DOI: 10.1111/bioe.13228

ORIGINAL ARTICLE

bioethics

🛒 Wiley

Opt-out, mandated choice and informed consent

Ben Saunders 💿

Politics and International Relations, University of Southampton, Southampton, UK

Correspondence

Ben Saunders, Politics and International Relations, University of Southampton, Southampton SO17 1BJ, UK. Email: b.m.saunders@soton.ac.uk

Funding information University of Southampton

Abstract

A number of authors criticise opt-out (or 'deemed consent') systems for failing to secure valid consent to organ donation. Further, several suggest that mandated choice offers a more ethical alternative. This article responds to criticisms that optout does not secure informed consent. If we assume current (low) levels of public awareness, then the explicit consent secured under mandated choice will not be informed either. Conversely, a mandated choice policy might be justifiable if accompanied by a significant public education campaign. However, if this entitles us to assume that members of the public are informed, then an opt-out system would also be justified in the same circumstances. The alleged advantages of mandated choice seem to rest on an unfair comparison, between mandated choice with a public education campaign and an opt-out system without one. While it may be that some countries with opt-out systems should do more to inform their publics. I see no reason to assume that this cannot be done. Indeed, advocates of mandated choice seem committed to thinking it possible to raise awareness. If opt-out systems adopt the same methods, such as writing to every individual, this should also address concerns about whether consent is informed.

KEYWORDS

consent, donation, mandated choice, opt-out, organs, presumed consent

1 | INTRODUCTION

Supply of organs for transplant is not enough to meet demand. Of course, if increasing supply were our only concern, then organs might be conscripted from cadavers, whatever the wishes of the deceased or their next-of-kin.¹ However, such approaches have found few defenders and would likely lead to public outcry, as in the case of Alder Hey, which was at the centre of a well-publicised scandal in the United Kingdom after it emerged that organs had been removed and

retained without authorisation.² The challenge is not simply increasing the supply of transplant organs, but doing so ethically.³ This is usually assumed to require some form of consent (or, at least, something like consent).⁴ The requirement of consent poses a

¹As suggested, though not necessarily endorsed, by Harris, J. (2003). Organ procurement: Dead interests, living needs, *Journal of Medical Ethics*, *29*, 130–134; Spital, A. (2005). Conscription of cadaveric organs: We need to start talking about it, *American Journal of Transplantation*, *5*, 1170–1171.

²See English, V., & Sommerville, A. (2003). Presumed consent for transplantation: A dead issue after Alder Hey? *Journal of Medical Ethics*, 29, 147–152.

³This qualification is explicit in titles such as Kluge, E. W. (2000). Improving organ retrieval rates: Various proposals and their ethical validity, *Health Care Analysis*, *8*, 279–295; Sterri, A. B., Regmi, S., & Harris, J. (2022). Ethical solutions to the problem of organ shortage, *Cambridge Quarterly of Healthcare Ethics*, *31*, 297–309.

⁴This assumption has been challenged, for instance, by Delaney, J., & Hershenov, D. B. (2009). Why consent may not be needed for organ procurement. *American Journal of Bioethics*, 9(8), 3–10; Zambrano, A. (2018). Should consent be required for organ procurement? *Bioethics*, 32, 421–429. I do not engage with these arguments here.

This is an open access article under the terms of the Creative Commons Attribution License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited.

 $[\]ensuremath{\mathbb{C}}$ 2023 The Authors. Bioethics published by John Wiley & Sons Ltd.

² WILEY- bioethics

problem for posthumous donations though, since the donor is no longer able to give consent at the time.⁵

It is usually assumed that individuals should have the option to give or refuse consent to the use of their organs while still alive. The debate is dominated by two systems for securing this prior consent: *opt-in* (in which someone's organs are not available for transplant, unless consent has actively been given) and *opt-out* (in which organs are available for transplant, unless there is an active refusal). However, these are not the only possibilities. Recently, a number of authors have instead suggested that *mandated choice* (in which everyone is required to make an active choice) is ethically superior to an opt-out system.⁶ Though there are important differences of detail between these authors, they all criticise the 'consent' secured by opt-out systems, generally arguing that it is not sufficiently informed or voluntary.⁷ Mandated choice, in contrast, is supposed to be more ethical because it secures express consent, which is assumed to be voluntary and informed.

