

## Response to the Government's consultation on introducing 'opt-out' consent for organ and tissue donation in England

March 2018

### Background

- 1 The Nuffield Council on Bioethics is an independent organisation that examines and reports on ethical issues arising from developments in biological and medical research that concern the public interest.
- 2 This consultation response draws on the conclusions and recommendations of our *Human bodies: donation for medicine and research* report, published in 2011.<sup>1</sup>

### Summary

- 3 In our report we take the view that opt-out systems can be ethical if people are well-informed, families are appropriately involved (are well-supported and not pressured), and trust in the organ donation system is not compromised. However, we also highlight the fact that there is no clear evidence that changing from an 'opt-in' system to an 'opt-out' system, in itself, achieves higher rates of donation. When we published our report, we did not recommend a change to an opt-out system, both because of this lack of evidence, and because of concerns that the requirements to ensure that any such system operates ethically are very onerous. We do not believe this situation has changed in the intervening time.
- 4 Trust plays a central role in creating systems in which people are willing to donate. Any change to the donation system therefore needs to be designed in such a way as to minimise the risk of any loss of trust. We are concerned that, in this current proposal, the Government is making a legislative decision that is not based on good evidence. Going ahead with a change in the law, accompanied by claims that this will save lives – but without a secure evidence base – could undermine public trust, with potentially serious consequences for organ donation rates. Furthermore, it could have a detrimental effect on the good work (such as that by the Organ Donation Taskforce) that has been done to increase the number of donated organs.

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<sup>1</sup> Nuffield Council on Bioethics (2011) *Human bodies: donation for medicine and research*, available at: <http://nuffieldbioethics.org/project/donation>.

- 5 We therefore suggest that, if the Government does choose to go ahead with introducing opt-out, it should pay serious attention to the following considerations:
- the overriding need to maintain trust in the organ donation system, in particular by being cautious on what is promised about the effect of opt-out, on the basis of the current evidence (which is described in the Department of Health’s own impact assessment as “ambiguous”);
  - the proven beneficial role of specialist nurses for organ donation (SN-ODs) in supporting bereaved families when faced with the prospect of donation, and the value of investing further in this network;
  - the importance of good family communication about individuals’ donation preferences; and
  - the need to ensure that families stay at the heart of the decision-making system, recognising that even if the law permits donation against family wishes (as it does at present), in practice, professionals rightly recognise the central role of the family at the moment of (often sudden) bereavement.

## Responses

### Q1. Do you think people should have more ways to record a decision about organ and tissue donation?

- 6 **Yes.** Organ donation should be based on the donor’s wishes. Increasing the opportunities for a person to record a clear decision about organ donation is strongly encouraged to increase the chance of their views being known after death.
- 7 Equally, it is important that people should also be able to **register willingness to donate organs to be used for research purposes where they are not appropriate for treatment.** Any routine information about organ donation should also include explicit reference to the potential research uses of organs and tissue. Potential donors should also have the option of authorising such uses in advance,<sup>2</sup> as happens with whole body donation after death (in medical schools). Research (which is essential for improving transplant outcomes, and making best use of organs donated for transplant) should not be seen as a ‘second-class’ use of organs, but instead should be promoted as a routine use of donations where transplant is not possible.
- 8 In our report, we suggest that registration with a new GP’s practice, or during a first appointment with a new GP, might provide opportunities for the NHS to log people’s wishes about organ donation, though care must be given to ensure that

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<sup>2</sup> Ibid., at paragraph 7.40.

individuals did not feel pressured in any way.<sup>3</sup> There have been significant technological advances since we published our report in 2011, and a key focus should be on technological solutions that provide opportunities to register a view (both in favour and against organ donation, as well as allowing people to consent to donate *some* organs).

### **Q3. How can we make more people aware of the new rules on organ donation?**

- 9 **If new rules are introduced, it is vital to have measures in place that encourage people to express and document their wishes about organ donation during their lifetime.** Otherwise, it is very hard indeed to claim that donation is in line with the wishes of the donor, or that consent can be 'deemed'.
- 10 We support the Government's consideration of an extensive communications campaign, but it is important that the Government commit to the ongoing expenditure required to ensure that people continue to be aware of the system, not just before and after the legislative change. The evaluation of opt-out introduction in Wales has drawn attention to how the initial increases in awareness generated by the discussion around the change in the law has not been maintained.<sup>4</sup>
- 11 It is also important that the methods used by the Government to increase awareness of opt-out organ donation also build trust in the system. People need to be well informed: information about the donation process must be easily accessible to those considering donation, and it must always be clear that more information is available if desired.
- 12 The involvement of SN-ODs in discussions with relatives at the appropriate time has had one of the greatest impacts on consent rates for organ donation.<sup>5</sup> More specialist nurses are needed in addition to more training for staff and others involved in the organ donation process.
- 13 Innovative uses of digital technology should be used to make it easy for people to register wishes and encourage family conversations.

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<sup>3</sup> Ibid., at paragraph 6.25.

