




# Deemed consent for organ donation: a comparison of the English and Scottish approaches

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## ABSTRACT

Deemed consent for organ donation has long been discussed as a potential solution to the shortage of organs for transplantation, with several countries having implemented it. In Great Britain, Wales was the first nation to introduce such a system, having done so in 2015. Now, the other two nations are following suit. In this paper, I compare the approaches of England and Scotland in moving to systems of deemed consent for organ donation. After outlining both sets of legislation, I focus on three points on which the two nations differ. First, the role of those close to the deceased in the consent process and the extent to which clinicians are required to consult them ahead of consent being deemed. Second, the role of government ministers in ensuring widespread public awareness. Third, the ways in which the two nations responded to the challenge of the COVID-19 pandemic in relation to the implementation of deemed consent. I conclude that on all three points, the Scottish approach is preferable.

## I. INTRODUCTION

There has long been a shortage of organs for transplantation. This is the case not only in Great Britain (GB),<sup>1</sup> but globally. Even in Spain, which is generally considered to be the shining beacon of hope in the organ procurement endeavor,<sup>2</sup> hundreds of patients die each year awaiting an essential transplant. Several ‘solutions’ have been proposed, though perhaps most commonly espoused is so-called deemed consent.<sup>3</sup> Departing from the more traditional express consent model of organ donation, whereby *not* donating was the default, deemed consent considers all those who die to be donors<sup>4</sup> in the absence of a formally expressed wish to the contrary. It is a system that has been implemented across the world,<sup>5</sup> and more countries consider the move each year.

Deemed consent is generally justified on the basis of a disparity between public support for organ donation and actual donation statistics. Further, the ethical defensibility of such systems is based on widespread awareness of how it operates and a suitably straightforward method for citizens to record their objection.<sup>6</sup> Rather than providing a detailed discussion now, I will explore these points throughout this article.

As of May 20, 2020, a system of deemed consent for organ donation has been in operation in England. A similar system was due to be introduced in Scotland later the same year but has since been postponed as a result of the COVID-19 pandemic. Several years before the English and Scottish acts began their journeys through their respective parliaments, Wales was already operating a system of deemed consent for organ donation. The Human Transplantation (Wales) Act 2013 (HTWA 2013) came into force in December 2015 to much praise. It was declared a ‘progressive policy’ for a ‘progressive nation’ by Mark Drakeford, the Cabinet Secretary for Health and Social

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- 1 NHS Blood and Transplant, *Organ Donation and Transplantation Activity Report 2019/20*, <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/19220/activity-report-2019-2020.pdf> (accessed Sept. 22, 2020). I refer specifically to Great Britain rather than the United Kingdom (UK) as in this article I discuss English, Scottish, and, to a lesser extent, Welsh legislation. Northern Ireland remains under a system of express consent, its Assembly having voted against the Human Transplantation Bill in 2016 which would have introduced a system of deemed consent. See Northern Ireland Assembly Committee for Health, Social Services and Public Safety, *Report on the Human Transplantation Bill*, [www.niassembly.gov.uk/globalassets/ts/documents/health-2011-2016/reports/report-on-the-human-transplantation-bill.pdf](http://www.niassembly.gov.uk/globalassets/ts/documents/health-2011-2016/reports/report-on-the-human-transplantation-bill.pdf) (accessed Sept. 22, 2020). However, on Dec. 11, 2020, the Northern Ireland Department of Health launched a public consultation on the introduction of an opt-out system which is due to close on Feb. 19, 2021. Northern Ireland Department of Health, Public Consultation Document on the introduction of a statutory opt-out system for organ donation for Northern Ireland, [www.health-ni.gov.uk/consultations/organ-donation](http://www.health-ni.gov.uk/consultations/organ-donation) (accessed Dec. 18, 2020). It is possible, then, that the whole of the UK will be operating some form of deemed consent within a few years.
  - 2 Spain is praised for having the highest rate of transplants. Although the United States carries out a far higher number of transplants annually, the rate in Spain per million of the population just creeps into first place.
  - 3 Deemed consent is also known as presumed consent under some systems and is more colloquially known as ‘opt-out’. I will proceed using deemed consent. However, it is important to note that in Scotland, the Human Tissue (Authorisation) (Scotland) Act 2019 uses the language of ‘deemed authorisation’.
  - 4 The use of the term ‘donor’ may not be appropriate where consent is not explicit. It might be questioned whether any organs procured from the deceased based on deemed consent are indeed donated. I consider the term ‘provider’ to be more appropriate, though I will continue with the commonplace terminology of donor for the sake of clarity and the avoidance of confusion.
  - 5 Variations of deemed consent are in place in several countries. For example, Spain, Croatia, Singapore, and Colombia.
  - 6 Ben Saunders, *Opt-out organ donation without presumptions*, 38 J. MED. ETHICS 69, 71 (2012).

Services at the time.<sup>7</sup> Under the HTWA 2013, any deceased adult who is not excepted<sup>8</sup> is deemed to consent to organ donation unless they had a decision relating to donation in force immediately before their death or had appointed a person or persons to handle the issue of consent on their behalf.<sup>9</sup> The Act also allows for a relative or friend of long standing of the deceased to object to donation proceeding based on views held by the deceased,<sup>10</sup> provided a reasonable person would conclude that the relative or friend knows that the deceased's most recent view would have been against consenting to donation.<sup>11</sup>

The intention of the HTWA 2013 was to improve transplant statistics in Wales. However, the extent to which deemed consent can be expected to improve donation and transplant statistics is contentious. Some evidence suggests an increase in consent, donation, and transplantation rates following the introduction of deemed consent,<sup>12</sup> and the success of Spain's organ donation is often attributed to it being based on deemed consent.<sup>13</sup> However, others question whether the legislation is responsible, suggesting that it is the role of transplant coordinators in Spanish hospitals that has improved transplantation figures and that the law itself is dormant.<sup>14</sup> The success of the HTWA 2013 has already been a point of disagreement,<sup>15</sup> and ahead of the passing of both the Organ Donation (Deemed Consent) Act 2019 (DCA 2019) in England and the Human Tissue (Authorisation) (Scotland) Act 2019 (ASA 2019) in Scotland it was again suggested that deemed consent was not the answer to the shortfall of organs for transplantation.<sup>16</sup> For the purposes of this article, deemed consent's potential in this respect is irrelevant. My concern is with the distinctions between the English and Scottish systems of deemed consent and which is preferable in terms of both ethical/legal defensibility and success—success here meaning self-adherence and longevity, whether donor rates improve or not.

