establishment of excluded categories of person based on mental capacity is hard to reconcile with the functional approach.

Both the MCA 2005 and the opt out legislation seemingly maintain the same goal of maximising personal autonomy and protecting those unable to make decisions for themselves. Of course, the HTWA 2013 and DCA 2019 centre this protective purpose to a lesser degree than the MCA 2005. Whilst the MCA 2005 exists for the purpose of protecting those with some manner of cognitive impairment, the underlying intention of both opt out systems is to increase organ donation and transplantation rates. This, however, is balanced by the protective safeguards built into these opt out systems. The HTWA 2013 and DCA 2019 are, seemingly, to some extent, positioning the utilitarian goal of maximising rates of donation and transplantation above the protective ideal, but there is an attempt to protect those unable to make an informed decision about organ donation prior to their death. On the question of protection, then, the MCA 2005 and two opt out systems have similar intentions but may offer different protection in practice.

To recap, the HTWA 2013 and DCA 2019 both frame their capacity exception as excluding any deceased adult who lacked the capacity to understand the concept of opt out 'for a significant period before dying'.[124] Let us also recall that both Codes of Practice

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[123] Crispin Blunt MP, for example, stated: 'I hope he will be able to look at just one thing in Committee: the issue of deemed consent involving people who lose capacity towards the end of their lives. I hope there will be more clarity in Committee to enable people who have made the decision that they want to make their organs available to do so, when just their brain is no longer of much use to anybody else and they do not have the capacity. I hope the Bill will be clear about such circumstances when people lose capacity towards the end of their lives but when the rest of the body can still be of use to others'. HC Deb 23 February 2018, vol 636, col 452. There is no record, however, that there was further detailed discussion on the question of mental capacity at Committee Stage.

[124] Section 5(3)(b) Human Transplantation (Wales) Act 2013; section 3(9)(b) Human Tissue Act 2004, as amended by section 1(5) Organ Donation (Deemed Consent) Act 2019.

clarify that ‘a significant period’ is to be understood as 12 months. Both Codes mention ‘the point at which a person lost capacity’. In practice, that can only feasibly refer to the point at which the deceased was either determined to lack decision-making capacity – likely in relation to something else – or diagnosed with something that is known to sometimes impair decision-making capacity. Given that a capacity assessment is not feasible at the time opt out would apply, this reference to ‘the point at which a person lost capacity’ simply cannot mean the point at which the deceased failed a capacity assessment in relation to organ donation.[125]

This interpretation is strengthened by the practical guidance provided for SNODs within the Codes of Practice. Several steps are outlined.[126] As earlier mentioned, this begins with a check of the deceased’s medical records for either:

> history of conditions or illness which may have impacted on the person’s capacity to understand the notion of consent being deemed or any assessment of the person’s capacity to understand the notion of consent being deemed.[127]

The starting point, then, is very much in line with a status-based test. A diagnosis of a *potentially* impairing condition becomes sufficient to ‘prompt further investigation by the SNOD’.[128] The same paragraph does acknowledge:

> It is important to note that a record of an episode or episodes of such an illness would not necessarily mean that a person would not have been able to understand the notion [of opt out].

However, this note is not taken on board in the full spirit of the MCA 2005 in the rest of the guidance. Where a condition or illness that may have impacted on the deceased’s capacity is identified, the SNOD is to discuss that with the deceased’s family and friends to better understand the impact that condition or illness *did* have on the deceased. Then if, after such discussions, ‘the SNOD is not satisfied on the balance of probabilities [. . .] that the person could have understood the notion of deemed consent [opt out], then the express consent process should be followed’.[129]

It is this final aspect that is most out-of-step with the MCA 2005. P’s diagnosis is taken as a starting point in considering whether the deceased falls within the capacity exception, which contrasts with the direction in *JB* to consider whether P is able to make

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[125] Of course, it is possible (though perhaps unlikely) that the question of organ donation had been previously raised with the deceased, and they were determined to lack the requisite capacity to make a decision with respect to donation. This would more closely reflect the decision-specific nature of capacity. However, it would still fall short on the MCA 2005’s notion of time-specific capacity.

[126] To avoid confusion, we will reference only the Welsh Code of Practice in outlining this guidance. Nonetheless, the English Code of Practice is the same with respect to the points highlighted.