My aim here is to respond to the argument that mandated choice is ethically superior to opt-out systems. I concede that it is reasonable to criticise opt-out systems where they are introduced without adequate public education. In such contexts, consent may not be informed. However, this is a matter of implementation, rather than a problem inherent to opt-out systems. This merely demonstrates the importance of education, which is necessary for any consent-based system. I contend that many of those who declare a preference for mandated choice on this basis are illicitly comparing an idealised form of mandated choice, following increased public education, to an optout system without similar education. For example, Symons and Poulden object that 'it is not at all clear that presumed consent is equivalent to an informed decision on the part of the donor' (p. 264) and advocate mandated choice, which they claim 'would address many of the concerns about informed consent' (p. 266), and yet, they go on to acknowledge that 'there would need to be significant investment in educational programs' (p. 266).⁸ This suggests that it is public education, rather than mandated choice per se, that is crucial to raising public awareness. They assume that their preferred mandated choice system would be accompanied by increased education, but do

not consider that similar efforts might be combined with an opt-out system. For instance, if mandated choice requires writing to every individual, to inform them of what they need to do, opt-out systems could employ similar measures. This would increase public awareness. Thus, while it may be true that some opt-out systems have not done enough to inform the public, this is not an inherent defect.

My argument is that opt-out and mandated choice systems stand or fall together once we are consistent in our assumptions about public awareness. If the public are not informed, then this is a problem for mandated choice systems as well as opt-out systems. On the other hand, if the public are sufficiently informed, then an opt-out system can secure informed consent. A fair comparison between optout and mandated choice should make similar assumptions about levels of education and information in both cases.

2 | CONSENT AND DEFAULTS

In *opt-in* systems, people's organs are not to be taken unless some express act of consent is given authorising this.⁹ Note that this formulation does not specify *whose* consent is necessary. Many jurisdictions allow the next-of-kin to authorise the taking of organs where the individual's wishes are not recorded.¹⁰ Nonetheless, *someone* must actively authorise retrieval. In contrast, *opt-out* systems reverse this default. In these systems, a cadaver's organs are considered available for transplant unless an explicit refusal has been recorded. Again, this general characterisation does not specify who has standing to refuse. It may be the individual only or also their next-of-kin.¹¹ However, unless someone explicitly objects, organs are deemed to be available.

These two systems are sometimes referred to by other names, such as 'informed consent' and 'presumed consent,' respectively. This need not be a problem if these labels are understood as terms of art. However, these names may be confusing, given the ordinary meanings and connotations of these terms.

It is misleading to *identify* opt-out systems with presumed consent. Admittedly, one *might* support an opt-out system because one thinks it justifiable to presume that people who do not actively object do, or would, consent to donation.¹² However, this is not the only basis on which such an opt-out system might be justified. For instance, some argue that the dead no longer have the same rights

⁵Depending on the system in question, it may be misleading to describe the process as a 'donation'. Since some systems are based on taking organs, it might be more accurate to refer to 'procurement'. However, there is no convenient term for the person whose organs are taken, if they are not a donor. I employ the common terminology, without attaching particular significance to this.

⁶For examples of those expressing a preference for mandated choice, over opt-out systems, see Austriaco, N. P. G. (2009). Presumed consent for organ procurement: A violation of the rule of informed consent? *The National Catholic Bioethics Quarterly*, *9*, 245–252; MacKay, D., & Robinson, A. (2016). The ethics of organ donor registration policies: Nudges and respect for autonomy. *American Journal of Bioethics*, *16*(11), 3–12; Symons, X., & Poulden, B. (2022). An ethical defense of mandated choice consent procedure for deceased organ donation. *Asian Bioethics Review*, *14*, 259–270; Qurashi, G. M. (Forthcoming). Opt-out paradigms for deceased organ donation are ethical incoherent. *Journal of Medical Ethics* (Online first, September 11, 2021. https://doi.org/10.1136/medethics-2021-107630). These authors offer a variety of arguments, so not everything that follows applies to each of them. See later notes for specific references.