In this article, I begin by outlining the deemed consent legislation of both England and Scotland. I then highlight three key issues on which the two systems differ and what they mean for the operation of deemed consent in the respective nations. First,

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- 7 BBC News, *Organ donation opt-out system given go-ahead in Wales*, <https://www.bbc.co.uk/news/uk-wales-politics-23143236> (accessed Sept. 24, 2020).
  - 8 Excepted adults are those who had not been ordinarily resident in Wales for the 12 months prior to their death or had lacked capacity to understand deemed consent for a significant period before their death. S.5 (3) Human Transplantation (Wales) Act 2013.
  - 9 SS.4 (2) (a) and 4 (3) Human Transplantation (Wales) Act 2013.
  - 10 S.4 (4) (a) Human Transplantation (Wales) Act 2013.
  - 11 S.4 (4) (b) Human Transplantation (Wales) Act 2013.
  - 12 See, for example, Mary Steffel, Elanor F. Williams, and David Tannenbaum, *Does changing defaults save lives? Effects of presumed consent organ donation policies*, 3 BEHAV. SCI. 73 (2017).
  - 13 See, for example, Sheila M. Bird and John Harris, *Time to move to presumed consent for organ donation*, 240 BMJ c2188 (2010).
  - 14 See, for example, John Fabre, Paul Murphy, and Rafael Matesanz, *Presumed consent: a distraction in the quest for increasing rates of organ donation*, 341 BMJ c4973 (2010).
  - 15 Jordan A. Parsons, *Welsh 2013 deemed consent legislation falls short of expectations*, 122 HEALTH POLICY 941 (2018); Andreas Albertsen, *Deemed consent: assessing the new opt-out approach to organ procurement in Wales*, 44 J. MED. ETHICS 314 (2018); Jordan A. Parsons, *Ensuring appropriate assessment of deemed consent in Wales*, 45 J. MED. ETHICS 210 (2019); Andreas Albertsen, *Assessing deemed consent in Wales—the advantages of a broad difference-in-difference design*, 45 J. MED. ETHICS 211 (2019).
  - 16 Adnan Sharif, *Presumed consent will not automatically lead to increased organ donation*, 94 KIDNEY INT. 249 (2018).

the role of those close to the deceased in the consent process and the extent to which clinicians are required to consult them ahead of consent being deemed. Second, the role of government ministers in ensuring widespread public awareness. Third, the ways in which the two nations responded to the challenge of the COVID-19 pandemic in relation to the implementation of deemed consent. I conclude that on all three points, the Scottish approach is preferable.

## II. THE NEW DEEMED CONSENT LAWS

Here I will outline the background to and key features of the new deemed consent laws in both England and Scotland. For now, I will intentionally omit certain elements of the new acts as they are points of difference which will be explored shortly.

### II.A. Organ Donation (Deemed Consent) Act 2019

In amending the Human Tissue Act 2004 (HTA 2004), the DCA 2019—also known as *Max and Keira's Law* in recognition of two children considered to have inspired the change after Max was saved by the donated heart of Keira<sup>17</sup>—brought into force a system of deemed consent for adults<sup>18</sup> in England<sup>19</sup> as of May 20, 2020. Prior to this change, under the HTA 2004 as enacted, donation could only take place with either the express consent of the individual (in writing if the individual was deceased), a person or persons appointed to deal with the issue in the event of the individual's death, or a person who stood in a qualifying relationship<sup>20</sup> with the individual prior to their death, in that order of succession.<sup>21</sup>

With regards to excluded groups, a person is considered a member of one—an 'excepted adult'—if they (a) had not been ordinarily resident in England for a period of at least 12 months immediately before dying, or (b) had for a significant period before dying lacked capacity to understand the effect of the move to deemed consent.<sup>22</sup> As consent cannot be deemed for excepted adults, a system of express consent continues to operate for such persons.<sup>23</sup>

17 NHS Blood and Transplant, *Keira's story—Max and Keira's Law*, [www.organdonation.nhs.uk/helping-you-to-decide/real-life-stories/families-who-donated-their-loved-ones-organs-and-or-tissue/keiras-story-max-and-keiras-law/](http://www.organdonation.nhs.uk/helping-you-to-decide/real-life-stories/families-who-donated-their-loved-ones-organs-and-or-tissue/keiras-story-max-and-keiras-law/) (accessed Sept. 24, 2020).

18 The Organ Donation (Deemed Consent) Act 2019 does not apply to those under the age of 18, as per s.54 (1) Human Tissue Act 2004.

19 The Organ Donation (Deemed Consent) Act 2019 does extend to both Wales and Northern Ireland too, but amendments therein to the Human Tissue Act 2004 are such that its introduction of deemed consent for transplantation applies only in England. See s.3 (6) (6A) Human Tissue Act 2004, as amended by s.1 (4) Organ Donation (Deemed Consent) Act 2019.

20 Qualifying relationships are grouped into eight and ranked from 'spouse, civil partner or partner' to 'friend of longstanding'. See s.27 (4) Human Tissue Act 2004.

21 S.3 Human Tissue Act 2004 [as enacted].

22 SS.3 (9) and 3 (10) Human Tissue Act 2004, as amended by s.1 (5) Organ Donation (Deemed Consent) Act 2019. These exemptions reflect the results of the public consultation on the new law, whereby the majority favoured the exclusion of both groups. Respondents to the consultation also supported the exclusion of those under the age of 18—albeit 53:47—which is also reflected in the new law. Department of Health and Social Care, *The New Approach to Organ and Tissue Donation in England: Government Response to public consultation*, [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/731913/govt-response-organ-donation-consent.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/731913/govt-response-organ-donation-consent.pdf) (accessed Sept. 22, 2020).