[127] Human Tissue Authority, ‘Code of Practice on the Human Transplantation (Wales) Act’, at [66a].

[128] Op. cit.

[129] Op. cit., at [66d].

a decision before engaging with the diagnostic test. The SNOD is essentially advised to err on the side of incapacity in their further investigations. The Codes of Practice on the opt out legislation suggest that the SNOD must be convinced of the deceased's past capacity, thus maintaining a presumption of *in*capacity, in stark contrast with the MCA 2005's explicit presumption of capacity.[130] These Codes advise that the deceased who was known to have had a *potentially* impairing condition and thus *may* have lacked capacity to understand opt out is excluded on this basis. What is ultimately an indication – a particular diagnosis – is taken as evidence of a lack of mental capacity. Moreover, as the assessment is invited to be made in retrospect, the deceased cannot be availed of any provisions of the MCA 2005 geared to support decision making.[131] That is, any supports that might have been provided to P when still alive to understand the nature of a decision about organ donation and potentially enable an informed decision by P become impossible when the question is being considered after P's death.

Of course, it is possible that there will be instances in which there is clearly recorded evidence of a capacity assessment being undertaken precisely on the question of organ donation, which may reduce the need for retrospectivity. Even then, however, the question would remain as to whether capacity in respect of that decision remained as assessed for a significant period. The same question would remain in the even more unlikely event that the deceased had had multiple documented capacity assessments related to organ donation during their lifetime because assessment data on inter-assessment capacity will be absent. Assumption and speculation on mental capacity during these periods appears to be invited as a matter of practical necessity by the HTWA 2013 and the DCA 2019.

Finally, there is the matter of the time- and decision-specific nature of capacity per the MCA 2005. We have already touched on this, but it is deserving of more attention. The MCA 2005 sets out tests for capacity in respect of specific matters such that there are to be no blanket determinations of incapacity.[132] Moreover, the MCA 2005 precludes determinations of capacity being made solely based on P's age or appearance.[133] Nor is capacity to be determined on the basis of a condition P has that 'might lead others to make unjustified assumptions about his capacity'.[134] The opt out laws and Codes of Practice conflict with this principle.[135] This point cannot be settled through the recent approach to 'longitudinal' capacity assessments in which Hedley J has argued that it is permissible to group certain kinds of routine decisions together for the purposes of assessment[136]

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[130] Section 1(2) Mental Capacity Act 2005.

[131] Recall the MCA 2005's requirement that, where an individual appears to lack capacity, this cannot result in a determination of capacity unless 'all practicable steps to help him to do so have been taken without success'. Section 1(3) Mental Capacity Act 2005.

[132] Section 2(1) Mental Capacity Act 2005.

[133] Section 2(3)(a) Mental Capacity Act 2005.

[134] Section 2(3)(b) Mental Capacity Act 2005.

[135] See also Tom Hayes, 'Donation and Devolution: The Human Transplantation (Wales) Act 2013' in Ralf J. Jox, Galia Assadi, and Georg Marckmann, eds., *Organ Transplantation in Times of Donor Shortage*, Vol. 59 (Springer International Publishing, 2016), pp. 150–151.

[136] *Cheshire West and Chester Council v PWK* [2019] EWCOP 57.

because the decision to donate organs cannot reasonably be seen as a recurrent type of decision, nor one sufficiently similar to any other healthcare decision.

Consider it as follows – in reverse chronological order for explanatory purposes. Take point C (after death) as when a decision as to donation is being considered under opt out. This is when the SNOD is collecting relevant information to make a decision. Point B is when the individual concerned dies.[137] It is the deceased's capacity at point A (before death) that is being considered in deciding whether the capacity exclusion is applicable.

A ------------------- B -------------------- C

before death death after death

At point C, then, the SNOD is considering the status of the deceased at the earlier point A. This simply cannot be considered as time-specific capacity, as it is a retrospective examination of the deceased's capacity. Given point A is the last point at which the deceased may have had capacity, it appears logical that it be the time point considered. However, with it being in the past, the deceased cannot be said to have failed a decision-specific capacity assessment at point A in accordance with the MCA 2005's functional test.