⁷Some deny that this is even consent at all, though by that, they seemingly mean that it is not *valid* consent. Some use the term 'mere consent' to refer to acts of consent that do not meet conditions of validity. For example, Zambrano, op. cit. note 4, p. 424. ⁸Symons & Poulden, op. cit. note 6.

⁹I use the terms 'express', 'explicit' and 'active' consent interchangeably throughout. These are contrasted with 'tacit', 'implicit', and 'passive' consent, which are also used interchangeably.

¹⁰Den Hartogh, G. (2012). The role of the relatives in opt-in systems of postmortal organ procurement. *Medicine Health Care and Philosophy*, 15, 195–205. Symons & Poulden, op. cit. note 6 (p. 261), consider systems with family involvement only *quasi*-opt-in, but I use the term more broadly.

¹¹In practice, organs are rarely taken when the family object, whatever the law says. See Neades, B. L. (2009). Presumed consent to organ donation in three European countries. *Nursing Ethics*, *16*, 267–282. This practice is criticised by Albertsen, A. (2020). 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. *Bioethics*, *34*, 272–280.

¹²For discussion over what exactly is presumed, and whether to understand consent as an act of authorisation or a mental attitude, see den Hartogh, G. (2019). Respect for autonomy in systems of postmortem organ procurement: A comment. *Bioethics*, 33, 550–556.

over their bodies as living people do and thus that retrieval of cadaveric organs does not require a positive act of consent but only the absence of an objection.¹³ If consent is not required, then there is no need to presume consent. Alternatively, it has been suggested that, when appropriate conditions are met, someone's silence or inaction can give consent, tacitly or implicitly.¹⁴ According to such arguments, people who do not opt out have actually consented, albeit tacitly rather than actively. Again, then, there is no need to *presume* their consent.¹⁵ Note that I am not defending either of these arguments here. Whether or not these justifications succeed in justifying an opt-out system, they show that an opt-out system need not be based on, let alone identified with, presuming consent.¹⁶

It is similarly misleading to identify opt-in systems with informed consent. Though such systems require that consent *actively* be given, there is no guarantee that this consent is informed. Someone could sign up to the donor register without knowing what this involved.¹⁷ Conversely, implicit consent may still be adequately informed. To be sure, some critics have questioned whether this is the case for many people in opt-out systems, citing evidence that public awareness and understanding of organ donation is low.¹⁸ Perhaps, where public understanding of organ donation is low, tacit consent tends to be mere (uninformed) consent. But surely some people, such as those involved in transplants, are adequately informed. Their consent is still informed, even if tacit. Thus, it is also a mistake to identify or conflate opt-in systems with informed consent.

Whether consent is actively (expressly) given or tacit (passive) has no bearing, conceptually, on whether it is informed. Consent can be active but uninformed; it can also be tacit, yet informed. To be sure, this does not mean that there is no connection between these things. One might still argue, for instance, that opt-in systems are better than opt-out systems, because it is more likely that the consent given is informed. However, this is not some conceptual or analytic truth. Rather, it depends on a substantive claim, that active consent is more likely to be informed than tacit (or passive) consent. This certainly has prima facie plausibility but, even to assess this claim, we need to recognise that active consent and informed consent are not simply two terms for the same thing.¹⁹

3 | CRITICISMS OF OPT-OUT SYSTEMS

Critics allege that the 'consent' secured by opt-out systems is inadequate, for instance, because it need not be voluntary or informed.²⁰ Some go so far as to say that this is not consent at all, though it seems that what they mean by this is that it is not *valid* consent. This objection raises important concerns. However, it is not an objection to opt-out systems *per se*, but rather a criticism of ways in which they have sometimes been implemented.