23 Human Tissue Authority, *Code of Practice F part two: Deceased organ and tissue donation*, at para 71.

There are limits to what human tissue falls within the remit of the new deemed consent model. Extensive listing of material that is not permitted is provided in the Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020,<sup>24</sup> which came into force on the same day as the DCA 2019. These regulations, despite listing only England in their title, apply to both England and Wales, having amended the HTA 2004.<sup>25</sup>

The rationale behind the move to deemed consent in England was, at least in part, evidence of public support. According to the explanatory notes to the DCA 2019, around 80 per cent of the public support organ donation ‘in principle’,<sup>26</sup> so the intention of the Act is to bring the reality in line with public opinion. Certainly, there has been a history of public support for organ donation in GB even with the disconnect between support and actual donation.<sup>27</sup>

### **II.B. Human Tissue (Authorisation) (Scotland) Act 2019**

In Scotland, a similar model of deemed consent is due to come into force in March 2021. Somewhat mirroring England, the ASA 2019 amends the Human Tissue (Scotland) Act 2006 (HTSA 2006) to allow the donation of a deceased adult’s<sup>28</sup> organs for transplantation to proceed where no objection has been raised.

The ASA 2019 has several exceptions that are the same as those in the DCA 2019. In Scotland, deemed consent will not apply to a person who (a) had in force an opt-out declaration at the relevant time,<sup>29</sup> (b) was not ordinarily resident in Scotland for at least 12 months before the relevant time,<sup>30</sup> or (c) is incapable of understanding the nature and consequences of deemed consent.<sup>31</sup> Here it is worth noting that while the DCA 2019 deploys the language of ‘immediately before dying’ for the purposes of temporal specifics, the ASA 2019 prefers the phrase ‘at the relevant time’. However, as is detailed in the notes on interpretation to the ASA 2019, the ‘relevant time’ is, for the purposes

24 S.2 Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020.

25 S.1 (2) Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020.

26 Explanatory Notes to the Organ Donation (Deemed Consent) Act 2019, para 5. There is no more detail as to the source of this statistic. Most likely, the statistic was lifted from the Government’s response to the public consultation on deemed consent. Department of Health and Social Care, *supra* note 21. However, the Government’s response also fails to provide an actual source. Further, the explanatory note states there is 80 per cent support for ‘organ donation’ generally rather than deemed consent specifically, and there is insufficient information to infer that what is meant is deemed consent.

27 King’s Fund Institute, *A Question of Give and Take: Improving the supply of donor organs for transplantation*, [https://archive.kingsfund.org.uk/concern/published\\_works/000011132?locale=fr#c=0&m=0&s=0&cv=0&xywh=-2303%2C-1%2C5974%2C1872](https://archive.kingsfund.org.uk/concern/published_works/000011132?locale=fr#c=0&m=0&s=0&cv=0&xywh=-2303%2C-1%2C5974%2C1872) (accessed Sept. 22, 2020).

28 As with the Organ Donation (Deemed Consent) Act 2019, deemed consent under the Human Tissue (Authorisation) (Scotland) Act 2019 does not apply to children. However, under s.60 (1) Human Tissue (Scotland) Act 2006 an adult is a person aged 16 or over. SS.13 to 18 Human Tissue (Authorisation) (Scotland) Act 2019 concern consent to donation for children (meaning those under the age of 16), but do not introduce deemed consent so will not be discussed here.

29 S.6D (1) (b) Human Tissue (Scotland) Act 2006, as amended by s.7 (2) Human Tissue (Authorisation) (Scotland) Act 2019.

30 S.6D (2) (a) Human Tissue (Scotland) Act 2006, as amended by s.7 (2) Human Tissue (Authorisation) (Scotland) Act 2019.

31 S.6D (2) (b) Human Tissue (Scotland) Act 2006, as amended by s.7 (2) Human Tissue (Authorisation) (Scotland) Act 2019.

of deceased donation, to be taken as ‘immediately before the person’s death.’<sup>32</sup> There is, then, a difference only in terminology and not in meaning.

Again, as in England, another individual will be able to demonstrate objection on behalf of the deceased.<sup>33</sup> However, there is no specification of the need for that individual to be in a qualifying relationship. Indeed, the ASA 2019 simply states that ‘a person’ may assume this role.<sup>34</sup> No further detail is provided in the Act’s notes on interpretation about who a ‘person’ can be in relation to the deceased. It might be taken as meaning ‘nearest relative’ as per the HTSA 2006.<sup>35</sup> Indeed, it seems reasonable to assume that this is how it will play out in practice, as clinicians working in areas relevant to the procurement of transplantable organs are accustomed to and trained in this system. However, it is important to recognize that the phrase actually used is ‘a person’, in legislation which does use the more familiar language of ‘nearest relative’ elsewhere.<sup>36</sup> For the avoidance of confusion, I will use the terminology of ‘qualifying relationship’ in the context of both the DCA 2019 and the ASA 2019.

Finally, as in England, certain body parts will be exempt from the forthcoming deemed consent legislation in Scotland. The ASA 2019 requires Scottish Ministers to provide regulations on which body parts are to be excluded,<sup>37</sup> which take the form of the Human Tissue (Excepted Body Parts) (Scotland) Regulations 2020. These regulations were passed on November 18, 2020 and come into force on the day that the new system of deemed consent does.<sup>38</sup>

### III. TO CONSULT OR NOT TO CONSULT

The central idea of deemed consent models is that express consent is not required. In the absence of an explicitly recorded wish of the deceased, donation is legally authorized. However, there is a necessary distinction between so-called ‘hard opt-out’ and ‘soft opt-out’, with systems of deemed consent existing on something of a spectrum between the two.<sup>39</sup>

Hard deemed consent is, in a sense, pure deemed consent. Where such a law operates, all that can prevent an individual becoming an organ donor upon their death is a formally recorded objection made by them prior to their death. Assuming, of course, that person’s organs are fit for transplantation and they are not within an excluded group. Such systems are rare. A notable example is that of Brazil. In 1997, Brazil

32 S.16 K (2) (b) Human Tissue (Scotland) Act 2006, as amended by s.27 (4) Human Tissue (Authorisation) (Scotland) Act 2019.

33 S.6D (2) (d) Human Tissue (Scotland) Act 2006, as amended by s.7 (2) Human Tissue (Authorisation) (Scotland) Act 2019.

34 *Id.*

35 S.7 Human Tissue (Scotland) Act 2006. If the ‘nearest relative’ approach is taken, then a ranked system similar to that in England (though with 11 rather than eight groups) will be utilized. See s.50 (1) Human Tissue (Scotland) Act 2006.