Given these issues with the application of the functional test in the context of opt out, something more akin to a status-based test would seemingly be more pragmatic. Certainly, it appears to be the only practical way to maintain a capacity exception to opt out. The issue is not, then, with the use of a status-based test, but with the failure for this to be debated in both the National Assembly for Wales and Houses of Parliament and, subsequently, suitably acknowledged in relevant materials (primarily the Codes of Practice). These complexities and differences between the two approaches are not acknowledged, which may prove problematic for reasons we will discuss in the following section.

Implications of inconsistency

Inconsistency between the MCA 2005's functionalist aspirations and the opt out legislation we have examined here is not problematic *per se*. Indeed, we acknowledged that there may well be good reason for adopting a more cautious approach to mental capacity in the context of deceased donor donation than in treatment decisions concerning the living. Consider, on one hand, someone presumed to lack mental capacity for a significant period but would not have failed a capacity assessment in respect of organ donation were one to have been conducted. On the other, consider someone who likely would have failed a capacity assessment in respect of organ donation for a significant period during their lifetime, had one been conducted, but who was not categorised as an excluded adult merely because they had not been assessed in respect of posthumous organ donation specifically. The failure to respect the former person's wishes for their organs to be used for transplantation after death could be viewed as a form of harm in failing to recognise

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[137] The SNOD may have begun their work around point B, but for simplicity of explanation, we will treat points B and C separately.

their autonomous wishes. But it is at least arguable that the latter will be exposed to a greater risk of harm, where that harm is recognised as having one's organs used for transplantation purposes without some manner of agreement from the individual,[138] hence our intuitive response to exclude as a default where there is any indication of incapacity in such situations.

We do not take issue with the nature of the exception, nor the inconsistency, but with the lack of transparency in the legislation to indicate that a different approach to mental capacity is a practical necessity in these circumstances. Moreover, the way the law is currently worded runs the risk of exacerbating confusion around mental capacity. The failure to highlight the inconsistency with the MCA 2005's approach introduces the possibility of error and misunderstanding, especially for healthcare professionals who work in roles that relate to organ donation. In the absence of clear guidance to the contrary, it is reasonable that healthcare professionals would assume the approach to mental capacity is consistent in law, with that stipulated in the MCA 2005 being more familiar to them.

This is particularly problematic given the issues that already exist with understanding and practice of the MCA 2005 in healthcare settings. As noted earlier, there are already concerns over capacity assessments not fully adhering to the MCA 2005 principles and decisions being unduly influenced by the characteristics of the individual subject to assessment.[139] Professionals working within both frameworks – that is, the MCA 2005 and opt out – may, given more recent training on it, take the approach of the opt out systems to be reflective of the MCA 2005. The risk being that the status approach becomes normalised and used in other areas of practice, resulting in inaccurate determinations of incapacity. Thus, without the difference being acknowledged, the status-based approach of opt out could bleed into wider practice, undermining the MCA 2005's functional approach and the autonomy of patients affected.

A way forward

As we have already noted, we do not see that the framing of the capacity exception is inherently problematic. Given that organ donation is a rather different scenario to more commonplace capacity assessments under the MCA 2005, it is far more defensible for something closer to a status-based test to be incorporated, not only in the interests of the deceased's autonomy but also for consequentialist reasons relating to public trust in the system.

Instead, our quarrel is with the tacit adoption of a status-based approach to determine mental capacity that is not compatible with the principles of the MCA 2005 and its

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[138] We speak of some manner of agreement here in recognition of the wider debate as to whether inaction can constitute consent. Similarly, we recognise many would disagree that this example of what is effectively posthumous harm warrants concern. Our recognition of it here accords with the principles underpinning the opt out systems (and organ procurement system more broadly), which ultimately characterise it as such.

[139] Donnelly, 'Capacity Assessment Under the Mental Capacity Act 2005'; Jayes et al., 'Literature Review'.

commitment to functionalism without any open and meaningful debate. Given the lack of transparency on such an important matter as well as the practical necessity of adopting a status-based approach in these cases, it would be appropriate for the relevant Codes of Practice to be amended accordingly to reduce the potential for confusion and harm. This is most important with the Human Tissue Authority's Codes of Practice, as it is these that professionals working in organ donation will most likely consult, and thus, these need to be very clear on any variation in the approach to determine capacity that might apply in this context. Nonetheless, for completeness and to avoid unnecessary confusion – which is central to our concern – it would also be appropriate for the MCA 2005 Code of Practice to be amended to also acknowledge any variation.