The proponents of opt-out systems have generally acknowledged that the justifiability of these systems requires certain conditions to be satisfied.²¹ It may be that, in some actual cases, these conditions are not satisfied. Those who defend opt-out systems, as justifiable in principle, are not committed to the view that such systems have always been implemented appropriately. For instance, it has been argued that England's adoption of deemed consent in May 2020 was overshadowed by the coronavirus pandemic and that this undermined public awareness of the change.²² If this is true, then this switch may indeed have been problematic. However, this does not show that deemed consent itself is unjustifiable, only that its introduction in this case was poorly timed.

The lesson to draw from such objections is not that we should abandon the idea of opt-out systems entirely, but that we must take care to ensure that whatever system is in place is implemented appropriately, with particular attention to public education. Thankfully, critics of opt-out systems not only draw attention to potential dangers, which must be guarded against, but also point to ways in which such systems might be implemented better. Considering their proposed alternative (mandatory choice) may suggest ways in which opt-out systems could be improved.

4 | MAKING CHOICE MANDATORY

Mandated choice policies are an alternative to both opt-in and optout systems. Individuals are required to make an active choice concerning organ donation. If everyone does this, then there is no longer any need for a default option, because there is no one whose

¹³For defences of such an approach, see Douglas, T. M., & Douglas, N. M. (2009). Absence of significant dissent should be sufficient for deceased donor organ procurement in New Zealand. Australian and New Zealand Journal of Public Health, 33, 449-454; Guibert Lafaye, C., & Kreis, H. (2013). From altruistic donation to conditional societal organ appropriation after death. Ethical Theory & Moral Practice. 16, 355-368.

¹⁴For such arguments, see den Hartogh, G. (2011). Tacitly consenting to donate one's organs. *Journal of Medical Ethics*, 37, 344–347; Saunders, B. (2012). Opt-out organ donation without presumptions. *Journal of Medical Ethics*, 38, 69–72.

¹⁵There may be other presumptions here, such as a presumption that people are aware of the law or that this tacit consent has the same normative significance as active consent. But there is no need to presume consent.

¹⁶Though this is not crucial for my argument, I also think it possible for people to act in ways that presume consent in the context of an opt-in system. For instance, suppose that 99% of people had opted in (giving their explicit consent). An irresponsible surgeon might remove organs from a cadaver without bothering to check the register, because they consider it overwhelmingly likely that the person had given their consent. It seems natural to describe the surgeon here as acting on a presumption of consent (in this case, wrongly). This further challenges any identification of presumed consent and opt-out systems.

¹⁷The point that active consent, either in an opt-in or mandated choice system, may be 'mere consent' rather than informed consent has been made by various authors. See, for instance, Gill, M. B. (2004). Presumed consent, autonomy, and organ donation. *Journal of Medicine and Philosophy*, *29*, 37–59, p. 53; Prabhu, P. K. (2019). Is presumed consent an ethically

acceptable way of obtaining organs for transplant? *Journal of the Intensive Care Society*, 20, 92–97, p. 94; Zambrano, op. cit. note 4, p. 424.

¹⁸For instance, MacKay, D. (2015). Opt-out and consent. *Journal of Medical Ethics*, 41, 832–835.

¹⁹Austriaco, op. cit. note 6, illustrates the dangers of conflating these terms. The article's titular question is whether presumed consent (i.e., opt-out) violates the requirement for informed consent. However, informed consent is defined as the requirement of *explicit* consent (p. 246). This stipulation effectively settles the question. (Strangely, this definition makes no reference to information!)

²⁰For instance, Qurashi, op. cit. note 6; MacKay, op. cit. 18.

²¹For example, den Hartogh, op. cit. note 14; Saunders, op. cit. note 14.

²²Parsons, J. A., & Moorlock, G. (2020). A global pandemic is not a good time to introduce 'opt-out' for organ donation. *Medical Law International*, 20, 155–166.