36 Those who are non-resident adults, and therefore out of the remit of deemed consent in Scotland, may have the use of their organs for transplantation authorized by their ‘nearest relative’. S.8 Human Tissue (Authorisation) (Scotland) Act 2019.

37 S.6D (5) Human Tissue (Scotland) Act 2006, as amended by s.7 Human Tissue (Authorisation) (Scotland) Act 2019.

38 Regulation 1 (1) Human Tissue (Excepted Body Parts) (Scotland) Regulations 2020.

39 James F. Douglas and Antonia J. Cronin, *The Human Transplantation (Wales) Act 2013: an Act of encouragement, not enforcement*, 78 MOD. LAW REV. 324 (2015)



introduced a hard deemed consent system, whereby only an objection by the potential donor was valid.<sup>40</sup> However, the system was abolished just 20 months later as a result of government mistrust and accusations of body snatching.<sup>41</sup> Arguably, the experience of Brazil demonstrates that hard deemed consent is not a feasible policy regardless of whether it improves donation statistics, and none of the deemed consent systems in operation, or soon to be in operation, in GB can be considered hard.

Far more common are systems of soft deemed consent, which afford those in qualifying relationships<sup>42</sup> to the deceased an opportunity to in some way prevent donation proceeding. It is such a system that operates in Wales.<sup>43</sup> Spain, which is often highlighted as a prime example of organ donation done well, also has soft deemed consent. Generally, the role of those in qualifying relationships to the deceased is limited to demonstrating that the deceased themselves would have objected to donation. There does not exist a right to veto based on those in qualifying relationships' own views and preferences. However, such a veto may be considered as operating in practice; understandably, whether dictated by law or not, clinicians will likely not wish to proceed with donation if the deceased's family strongly opposes it.<sup>44</sup>

Here one might consider how objections from those in qualifying relationships may vary in nature. As highlighted by Shaw, we might distinguish between three types of veto (or 'overrule', to use Shaw's terminology).<sup>45</sup> First, new evidence provided by someone in a qualifying relationship that demonstrates the deceased's own refusal. Second, the suggestion by someone in a qualifying relationship that the deceased would have opposed donation in a particular set of circumstances. Third, an objection based on

40 Claudia Csillag, *Brazil's law on organ donation passed*, 349 LANCET 482 (1997).

41 Claudia Csillag, *Brazil abolished 'presumed consent' in organ donation*, 352 LANCET 1367 (1998).

42 I will continue to use this terminology for the sake of consistency. However, readers should note that it is not deployed in all countries.

43 The Human Transplantation (Wales) Act 2013 does formally make the distinction between the deceased having a decision in force immediately before dying and not, stating that in the former situation the deceased's express consent is required. SS.4 (2) (a) and 4 (3) Human Transplantation (Wales) Act 2013. This suggests that a person in a qualifying relationship can only demonstrate the deceased's objection to donation if the deceased was *not* a registered organ donor. However, in practice, objection to donation by those in qualifying relationships is likely to prevent donation proceeding. See, for example, Douglas and Cronin, *supra* note 39, at 341.

44 It is worth noting that the family veto, in its various degrees of formality across jurisdictions, is rather controversial. Allowing the family to set aside the wishes of the deceased raises a serious question of respect for the deceased's autonomy—particularly if the deceased had actively joined the organ donation register. This is, however, not the place for an in-depth discussion of these issues. For further discussion of the issues see Andreas Albertsen, *Against the family veto in organ procurement: why the wishes of the dead should prevail when the living and the deceased disagree on organ donation*, 34 BIOETH. 272 (2020); David Shaw, Denie Georgieva, Bernadette Haase, Dale Gardiner, Penney Lewis, Nichon Jansen, Tineke Wind, Undine Samuel Maryon McDonald and Rutger Ploeg on behalf of the ELPAT Working Group on Deceased Donation, *Family over rules? An ethical analysis of allowing families to overrule donation intentions*, 101 TRANSPLANTATION 482 (2017); and Alexander Zambrano, *Patient autonomy and the family veto problem in organ procurement*, 43 SOC. THEORY PRACT. 180 (2017). Further, the language of 'veto' may itself be problematic when the law requires those in qualifying relationships seeking to prevent donation proceeding as they are required to provide some level of evidence to justify this. However, in recognition of its prevalence in the literature, I will proceed with the term.

45 Shaw uses the terminology of 'overrule' rather than 'veto'. He also suggests that not all three types ought to be considered vetoes/overrules, as 'there is clearly an ethical hierarchy of reasons'. David M. Shaw, *The consequences of vagueness in consent to organ donation*, 31 BIOETH. 424, 429 (2017).

the wishes of those in qualifying relationships, which Shaw terms ‘genuine overrules.’<sup>46</sup> It is the first two that Shaw suggests are most ethically important. Indeed, it is the first two that laws generally afford importance to. However, in practice it may be difficult to distinguish between them, resulting in the wishes of those in qualifying relationships taking on the significance of the deceased’s own wishes.<sup>47</sup>

The distinction between hard and soft deemed consent, then, is in the role of those in qualifying relationships to the deceased. This is incorporated into law in the form of requirements to consult them. Both the English and Scottish systems include such a requirement, though an interesting difference exists that places Scotland closer to a system of hard deemed consent.

Under the new system in England, in the absence of a formally recorded objection any person aged 18 or over who is not in one of the excluded groups is deemed to have consented to donation unless a person who, immediately before the potential donor’s death, stood in a qualifying relationship to the person concerned ‘provides information that would lead a reasonable person to conclude that the person concerned would not have consented.’<sup>48</sup> As for what constitutes sufficient evidence to conclude that the deceased would not have consented, the DCA 2019 places responsibility on the Human Tissue Authority (HTA) to provide guidance to this effect.<sup>49</sup> The HTA Code of Practice, as updated on May 20, 2020, notes that the role of those in qualifying relationships is important, and that sensitive communication and engagement with them is essential.<sup>50</sup> Where deemed consent applies, the guidance states that the Specialist Nurse should explain the situation to those in qualifying relationships, thereby giving them an opportunity to demonstrate that the deceased would not have wanted to be a donor.<sup>51</sup> Of note, if it is not possible to speak with those in qualifying relationships to the deceased, the HTA Code of Practice states that donation should *not* proceed.<sup>52</sup> This is on the basis that it risks undermining public confidence which might outweigh the benefits of donation.<sup>53</sup>

Herein lies England’s new system’s classification as soft deemed consent. The decision still falls to those in qualifying relationships.<sup>54</sup> Interestingly, the public consultation on deemed consent in England asked whether the family should have the final say in the absence of a recorded objection from the deceased, yet the eventual law

46 Shaw, *supra* note 45, at 429.

47 Shaw does propose a way to overcome this by a system of ‘personalized organ donation directive[s]’, the creators of which are annually prompted to reaffirm. Shaw, *supra* note 45, at 429. However, in addition to potentially being overly cumbersome, such a system would not prove useful in a system of deemed consent.