This recommendation is pragmatic. Such amendments to the various Codes of Practice acknowledge that professionals working in organ donation are already operating under two systems of capacity and, in response, provide important clarity. Addressing this via the Codes of Practice – particularly those of the Human Tissue Authority – is to direct this clarity towards professionals. The intended result being a recognition among healthcare professionals that a status-based approach may be necessary for a capacity exclusion to exist in opt out systems, but functionalism remains the guiding approach in all other healthcare settings – this being especially important to reducing the risk of confusion that may lead to greater use of a status-based test in wider healthcare practice.

This is not a perfect remedy, however, as a clear adoption of a status-based approach in this way, regardless of any necessity, ought to have received the opportunity for debate in the respective legislatures in both Cardiff and Westminster. During the legislative processes leading to the HTWA 2013 and DCA 2019, there was no shortage of opportunities to explore these disparate framings of mental capacity and consider more clearly whether the test for capacity within the MCA 2005 is appropriate in the opt out context. In Wales, for example, the explanatory memorandum to the earlier Bill mentions (somewhat in passing) the MCA 2005.[140] This presented a perfect opportunity, early in the legislative process, to air and resolve the inconsistencies we have highlighted, but the matter was not debated.[141]

In relation to the DCA 2019, too, when introducing the Bill to the House of Lords, Lord Hunt of Kings Heath stated:

> The Bill also provides a safeguard for people who lack the capacity to understand the concept of deemed consent [opt out] for a significant period before their death. The decision on whether a person lacks capacity *will continue to be established in accordance with the Mental Capacity Act 2005*.[142]

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[140] Welsh Government, 'Human Transplantation (Wales) Bill Explanatory Memorandum incorporating the Regulatory Impact Assessment and Explanatory Notes', available at https://content.hta.gov.uk/sites/default/files/2020-11/Code%20of%20Practice%20on%20the%20Human%20Transplantation%20%28Wales%29%20Act%202013.pdf (accessed 25 August 2023) at [36].

[141] Op. cit., at [38].

[142] HL Deb vol 794 col 411 23 November 2018 [emphasis added].

This suggests that there may in fact have been a lack of awareness of the differences we have highlighted, as there was an expectation that capacity determinations within the opt out system would operate in line with the MCA 2005. Politicians may be afforded some grace in that the Supreme Court's clarification on the ordering of the functional and diagnostic tests in the application of the MCA 2005 only came in 2021.[143] Nonetheless, this need for resolution remains and is, if anything, strengthened by the 2021 ruling. We suggest, then, that this ought to be addressed in the first instance through revised guidance in the relevant Codes of Practice.

Scotland and Northern Ireland

We have thus far concerned ourselves only with Wales and England. The reasoning being their opt out legislation matches the jurisdiction of the MCA 2005, making for a clean comparator. For the sake of completeness, however, it is also worth considering the situation in Scotland and Northern Ireland. Mental capacity and organ donation are both governed by different bodies of legislation in these two nations. Nonetheless, there are significant similarities, such that much of what we have argued in relation to Wales and England holds true across the UK.

Scotland

In Scotland, the Adults with Incapacity (Scotland) Act 2000 defines someone to be 'incapable' where they are unable to: (a) act, (b) make decisions, (c) communicate decisions, (d) understand decisions, or (e) retain the memory of decisions.[144] Whilst worded differently and presented in an alternate order, the parallels with the MCA 2005 conception of capacity are clear – this is the same take on a functional approach. Furthermore, the associated diagnostic element is similarly present:

> by reason of mental disorder or of inability to communicate because of physical disability; but a person shall not fall within this definition by reason only of a lack or deficiency in a faculty of communication if that lack or deficiency can be made good by human or mechanical aid (whether of an interpretative nature or otherwise).[145]

Again, this reflects the requirement of the MCA 2005 in that individuals should not be treated as having failed the functional test merely because they have not received support, instead there must be a failure *based on* 'mental disorder or [. . .] inability to communicate'. In guidance for healthcare workers, the Scottish Government has implied that the diagnostic element should precede the functional.[146] However, this is not explicitly

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[143] *A Local Authority v JB*.

[144] Section 1(6) Adults with Incapacity (Scotland) Act 2000.

[145] Op. cit.