WILEY- bioethics

wishes are unknown.²³ Some advocates propose that this will also remove the need for decisions by next-of-kin.²⁴ However, while this is an option, it need not be part of a mandated choice system. If one thinks that surviving relatives have independent standing to override the individual's choice, then this could still be permitted. Indeed, individuals might even be given the option to delegate the decision to a nominated surrogate.²⁵

Advocates of mandates do not always make clear how exactly people will be made to choose, beyond referring to the choice as being mandatory. It is not even obvious what this means. Some use 'mandatory' synonymously with 'compulsory'.²⁶ However, others distinguish between these two terms.²⁷ Thus, further elucidation is necessary to clarify the sense in which choice will be mandatory. I assume that there would be a legal requirement to choose. Further, to ensure compliance, this mandate would presumably have to be backed by nontrivial sanctions.

By these standards, some proposals do not really amount to mandates. For instance, it has been suggested that individuals should be asked about organ donation when applying for a driving licence.²⁸ Simply asking people is not a genuine mandate though: there must be some requirement for them to answer. This could qualify as a mandate if the licence application cannot be completed without answering the question about organ donation, since those who refuse would be excluded from driving. However, while donor organs often come from traffic accidents, I see no reason why only (wouldbe) drivers should be required to declare their preferences. If the required declaration is combined with other state bureaucracy, it ought to be something applicable to everyone.²⁹

Those who proclaim the superiority of mandated choice systems often contend that these are more ethical than opt-out systems because, under mandated choice, organs are only removed from those who have given active consent. It is argued that, given low

public awareness of organ donation, tacit (or 'deemed') consent need not be informed or voluntary.³⁰ The point here, I assume, is not that it is impossible for someone to give informed consent in an opt-out system.³¹ However, these critics argue that opt-out systems fail to ensure that the consent (deemed to be) given is informed. So long as some people lack the necessary information, there is a danger that their organs may be taken without their informed consent.

This is a legitimate concern, but it is not clear whether mandated choice succeeds in overcoming this problem either. It may ensure that organs are only taken from those who have actively given consent, but there is no guarantee that this active consent is informed.³² Even under a voluntary opt-in system, someone could sign up as a donor without really understanding what this involves. This is even more of a danger where citizens are forced to make a choice. Someone may thoughtlessly check a box, simply because they have to do something, without knowing what this entails. (Consider here how often people check boxes consenting to website cookie policies, or End User Licence Agreements on software, that they have not even read.) This is probably even more likely when this choice is presented along with some other task, such as applying for a driving licence, voting, or completing a tax return. People's attention in these cases is likely to be focused on the task in hand, rather than on organ donation. Though they may check the 'yes' box, thereby actively giving consent, there is no guarantee that their choice is informed or voluntary.

It is often acknowledged that mandated choice systems would require an extensive public information programme.³³ Perhaps there are limits to how far this should go, since constantly bombarding people with health information can itself be objectionably intrusive.³⁴ Moreover, there are both financial and opportunity costs to such campaigns. Increasing awareness of organ donation might, in practice, come at the expense of other public health campaigns. Nonetheless, given the evidence that public awareness of organ donation is low in many counties, greater efforts to inform the public are generally welcomed by all. However, if mandated choice is only justifiable after greatly increased public education, then it is no longer obvious why it should be thought better than an opt-out system.

As we have seen, opt-out systems are often criticised on the basis that tacit consent may be uninformed. But this criticism is based on currently low levels of public awareness, rather than what is possible following extensive education campaigns. If we take low levels of awareness for granted, then mandated choice suffers similar problems to opt-out: people's consent, even though active, may not be informed. Alternatively, if we assume that education could

³²See references in note 17.

²³In practice, assuming some noncompliance with the mandate, a default may still be necessary in some cases. Spital, A. (1991). The shortage of organs for transplantation: Where do we go from here? New England Journal of Medicine, 325, 1243-1246, suggests consulting the family in these cases, though recommends that only objections-not positive consentshould be sought (p. 1245). This makes his proposed system rather like a soft opt-out. Presumably, though, those who think that mandated choice is more ethical than opt-out systems would prefer a default of nondonation.

²⁴Spital, op. cit. note 23; Symons & Poulden, op. cit. note 6, p. 266.