48 SS.3 (6) (6B) and 3 (9) Human Tissue Act 2004, as amended by ss.1 (4) and 1 (5) Organ Donation (Deemed Consent) Act 2019.

49 S.27 (8) (8ZB) Human Tissue Act 2004, as amended by s.2 (4) Organ Donation (Deemed Consent) Act 2019.

50 Human Tissue Authority, *supra* note 23, at para 80.

51 Human Tissue Authority, *supra* note 23, at para 87.

52 Human Tissue Authority, *supra* note 23, at para 91.

53 *Id.*

54 One might conceive of a person in a qualifying relationship as having more power in their absence than in their presence under the DCA 2019 (or, more specifically, the HTA Code of Practice) as they would have to provide some form of evidence to stop donation proceeding if present, but if they are not contactable then donation would not be permitted even if there were no indication that the deceased would object. I am grateful to an anonymous reviewer for this point.



departed from the result of this question. Only 25 per cent of respondents felt that the family should make the final decision, and most of the support for this position came from Jewish and Muslim respondents.<sup>55</sup> A far more decisive 48 per cent answered no, with 27 per cent feeling that as standard the answer should be no, but there should be exceptions.<sup>56</sup> However, it appears that the minority view prevailed on this particular point. Arguably, there was an attempt to achieve the best of both worlds in the new system allowing those in qualifying relationships to demonstrate the deceased's objection rather than explicitly allowing the choice to fall to them, but the value of this distinction in practice is questionable because they are afforded a veto.<sup>57</sup>

Unlike England, Scotland appears to have adopted something of a middle ground between hard and soft deemed consent. When the ASA 2019 comes into force, clinicians in Scotland will have a 'duty to inquire' when deemed consent becomes relevant in the context of a particular patient; that is to speak to those in qualifying relationships 'so far as is reasonably practicable'.<sup>58</sup> The ASA 2019 does not stipulate that donation should not proceed in the event that it is not reasonably practicable to speak to such persons. In that sense, the Scottish model places less weight on the role of those in qualifying relationships and more on the very principle of deemed consent. Nonetheless, it retains a significant enough role for those in qualifying relationships to avoid becoming hard deemed consent and potentially facing the issues that arose in Brazil.

Of course, the DCA 2019 does not itself outline the absolute requirement to consult those in qualifying relationships before proceeding with donation. That requirement is stipulated in the HTA Code of Practice. It is possible, then, that when deemed consent does eventually come into force in Scotland that similar guidance will be published, placing both nations on the same footing regarding this point. However, in the absence of such guidance in Scotland, the soft deemed consent system of Scotland is less soft than that of England.

In slightly reducing the importance of the role of those in qualifying relationships, the Scottish system of deemed consent remains within the requirements of the European Convention on Human Rights. In a 2015 case in the European Court of Human Rights (ECtHR)—*Elberte v. Latvia*<sup>59</sup>—the Court was of the view that where the wishes of the deceased are not 'sufficiently clearly established', the state should make 'reasonable enquiries' to ascertain from relatives whether the deceased would object, whether under a system of expressed consent or deemed consent.<sup>60</sup> This aligns with the requirement noted in the earlier case of *L.H. v. Latvia* that domestic law 'must indicate with sufficient clarity the scope of discretion conferred on the competent authorities and the manner of its exercise'.<sup>61</sup> The failure of the state to do so in *Elberte* resulted in a successful claim by the wife of the deceased of a violation of her Article 8<sup>62</sup> right to

55 Department of Health and Social Care, *supra* note 22.

56 *Id.*

57 At most, the change constitutes the introduction of nudge tactics.

58 S.16H (2) (4) Human Tissue (Scotland) Act 2006, as amended by s.24 Human Tissue (Authorisation) (Scotland) Act 2019.

59 *Elberte v. Latvia* [2015] ECtHR no. 61243/08.

60 *Elberte*, *supra* note 59, at para 113.

61 *L.H. v. Latvia* [2014] ECtHR no. 52019/07, at para 47.

62 Art.8 (1) European Convention on Human Rights 1953.

respect for private and family life.<sup>63</sup> The ECtHR did not, however, opine that should these reasonable enquiries not be fruitful donation may not proceed on the basis of deemed consent. As such, the Scottish requirement to consult ‘so far as is reasonably practicable’<sup>64</sup> aligns well with the judgment of the ECtHR, and the English requirement that donation not take place in the absence of consultation is not necessitated by the European Convention on Human Rights.

In placing more weight on the principle of deemed consent, the Scottish model is preferable. One of the biggest obstacles to organ donation has historically been the family veto, which often represents a disconnect from the patient’s own wants.<sup>65</sup> Deemed consent is supposed to overcome this. The English system is, in effect, unchanged; the final decision rests with those in qualifying relationships even if the way clinicians approach them is different. The Scottish system *actually* deems consent, and therefore has greater potential to increase donation rates.<sup>66</sup> If there is a high level of public awareness—and the if is important here—the Scottish approach is ethically justified.<sup>67</sup> Further, it aligns with the results of the consultation that took place in England.<sup>68</sup>

#### IV. A DUTY ON MINISTERS?

Another interesting difference between the two systems concerns the role of government ministers in ensuring public awareness. The earlier HTWA 2013 placed a duty on Welsh Ministers to promote transplantation by supporting a campaign at least once every 12 months to inform the public of how deemed consent operates in the absence of express consent.<sup>69</sup> Further, for the first five years after the Act’s coming into force, Welsh Ministers were required to report what has been done to fulfil this duty to the National Assembly for Wales annually.<sup>70</sup> One would expect a similar duty to find its way into the English and Scottish acts, but this is true only of the latter.