[146] Scottish Government, 'Communication and Assessing Capacity: A Guide for Social Work and Health Care Staff' available at https://www.gov.scot/binaries/content/documents/govscot/publications/advice-and-guidance/2008/02/adults-incapacity-scotland-act-2000-communication-assessing-capacity-guide-social-work-health-care-staff/documents/0055759-pdf/0055759-pdf/govscot%3Adocument/0055759.pdf (accessed 30 October 2024), [6].

stated. Furthermore, this guidance is from 2008, so although Scottish legislation differs from that of England and Wales, this position might be influenced by the more recent Supreme Court clarification in *JB*.

The 2000 Act does require capacity to be specific to a given decision,[147] but the same time-specific element is absent. Indeed, the approach to time and capacity is slightly different in Scotland, in that a certificate of incapacity is issued with a defined period in which healthcare can be provided to the person's benefit.[148] Such a system does, we suggest, strengthen the suggestion that the Scottish approach places the diagnostic element ahead of the functional – a section 47 certificate has a clear requirement for diagnostic justification. This difference does arguably impact the comparability of the Scottish system with those of Wales and England, which we will revisit shortly after outlining Scotland's opt out system.

Deemed authorisation[149] in Scotland operates much the same as opt out in Wales and England. The same capacity requirement is present, framed as 'an adult who is incapable of understanding the nature and consequences of deemed authorisation'.[150] This is supplemented by similar notes about a 'significant period'[151] and what a 'reasonable person' would conclude.[152] Of note, there is no clarification in the accompanying guidance for professionals to state that 12 months – or any other period – can be treated as the 'significant period' for practical purposes, the reasoning being to 'enable the specific circumstances in each case to be taken into account and to recognise that capacity may fluctuate over time'.[153] However, this variation is minor, not least because it is not a legislative stipulation in Wales and England and is only a suggestion of the Codes of Practice.

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[147] Section 47(1)(a) Adults with Incapacity (Scotland) Act 2000.

[148] Section 47(5) Adults with Incapacity (Scotland) Act 2000. 'Benefit' being the language used in the Scottish system, rather than the 'best interests' familiar in Welsh and English law. See Scottish Government, 'Adults with Incapacity (Scotland) Act 2000 Code of Practice (Third Edition) for Practitioners Authorised to Carry Out Medical Treatment or Research Under Part 5 of the Act' available at https://www.gov.scot/binaries/content/documents/govscot/publications/advice-and-guidance/2010/10/adults-incapacity-scotland-act-2000-code-practice-third-edition-practitioners-authorised-carry-out-medical-treatment-research-under-part-5-act/documents/0105906-pdf/0105906-pdf/govscot%3Adocument/0105906.pdf (accessed 30 October 2024), [1.4.1].

[149] Recall our earlier note on the differing language used in Scotland.

[150] Section 6D(2)(b) Human Tissue (Scotland) Act 2006, as amended by section 7(2) Human Tissue (Authorisation) (Scotland) Act 2019.

[151] Section 6D(3) Human Tissue (Scotland) Act 2006, as amended by section 7(2) Human Tissue (Authorisation) (Scotland) Act 2019.

[152] Section 6D(4) Human Tissue (Scotland) Act 2006, as amended by section 7(2) Human Tissue (Authorisation) (Scotland) Act 2019.

[153] Scottish Government, 'Guidance on Deceased Organ and Tissue Donation in Scotland: Authorisation Requirements for Donation and Pre-Death Procedures' available at https://www.gov.scot/binaries/content/documents/govscot/publications/advice-and-guidance/2021/03/guidance-deceased-organ-tissue-donation-scotland-authorisation-requirements-donation-pre-death-procedures-1st-edition-published-march-2021-1st-ed/documents/guidance-deceased-organ-tissue-donation-scotland-authorisation-requirements-donation-pre-death-procedures/

Guidance for professionals outlines very similar steps to the opt out Codes of Practice found in Wales and England, requiring the SNOD to check medical records for a history of potentially impairing conditions and consult with the individual's family and friends.[154] Relating to the matter of time, there is a unique possible confusion in the Scottish system in that there is no mention of certificates of incapacity. Whilst one would assume the presence of such a certificate would be treated by a SNOD as a partial basis to exclude the individual from deemed authorisation on capacity grounds, this is not made clear. There is, then, an additional need in Scotland for clarity in the opt out guidance on how the presence of a recent section 47 certificate is to be considered, if at all.