²⁵Herz, S. E. (1999). Two steps to three choices: A new approach to mandated choice. Cambridge Quarterly of Healthcare Ethics, 8, 340–347, 341; Austriaco, op. cit. note 6, p. 249. ²⁶For an example of the explicit identification of these terms, see Camilleri, F. (2019). Compulsory vaccinations for children: Balancing the competing human rights at stake. Netherlands Quarterly of Human Rights, 37, 245-267, p. 249, n35.

²⁷For instance, Navin, M. C., & Largent, M. A. (2017). Improving nonmedical vaccine exemption policies: Three case studies. Public Health Ethics, 10, 225-234, p. 226. They use 'mandatory vaccination' to refer to policies whereby the unvaccinated are merely excluded from certain goods and services, such as schools or public transport, whereas they use 'compulsory vaccination' to refer to the criminalisation of vaccine refusal. ²⁸Spital, op. cit. note 23. This may be an instance of *voluntary* active choice.

²⁹Of course, it may be difficult to realise this ideal in practice. Symons & Poulden, op. cit. note 6, p. 267, propose choosing alongside voting, seemingly on the assumption that this is compulsory (as it is in some countries, such as Australia and Belgium). Thaysen, J. D., & Albertsen, A. (2021). Mandated choice policies: When are they preferable? Political Research Quarterly, 74, 744-755, p. 752, propose tax returns. However, these may not be universal either. Some countries have social security numbers or identity cards that may be more universal, though even these may not reach everyone (e.g., undocumented migrants or temporary visitors).

³⁰See MacKay, op. cit. note 18; Qurashi, op. cit. note 6.

³¹The title of Qurashi's article (op. cit. note 6) refers to opt-out as 'ethically incoherent' but, far from demonstrating such incoherence, he appears to concede that tacit consent could be justified if there were universal public awareness (p. 5). His concern is merely that this is virtually impossible in practice, not that it is incoherent.

³³See, for example, Herz, op. cit. note 25, pp. 340–341; Austriaco, op. cit. note 6, p. 251; Symons & Poulden, op. cit. note 6, pp. 266-267.

³⁴For a vivid illustration of how intrusive noncoercive messaging might be, when taken to extremes, see Conly, S. (2014). Response to Resnik. Public Health Ethics, 7, 178-179, p. 179.

increase awareness enough that mandated choice would be justifiable, then presumably, similar education would also make opt-out systems justifiable. It is not obvious that mandated choice is preferable to opt-out, assuming similar levels of awareness in both cases.

5 | HOW TO ASK FOR CONSENT

I have suggested that an opt-out system could be justifiable if a mandated choice one is. In fact, the two systems may be implemented similarly. Assume that, whichever system is in place, we want to inform everyone about organ donation. One option is to write to every individual. This might be a one-off message, at some point approaching adulthood, or it might be repeated at certain intervals.³⁵ To keep costs down, this could be combined alongside other messaging, for instance, concerning social security/national insurance, voter registration, taxes, or something like that, though information about organ donation would have to be clearly separated from other contents of the letter and sufficiently prominent that it does not get overlooked. A separate communication might be better, even if more costly.³⁶ However, it would be no more costly to send out forms and information for an opt-out system than for a mandated choice one.

This message should include some basic information about organ donation. It is unclear exactly what this should encompass. We cannot realistically expect full information. However, the material provided could signpost readers to where they can find out more, should they feel the need for additional information.³⁷ Also up for debate is whether this information should be neutral, that is, 'just the facts', or whether it is legitimate for it to encourage or promote donation.³⁸ I do not attempt to settle these specifics. I simply assume that whatever is provided will be sufficient for consent to count as informed. Moreover, all of this should be available in various languages and formats, such as braille. Further, special efforts may have to be made to reach out to certain groups that historically have low trust in the state or medical system. It might be useful to enlist the help of community leaders from such groups, though the need for this depends on the context in question. Again, I do not attempt to specify these details here. My point is that, if these measures (whatever they are) are sufficient that people are informed, this would make an opt-system justifiable as well as mandated choice.