63 The Court recognized the wife’s right in relation to consent for the use of her husband’s tissue. Not that she held property rights in his tissue, but that she ‘was not informed of [the removal of her husband’s tissue] and could not exercise certain rights established under domestic law’—notably the right to express consent or refusal in relation to the removal of tissue from her husband’s body. Elberte, *supra* note 59, at para 105. The Court also held the applicant’s complaint under Article 3—the right not to be subjected to torture or to inhuman or degrading treatment or punishment—but I will not be discussing that here. For further analysis of this case see Rajam Neethu, *Elberte v Latvia: the to be or not to be question of consent*, 25 MED. LAW REV. 484 (2016).

64 S.16H (2) (4) Human Tissue (Scotland) Act 2006, as amended by s.24 Human Tissue (Authorisation) (Scotland) Act 2019.

65 F. Ghorbani, H.R. Knoddami-Vishteh, O. Ghobadi, et al., *Causes of family refusal for organ donation*, 43 TRANSPLANT. PROC. 405 (2011).

66 That is not to say that donation rates will increase in Scotland when the ASA 2019 comes into force. As earlier noted, there is disagreement as to whether deemed consent does (or can) achieve this.

67 I will look more at the question of ensuring public awareness in the next section.

68 Department of Health and Social Care, *supra* note 22.

69 S.2 (2) Human Transplantation (Wales) Act 2013.

70 S.2 (3) Human Transplantation (Wales) Act 2013. The law came into force in Dec. 2015, with the first report laid before the National Assembly for Wales on Dec. 4, 2016. Welsh Government, *Human Transplantation (Wales) Act 2013: Report laid before the National Assembly for Wales under Section 2.(3)*, <https://gov.wales/sites/default/files/publications/2018-11/organ-donation-wales-communications-activity-2016.pdf> (accessed Sept. 22, 2020). As such, the final report would have been expected in early Dec. 2020. However, as of Dec. 18, 2020, the report is not available on the Welsh Government website (nor, incidentally, is the 2019 report)—though the law only requires reports to be presented to the Welsh Government and does not stipulate that it must be publicly available, so this is likely the reason for its absence.

Upon introducing deemed consent, Scottish Ministers are legally responsible for implementing means of public awareness; not only of the nature of deemed consent in terms of authorization of transplantation, but also of pre-death procedures.<sup>71</sup> Similarly to Wales, Scottish Ministers must ensure continued promotion, not less than once each calendar year.<sup>72</sup> Whilst promotion is required annually, there is a lesser level of scrutiny in that there is no requirement to report activities to the Scottish Parliament. Nonetheless, this is more than is required by the DCA 2019 in England.

Communication campaigns have always been considered an important factor in the introduction of deemed consent in England. Following the public consultation on deemed consent in 2018, the Government announced that they ‘want to raise awareness of these important issues and support the public to make informed decisions.’<sup>73</sup> In this response they also stated the intended launch of a communication campaign in 2019,<sup>74</sup> but whilst this campaign has started there was not a notable increase in visibility in the initial weeks of the DCA 2019 being in force. Further, the DCA 2019 details no duty on Ministers like those in the Welsh and Scottish acts. There is, then, no formal recognition of public awareness as central to the ethical defensibility of deemed consent as a model for organ donation. The importance of public awareness may be considered tacitly acknowledged in the DCA 2019 in that those lacking the capacity to understand the impact of deemed consent are exempt from its reach, but that is the extent of the recognition afforded to awareness. In choosing to depart from the legislative model provided by Wales years earlier, it can be concluded that the Government does not wish to take legal responsibility for awareness in England, but instead have it as a preferable addition to legislative change where possible.

On this matter Scotland can, again, be considered as taking a preferable approach. This is because widespread public awareness is recognized as essential to the ethical defensibility of deemed consent as an approach to organ donation; it upholds the principle of autonomy.

It is widely held that autonomous choice requires the agent to be sufficiently informed with respect to the choice in question. The widely cited account of Beauchamp and Childress holds ‘a substantial degree of understanding’ as one of three criteria of autonomous action.<sup>75</sup> In applying this idea to deemed consent, Saunders argues that such a system can only be considered as constituting consent where (1) there has been a clear communication of the change of system to citizens, so that inaction can feasibly be interpreted as consent, and (2) the process for formally recording one’s objection is not unreasonably costly.<sup>76</sup> These criteria have been criticized, with MacKay arguing that they do not necessarily entail understanding; indeed, he suggests that such understanding ‘is highly unlikely to be satisfied in many

71 SS.1 (1) (d) and 1 (1) (e) Human Tissue (Scotland) Act 2006, as amended by s.2 (1) Human Tissue (Authorisation) (Scotland) Act 2019.

72 S.1(2) Human Tissue (Scotland) Act 2006, as amended by s.2 (3) Human Tissue (Authorisation) (Scotland) Act 2019.

73 Department of Health and Social Care, *supra* note 22.

74 *Id.*

75 TOM L. BEAUCHAMP AND JAMES F. CHILDRESS, *PRINCIPLES OF BIOMEDICAL ETHICS* (2013) 59. There are many accounts of autonomy which might be applied, but for the avoidance of confusion I will proceed with this procedural account in recognition of the prevalence of it, or at least variations on it.

76 Saunders, *supra* note 6.

jurisdictions.<sup>77</sup> However, MacKay seems to consider the notion of deemed consent to be particularly complex in his concerns. The idea of ‘X will happen if you do not do Y’, which is the underlying concept of the deemed consent system, is straightforward and can feasibly be communicated in a simple manner. Assuming efforts by the relevant parties<sup>78</sup> to ensure awareness, it is reasonable to assume that a level of understanding that can be considered ‘sufficient’ will be met and those who object to being donors will take the necessary steps to formally record this. With the additional safeguards of excluded groups and the role of those in qualifying relationships—found in both the DCA 2019 and ASA 2019—Saunders’ criteria are appropriate in that they suitably ensure the validity of consent.

However, neither of Saunders’ criteria can be considered certain when ministers are not duty-bound to make efforts in communicating the change to the population. Where communication falls short, the second criterion—reasonable process for recording an objection—is problematized; even if the system in place is simple and not unreasonably costly, individuals being unaware of it renders it somewhat meaningless. Not knowing that one needs to record an objection means that those who do object will, for the most part, not formally do so. As a result, a key element that provides ethical defensibility for deemed consent is absent.