Of course, the presence of a valid certificate of incapacity at the time of an organ donation decision does affect the applicability of our critique to Scotland slightly. Where there is a certificate in force at the time of someone's death, they may be excluded from opt out on a basis that is at least closer to a functional test than that in Wales and England – albeit not truly a functional test. Such an individual had at least undergone a recent capacity assessment on the basis of a functional test and is not being excluded from opt out purely on the basis of diagnostic status. However, the decision with which that capacity assessment would have been concerned would not have been organ donation.[155] The exclusion of that individual from opt out, then, is effectively still through a status-based approach, albeit of a slightly different nature and with more information to draw on in making the determination. Hence, this slight variation does not undermine the applicability of our critique to Scotland.

Northern Ireland

Northern Ireland has less divergence from Wales and England. The Mental Capacity Act (Northern Ireland) 2016 – a rather more recent addition to the statute books – provides the same four-part functional test for capacity as the MCA 2005, requiring an individual to understand, retain, and use and weigh information to reach a decision, before communicating that decision.[156] The 2016 Act more unusually provides a little more detail on the understanding element, noting that someone should not be deemed unable to understand relevant information 'if the person is able to understand an appropriate explanation

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guidance-deceased-organ-tissue-donation-scotland-authorisation-requirements-donation-pre-death-procedures/govscot%3Adocument/guidance-deceased-organ-tissue-donation-scotland-authorisation-requirements-donation-pre-death-procedures.pdf (accessed 25 August 2023) at [135].

[154] Op. cit., [138]. Indeed, Scotland is unique in having a statutory 'duty to inquire'. Section 16H(2)(4) Human Tissue (Scotland) Act 2006, as amended by section 24 Human Tissue (Authorisation) (Scotland) Act 2019. Thus, whilst the guidance may be comparable, it is on a statutory footing in Scotland but not in England and Wales.

[155] Of course, it is not impossible that the individual had sought to register an organ donation decision through discussion with a healthcare professional, which triggered a capacity assessment, but this seems incredibly unlikely.

[156] Section 4(1) Mental Capacity Act (Northern Ireland) 2016.

of the information'[157]; appropriate explanation meaning appropriate to their circumstances, 'using simple language, visual aids or any other means'.[158] Then, in line with the other UK nations, there is a more general stipulation requiring 'all practicable help and support' to enable an individual to satisfy the functional test.[159] Furthermore, capacity is taken to be specific to both time and decision.[160] There are, then, no pertinent differences in the general approach to mental capacity in Northern Ireland that affect the applicability of our critique of Wales and England.

Regarding opt out and the in-built capacity requirement, the Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022 essentially mirrors England's DCA 2019, amending the Human Tissue Act 2004 such that the same stipulations as inserted by the DCA 2019 apply in Northern Ireland.[161] As such, there is the same framing of the capacity requirement, save the small difference in Northern Ireland not including the further stipulation concerning a 'significant period'. Northern Ireland utilises the same Code of Practice as England, so the guidance provided on the capacity requirement is identical. As with its general mental capacity legislation, the approach to opt out in Northern Ireland is wholly comparable with that in Wales and England. That said, implementation of Northern Ireland's opt out system is rather more recent and remains ongoing, in part due to its introduction as a result of Westminster intervention.[162] There is, then, an extent to which its approach to capacity remains to be seen.

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The similarities between both mental capacity and opt out legislation in Northern Ireland and Wales and England are such that the same charge of inconsistency holds weight. That is, the relevant legislation is almost identical. The same issues of possible misunderstanding arise, resulting from a failure to acknowledge a difference in the framing of capacity. With Scotland, this is slightly less clearly the case. There remain substantial similarities in the framing of mental capacity and opt out in Scotland and other UK nations, but on the matter of time, as it relates to mental capacity, there is a small divergence. This does not wholly undermine the applicability of our aforementioned discussion to Scotland but does alter it slightly. In particular, the relevance of certificates of incapacity introduces a further consideration that perhaps places the approach to capacity assessment in the opt out context in Scotland (in very particular circumstances where there is a valid certificate of capacity at the time) somewhere between a functional and status-based approach – though certainly closer to status-based.