The crucial difference between a mandated choice system and an opt-out system is simply what is required of people. In a mandated choice system, individuals receive a declaration form, along with information about donation. They are required to select one of the available options and return the form, whatever option they choose. For this to be justifiable, we must assume that individuals are aware both of what they need to do and of what is involved in organ donation, so the consent they give (if any) is genuinely informed. However, an improved opt-out system might look very similar. Again, everyone could be sent written information about donation, along with a consent form, giving them all the same options as in the mandated choice case, whatever these are. There are two key differences. First, there is no obligation to return the form. Second, it being an opt-out system, the default rule applied in these cases is donation.

In the opt-out case, those who are willing to donate need not return the form: their silence is taken to be consent. This is informed and, for these people, more convenient than mandated choice. On the other hand, those who do not want to donate (including perhaps those who wish to delegate the decision to someone else) must return the form, indicating their wish to depart from this default. These people are required to do something, but what is required of them here is no more onerous or demanding than what would be required by a mandated choice system. In either system, they would be required to return the form, indicating that they do not want their organs to be taken. Admittedly, this 'requirement' takes slightly different forms. In a mandated choice system, it is a legal obligation to return the declaration. In an opt-out system, it is rather something that they have to do to avoid their organs being taken. Nonetheless, what they must do is the same. Provided that registering one's objection to donation is relatively easy and costless, I do not think that this objectionable. In any case, since it must be done in both the opt-out and mandated choice system, it does not give us reason to prefer either one to the other.

6 | POTENTIAL OBJECTIONS

It is sometimes objected that opt-out systems do not adequately respect the negative right to bodily integrity, since they require people to do something to prevent their organs from being taken, rather than considering noninterference the default. Full consideration of this objection would require a more detailed examination of the arguments for and against opt-out systems than I have space for here, so I will have to confine myself to some brief remarks.

First, noninterference is not an option here.³⁹ Something must be done with cadavers, for they cannot simply be left to rot wherever they happen to be. Therefore, any suggestion that it is wrong to interfere with a dead body, without explicit consent, is implausible. Second, giving individuals the option to opt out of organ donation

³⁵The Netherlands recently introduced such a system. See den Hartogh, op. cit. note 12, p. 555.

³⁶Bramhall, S. (2011). Presumed consent for organ donation: A case against. *The Annals of The Royal College of Surgeons*, 93, 268–272, p. 271, objects to the costs of an opt-out system, on the assumption that every member of the public would need to be contacted and offered the choice of opting out. This does not always happen, but perhaps it should. The cost may be a price worth paying to ensure informed consent. (And, if this is not worth the cost, it likely condemns mandated choice too.)

³⁷As suggested by O'Neill, O. (2003). Some limits of informed consent. *Journal of Medical Ethics*, *29*, 4–7, p. 6.

³⁸A nonneutral approach, encouraging donation, is proposed by Chouhan, P., & Draper, H. (2003). Modified mandated choice for organ procurement. *Journal of Medical Ethics*, 29, 157–162.

³⁹See Gill, op. cit. note 17, pp. 44-45.

WILEY- bioethics

means that (unless we allow family overrules) they retain final control of what happens to their body.⁴⁰ Though this does place an onus on those who do not want their organs taken to act, registering their objection provides safeguards against organ removal. This may better protect their organs than many opt-in systems, which may allow the family to donate organs against the individual's wishes. Third, if requiring people to specify that they do not want their organs taken is somehow objectionable, then this tells against a mandated choice system too, since it also requires such a declaration. So, even if this objection is a genuine problem for opt-out systems, it does not show that mandated choice is any better.

It is sometimes objected that tacit consent, which is deemed to be given by those who do not register an objection, is an unreliable indicator of someone's real preferences.⁴¹ If someone actively completes and returns a form then, while they may not have given the matter much thought, we can reasonably take this as evidence of their wishes. Further, they must at least know that something was required of them. However, the objection is that we cannot reliably infer someone's wishes or awareness from their inaction. It might be, for instance, that, despite receiving notification, they were unaware that they needed to do something or what it was that they needed to do.