Of course, the ability of those in qualifying relationships to demonstrate objection on behalf of the deceased to some extent constitutes a safeguard against this undermining of autonomy. However, with insufficient public awareness, those in qualifying relationships are also unlikely to be aware of the change and, therefore, the role they can play; beyond simply understanding that the deceased’s consent is deemed, those in qualifying relationships also need to understand that they have a right to object on the deceased’s behalf. Of course, the clinical team will raise the matter of deemed consent with those in qualifying relationships, as is required by the HTA Code of Practice.<sup>79</sup> However, not having been aware of the new system prior to their loved one’s death, those in qualifying relationships will not have been prompted to discuss the matter with their loved one and may be unaware of their loved one’s wishes. After all, the role of those in qualifying relationships is intended as a safeguard for when the deceased had not made their wishes known.

## V. RESPONDING TO A PANDEMIC

A final difference I will consider, and one that is especially pertinent of late, is the ways in which the governments of England and Scotland responded to the COVID-19 pandemic in terms of the move to deemed consent.

### V.A. Pandemic Impact

As with near enough every aspect of health care, organ donation and transplantation have been affected by the COVID-19 pandemic. A colleague and I have outlined and

77 Douglas MacKay, *Opt-out and consent*, 41 J. MED. ETHICS, 832, 834 (2015).

78 Relevant parties meaning those acting on behalf of the state. This may (and inevitably will) include agencies such as NHS Blood and Transplant, though I am concerned with such efforts receiving the support of Ministers.

79 Human Tissue Authority, *supra* note 23.

discussed these issues elsewhere,<sup>80</sup> so here I will provide only a brief overview as necessary for the discussion that follows.

First is the direct impact on transplant activity. During the initial stages of the pandemic, hospitals anticipated surges of patients infected with COVID-19 and prepared themselves by restructuring various systems and redeploying staff to ensure vital services were maintained (notably intensive care units). At the time of writing, almost all transplant centers in the UK are open. However, at the height of the first surge of the pandemic, large numbers suspended operations; when the DCA 2019 came into force, no pancreas or islets transplants were taking place and only nine kidney transplant centers were operating.<sup>81</sup> Even where transplants have gone ahead throughout the initial peak in COVID-19 infections, advice to clinicians from NHS Blood and Transplant (NHSBT) has been to consider cases on an individual basis, taking account of both urgency and local resources when making decisions.<sup>82</sup> Whilst the first surge has passed, resource concerns remain in transplant centers as a second surge is anticipated. In August 2020, NHSBT released a document detailing its planning ahead of the expected second surge, including advice for transplant centers on handling closures where they are required in exceptional circumstances.<sup>83</sup> There is, then, an acknowledged concern that transplant center closures may become necessary again, reducing capacity for transplant activity.

A second impact, which is specifically an impact on deemed consent itself, is the challenge to public awareness. The media is understandably focused on the pandemic itself, making it difficult for any other news item to cut through and be heard. Certainly, there was little coverage of the move to deemed consent in England at the time. It is legitimate to question, then, whether any attempt at raising public awareness of the new system could succeed until after the pandemic.<sup>84</sup> The lack of awareness is problematic not only in respect of individuals who may wish to declare their own objection to organ donation, but also those in qualifying relationships who may perceive a duty to serve the deceased's interests where applicable.

What is clear is that the organ donation and transplantation landscape is not as stable as it usually is, and that public awareness of any change in policy that is not directly related to COVID-19 will get little, if any, airtime. As such, one might question whether it is an appropriate time to introduce a system of deemed consent.<sup>85</sup>

80 Jordan A. Parsons and Greg Moorlock, *A global pandemic is not a good time to introduce 'opt-out' for organ donation*, 20 MED. LAW INT. 155 (2020).

81 These figures were obtained from NHS Blood and Transplant shortly after the Organ Donation (Deemed Consent) Act 2019 came into force and have since been updated. NHS Blood and Transplant, *Transplant centre closures and restrictions: Current UK transplant centre closures or restrictions as a result of COVID-19*, [www.odt.nhs.uk/deceased-donation/covid-19-advice-for-clinicians/transplant-centre-closures-and-restrictions/](http://www.odt.nhs.uk/deceased-donation/covid-19-advice-for-clinicians/transplant-centre-closures-and-restrictions/) (accessed May 22, 2020).

82 NHS Blood and Transplant, *COVID-19 Bulletin*, 17<sup>th</sup> March 2020, <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/18021/covid-19-bulletin-1-17-03-2020.pdf> (accessed Sept. 22, 2020).

83 NHS Blood and Transplant, *COVID-19 Second Surge Planning*, <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/19464/pol301.pdf> (accessed Sept. 22, 2020).

84 I use the phrase 'after the pandemic' reluctantly, as what appears more likely is that it will continue for a significant period in some form. Nonetheless, I am referring to the period in which there is widespread disruption to society.

85 Parsons and Moorlock, *supra* note 80.

### V.B. The English Response

The English response is rather straightforward, in that there was not one. Despite the impact of the COVID-19 pandemic on the move to deemed consent, the Government forged ahead with the originally planned date of introduction, seeing the change take place at the height of the first surge. Further, at the time of writing, no announcement has been made by the Department of Health and Social Care to indicate how public awareness might be ensured amidst the media storm surrounding the pandemic. Whilst there was media attention concerning the new law at the time it was passed (March 2019), that was more than a year before it came into force (May 2020). As such, it is legitimate to question the adequacy of public awareness stemming from this.

This decision to proceed with the change in England might, at least in part, be attributable to the lack of legal duty placed on Ministers by the DCA 2019 to ensure public awareness. In the absence of such a duty, the Government need not be concerned about its ability (or lack thereof) to successfully implement a public awareness campaign during the COVID-19 media storm. However, this is problematic in terms of the ethical defensibility of the new system. As noted above, the justification for deemed consent comes in there being sufficient awareness for it to be reasonable to take the lack of a formal objection by the deceased as implied consent. If the figure of 80 per cent public support mentioned in the DCA 2019 is accurate, there remains a significant 20 per cent of the population who might object to donation, some of whom may well be deemed to consent.