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157. Section 4(3) Mental Capacity Act (Northern Ireland) 2016.
158. Section 4(4) Mental Capacity Act (Northern Ireland) 2016.
159. Section 5(1) Mental Capacity Act (Northern Ireland) 2016.
160. Section 3(1) Mental Capacity Act (Northern Ireland) 2016.
161. Section 3(9A)(b) Human Tissue Act 2004, as amended by section 1(4) Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2022.
162. Northern Ireland (Executive Formation and Organ and Tissue Donation) Act 2023. See also Reed-Berendt et al., 'The Connection-Friction Axis'.

Overall, though, the similarities are uncanny. Our critique of unacknowledged inconsistency in Wales and England holds true when applied to both Scotland and Northern Ireland, just lodged against different legislation.

Conclusion

Ensuring a fair opportunity to opt out of becoming an organ donor is key to the legitimacy of soft opt out systems.[163] Without it, there could be no argument that it remains a consensual system notwithstanding the absence of a requirement for a positive act of consent. But, in order to be able to properly consider the choice to opt out, mental capacity is a necessary prerequisite. Consequently, it is essential to have proper safeguards in place to ensure that those who lacked the requisite capacity to opt out are not included within the purview of opt out.

Both the HTWA 2013 and DCA 2019 make provision for this but, as we have argued, those provisions do not sit well with the MCA 2005's core principle of functionalism. Under both systems, healthcare professionals (SNODs in particular) are invited to make retrospective assessments of mental capacity in respect of organ donation. The information available to the SNOD will be incomplete, there will be no opportunity for dialogue with the person nor to provide them with any support, and there would need to be a heavy reliance on making precisely the kind of assumptions about the person based on their reported diagnoses and condition that the MCA 2005 warns against. In practical terms, the need for these assumptions may be considered unavoidable. However, that this goes unacknowledged in both the statutes and Codes of Practice leaves us with an ultimately unjustified divergence from the long-established principles of the MCA 2005. There is a need for greater clarity from legislators as to how intentional such a divergence was and, if indeed intentional, a clear statement of this for the avoidance of doubt among those required to put such procedures into practice.

In Scotland and Northern Ireland, similar issues arise. With much the same framing of both capacity and opt out in these two nations as in Wales and England, the commonalities are such that our critique largely holds true. Nonetheless, capacity legislation in Scotland approaches the matter of time slightly differently, in such a way that there are additional considerations around the relevance of certificates of incapacity to opt out decisions.

The consequences of the de facto status-based approach being embedded into these systems may not cause immediate harm, and it is arguable that a more cautious approach to mental capacity based on status is warranted here. However, that argument should have been made in the National Assembly for Wales and Houses of Parliament, respectively.[164] Moreover, the potential for these laws to generate confusion regarding the operation of the MCA 2005 in respect of capacity assessments does present the risk of harm in other areas of practice because it may lead to people wrongly being assessed as lacking capacity and provided with treatment against their wishes as a result. In the short

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[163] Price, *Human Tissue in Transplantation and Research*.

[164] And, indeed, in the Scottish Parliament and Northern Ireland Assembly.

term, therefore, the Codes of Practice for both organ donation and the MCA 2005 should be updated to make it clear that there is a difference in the approach to mental capacity here compared to other situations. The draft of the updated MCA 2005 Code of Practice has not yet been implemented,[165] but plans should be made now to update the Codes of Practice for opt out legislation so that new versions can be published alongside the updated MCA 2005 Code of Practice. Beyond this, the approach to the assessment of capacity in the context of organ donation is deserving of scrutiny and debate. Pretending that functionalism operates in these organ donation systems is even harder to sustain here than it is in respect of other aspects of healthcare law. Such clarity from both legislators and regulators is vital given that certain healthcare professionals will be working within the frameworks of both opt out and the MCA 2005, and that they are, very reasonably, reliant on guidance documents for lack of legal expertise.

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[165] HM Government, 'Draft Mental Capacity Act 2005 Code of Practice Including the Liberty Protection Safeguards' (Department of Health and Social Care, Ministry of Justice, Department for Education and Welsh Government, 2022) available at https://assets.publishing.service.gov.uk/media/62962d1f8fa8f50395c0a054/draft-mental-capacity-act-code-of-practice.pdf (accessed 28 October 2024).