Once again, though, this objection to opt-out systems is not particularly congenial for advocates of mandated choice. Under a mandated choice system, people are required to declare their wishes and potentially penalised if they do not. For this to be fair, it must be assumed that people are aware both that they have to do something and what it is that they have to do. So, the advocate of mandated choice must assume a sufficient public education campaign that this knowledge can be taken for granted. But, if we are justified in assuming this knowledge, then once again, it seems that an opt-out system would also be justifiable. Of course, one might be sceptical as to whether any feasible education will be enough that this level of knowledge can be assumed. However, that scepticism ought to tell against mandated choice too. If the advocate of mandated choice is entitled to assume this awareness, then it is only fair to grant a similar assumption to an opt-out system, implemented alongside a similar education campaign (such as individual notification).

It could be objected that equal awareness is impossible or at least unlikely, because an opt-out system cannot raise awareness in the same way. The mandated choice system would raise awareness partly through punishing people who did not return their declaration forms. If someone is fined (or otherwise punished) for noncompliance with the mandate to choose, this will make them aware that something needs to be done. In contrast, because an opt-in system will not impose penalties, it does not demand people's attention in the same way. Even if periodic reminders are sent out, these can easily be

ignored. Thus, it might be argued, opt-out systems cannot assume the same awareness as mandated choice systems.

However, while I acknowledge that penalising those who do not return their declarations will increase awareness of the requirement to choose, advocates of mandated choice should not rely on this to raise the necessary awareness. If higher levels of public awareness are a requirement for the mandated choice regime to be implemented legitimately, then they must already be in place before it is introduced, and thus before any penalties are meted out. They cannot rely on the system already being in place to create the awareness that is a condition of its own legitimacy. Therefore, the advocate of mandated choice appears committed to thinking that sufficient levels of public awareness could first be achieved by other means. Again, whatever system of messaging and education is needed to create this awareness should, in principle, be possible with an opt-out system too.

CONCLUSION 7

I have not attempted to offer a full defence of opt-out systems here. Nor is my argument intended as a defence of the opt-out arrangements currently in place in many countries including, as of recently, Great Britain. It may be true that some countries have not done enough to educate the public about organ donation. If so, their practices are potentially criticisable. However, the problems here are not inherent to opt-out systems. If there is a lack of public awareness, this might be overcome by better public education.

Those who propose a mandated choice system seem committed to thinking that it is possible to increase awareness. Otherwise, their proposal would involve unfairly penalising people, for not complying with requirements that they were unaware of, while also taking organs from people whose consent-though active-was not informed. Raising awareness may require some effort, such as writing to every individual about their choices. However, whatever methods would be needed to make mandated choice justifiable could also be employed alongside an opt-out system. If we are entitled to presume people informed, then we no longer need to worry that tacit consent is uninformed. In short, both opt-out and mandated choice systems require public awareness. But, provided sufficient educational efforts are made, opt-out systems are no less justifiable than mandated choice.

ACKNOWLEDGEMENTS

I thank my employer, the University of Southampton, for a period of research leave, during which this article was written and later revised. I am also grateful to two anonymous referees for their comments and suggestions.

ORCID

Ben Saunders D http://orcid.org/0000-0002-5147-6397

⁴⁰See den Hartogh, op. cit. note 12, p. 551.

⁴¹This point is well made by Williams, N. J., & Manson, N. C. (2022). 'Take my kidneys but not my corneas'—Selective preferences as a hidden problem for 'opt-out' organ donation policy. Bioethics, 36, 829-839, p. 833. However, they note (p. 835) that this problem is more significant for systems based on presumed consent, rather than deemed consent.

bioethics

AUTHOR BIOGRAPHY

Ben Saunders is associate professor in the Department of Politics and International Relations at the University of Southampton (UK). His research interests include democracy, the thought of John Stuart Mill, and various topics in practical ethics. How to cite this article: Saunders, B. (2023). Opt-out, mandated choice and informed consent. *Bioethics*, 1–7. https://doi.org/10.1111/bioe.13228