Even if one excludes the fact that Government Ministers are not themselves responsible for awareness under the DCA 2019, the decision to proceed with the change at such a time hinders the ability of other organizations—be they medical bodies, news outlets, community organizations, or other—from promoting public awareness of the new system. The decision, then, demonstrates a clear disregard for the importance of widespread understanding of the new system. This introduces the possibility of future public distrust in a system that, realistically, is a one shot thing. If public mistrust resulted in a return to express consent, it is extremely unlikely that a future government could attempt to implement deemed consent again. It is, then, important to ensure an effective change if longevity is sought.

The reduction in donation and transplantation activity that persisted at the time of the move to deemed consent in England limited the new system's potential to increase donation rates.<sup>86</sup> This would, of course, be equally true of any new system of organ donation introduced in such circumstances. It is far too soon to judge the success of the change—and it will always be difficult to assess fully given the unprecedented confounding factors—but even the first three months of the new system have seen no increase beyond expected annual fluctuation.<sup>87</sup> It is reasonable to question, therefore, what was gained by England forging ahead with the change amidst a pandemic, save a small administrative reprieve from not having to set a new date. If there were a significant gain it would remain ethically dubious, but there would at least be some

86 Parsons and Moorlock, *supra* note 80.

87 NHS Blood and Transplant, *Donation and Transplantation Monthly Activity Report August 2020—data as at 11 September 2020*, <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/19697/monthly-stats.pdf> (accessed Sept. 22, 2020).



level of reasoning if proceeding with the change would cause donation rates to increase significantly.

### V.C. The Scottish Response

In stark contrast to England, the Scottish Government took the decision early in the COVID-19 pandemic to delay the coming into force of the new system of deemed consent.<sup>88</sup> It was later announced, in September 2020, that the transition is now intended to take place on March 26, 2021.<sup>89</sup> Unsurprisingly, the initial announcement of postponement highlighted the prioritization of the response to the pandemic as leading to the decision. The reasoning provided was to ‘ensure the legislation is implemented successfully and delivers on its stated aims.’<sup>90</sup>

Another factor that may have contributed to this decision is the duty on Scottish Ministers to promote public awareness. Recognizing that this would not be feasible during the pandemic, they may have postponed the introduction of deemed consent to ensure that upon its introduction an effective public awareness campaign will be possible. Whether this is true or not and, if true, the extent to which it guided the decision are matters for speculation. Nonetheless, the decision to postpone makes the Scottish response preferable because it respects the ethical justification of deemed consent.

Clear communication is not a realistic expectation during a pandemic for the reasons earlier outlined. Where deemed consent is introduced at this time, this key safeguard against the removal of a deceased’s organs for transplantation without appropriate consent is absent. Even other safeguards are affected by the public awareness challenges posed by the COVID-19 pandemic. For example, in England the organ donation register remains as an option for individuals to ‘opt out’ by registering their objection to being a donor, which is now possible in a variety of ways including the NHS mobile app. Such a register is also in operation in Scotland, as required by the ASA 2019.<sup>91</sup> However, the absence of a suitable level of public awareness impairs the register’s ability to act as an effective safeguard. It is public awareness that leads individuals who do not wish to become donors to pursue these routes to registering their objection, meaning this safeguard also suffers in present circumstances. To not provide appropriate safeguards that allow these individuals to possess the awareness to note their objection is to violate their autonomy.<sup>92</sup> Whilst it is argued that certain defaults, such as deemed consent, can enhance the autonomy of individuals by not requiring us to waste our ‘limited

88 Organ Donation Scotland, *Human Tissue (Authorisation) (Scotland) Act 2019—update*, [www.organdonationscotland.org/news-events/human-tissue-authorisation-scotland-act-2019-%E2%80%93update](http://www.organdonationscotland.org/news-events/human-tissue-authorisation-scotland-act-2019-%E2%80%93update) (accessed Sept. 22, 2020).

89 Scottish Government, *Organ and tissue donation opt out system*, [www.gov.scot/news/organ-and-tissue-donation-opt-out-system/](http://www.gov.scot/news/organ-and-tissue-donation-opt-out-system/) (accessed Sept. 22, 2020).

90 Organ Donation Scotland, *supra* note 88.

91 Scottish Ministers are required by the ASA 2019 to make arrangements for the establishment and maintenance of a register so that those who do not wish to donate their organs may formally record this. S.2A Human Tissue (Scotland) Act 2006, as amended by s.3 (2) Human Tissue (Authorisation) (Scotland) Act 2019. This register has been established and can be accessed through the Organ Donation Scotland website. Organ Donation Scotland, [www.organdonationscotland.org/](http://www.organdonationscotland.org/) (accessed Sept. 25, 2020).

92 Council on Ethical and Judicial Affairs, American Medical Association, *Strategies for Cadaveric Organ Procurement: Mandated Choice and Presumed Consent*, 272 JAMA 809 (1994).

bandwidth;<sup>93</sup> it is still essential that, in line with Saunders' suggestion,<sup>94</sup> the public are aware of the change and are able to reasonably register objection. The decision to delay the introduction of deemed consent in Scotland ensures that these conditions are met and is, therefore, preferable to the English course of action.

## VI. CONCLUSION

What I have not done here is consider whether deemed consent is a worthwhile endeavor. As highlighted, it remains a point of contention whether it is an approach that can reliably increase the number of transplants performed in a country. Rather, my focus has been on comparing the deemed consent systems introduced and soon to be introduced in England and Scotland, respectively.

On all three points on which the two systems differ, I have argued that the approach taken in Scotland is preferable. First, in slightly reducing the influence of those in qualifying relationships, deemed consent in Scotland has greater potential to overcome the key obstacle of the so-called family veto. Doing so greater respects the principle of deemed consent without risking undermining the autonomy of potential donors. Second, the duty on Scottish Ministers to promote public awareness demonstrates a willingness to take responsibility for the change and its success moving forward; the failure to do so in England could, if one were to be cynical, be taken to suggest that introducing the DCA 2019 was viewed as merely a way of satisfying the long-standing calls of those campaigning for such a system. Finally, in choosing to delay the introduction of deemed consent in response to the COVID-19 pandemic, the Scottish Government has acknowledged the importance of public awareness to respecting the autonomy of potential donors, thereby demonstrating a commitment to the ethical justification of deemed consent.

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93 Cass R. Sunstein, *Autonomy by Default*, 16 AM. J. BIOETH. 1 (2016).

94 Saunders, *supra* note 6.