<sup>4</sup> Welsh Government (2017) Evaluation of the Human Transplantation (Wales) Act: impact evaluation report, available at: <http://gov.wales/docs/caecd/research/2017/171130-evaluation-human-transplantation-wales-act-impact-en.pdf>, at page 3.

<sup>5</sup> [Table 13.1](#) of the [National Potential Donor Audit](#) covering the period 1 April 2016 to 31 March 2017 showed that rates of consent or authorisation were 68.6% when a specialist nurse for organ donation (SN-OD) was involved in the approach to the family. This dropped to 27.5% when they were not involved. When a SN-OD was involved in approach *and* the patient was known to be on Organ Donor Register at time of potential donation, the consent rate was 92.6%. Whilst not directly comparable, a relatively high rate of refusal occurred when deemed consent applied, with a figure of 60.6% for the consent rate, meaning that donation was not supported by nearly two in five families. This suggests that the key issue is knowledge of the deceased's intentions and skilled support in discussing the possibility of donation with the family rather than the legal basis for donation.

**Q5. If the law changes, people would be considered willing to be an organ donor unless they have opted out.**

**Do you think this change could have a negative impact on people from some religious groups or ethnic backgrounds?**

- 14 The reasons for lower levels of donation amongst some religious and ethnic groups are complex. While studies have consistently demonstrated that faith leaders at national level in the UK are united in support of organ donation and transplantation,<sup>6</sup> they have not, on the whole, identified what would motivate more people to come forward as potential donors, although there are some indications that ‘grassroots’ community networking may be more effective than the use of educational materials.<sup>7</sup>
- 15 ‘Medical mistrust’ is cited as a reason for people to hold back from donating bodily material.<sup>8</sup> This may be associated with anxiety that a potential organ donor would not receive the appropriate medical care, or concerns about consent: both that the terms of consent will be abused and that additional material may be taken without explicit consent. **Medical mistrust is a factor that must be taken into account when changing the model of consent. In particular, it must be clear that it will not (as has been voiced in some recent media)<sup>9</sup> lead to the state ‘taking’ organs against family wishes.<sup>10</sup>**

**Q6. If the law changes and someone has died, and they have not opted out of organ donation, should their family be able to make the final decision?**

- 16 **Yes.** Again, we reiterate the importance for individuals to make their organ donation wishes known to loved ones during their lifetime and, even better, to record those wishes. Greater awareness and more conversations within families are clearly associated with higher organ donation rates, and greater confidence that the person’s wishes are being followed. However, in the absence of such documentation, information as to the deceased’s likely wishes should be sought by those closest to the deceased person, who are usually best placed to know

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<sup>6</sup> Randhawa G, Brocklehurst A, Pateman R, and Kinsella S (2009) Faith leaders united in their support for organ donation: findings from the UK organ donation taskforce study *Transplant International* **23(2)**: 140-6.

<sup>7</sup> Davis C and Randhawa G (2006) The influence of religion on organ donation and transplantation among the Black Caribbean and Black African population: a pilot study in the United Kingdom *Ethnicity and Disease* **16**: 281-5. See also: Nuffield Council on Bioethics (2011) *Human bodies: donation for medicine and research*, at paragraph 6.6.

<sup>8</sup> See, for example, Shepherd L and O’Carroll RE (2014) When do next-of-kin opt in? Anticipated regret, affective attitudes and donating deceased family members’ organs *Journal of Health Psychology* **19(12)**: 1508-17. See also: Morgan M, Harrison TR, Afifi WA, Long SD and Stephenson MT (2008) In their own words: the reasons why people will (not) sign an organ donor card *Health Communication* **23(1)**: 23-33 and NHS Blood and Transplant (24 February 2009) *Will they respect my body after I am dead?* (noted at paragraph 6.8 of our report) which details an online survey which found that, of respondents who stated that they were undecided or against joining the ODR, more than half said that they were worried about how their body would be treated after death.

<sup>9</sup> See, for example, [Telegraph Letters](#), 28 February 2018 and [Daily Mail](#) 26 February 2018.

<sup>10</sup> Nuffield Council on Bioethics (2011) *Human bodies: donation for medicine and research*, at paragraph 6.31.

the deceased's wishes, and who themselves, in their bereavement, have their own stake in how their deceased relative's body is treated.<sup>11</sup>

**Q7. Do you think someone's family should be able to decide if their organs are donated, if it is different to the decision they made when they were alive?**

17 **Yes.** The option of refusal should rest with the family of the deceased, even where the deceased has left clear evidence of their wishes to donate. Such refusal (where applicable) may be based on the families' own knowledge of the deceased's most recent attitudes to donation, or it may also be understood as an expression of their own needs as bereaved family members.<sup>12</sup> The outcry around tissue retention in the NHS in the past highlighted the complex meanings and associations that may be held in connection with the deceased bodies of loved ones, and a failure to take these into account could seriously jeopardise trust in the whole system.<sup>13</sup>

18 Moreover, in practice, it appears that when families are aware of deceased relatives' wishes, then they are very unlikely to refuse consent to organ donation. Again, this demonstrates the importance of making organ donation wishes known to loved ones during a lifetime. We note that the number of occasions when families actually feel unable to acquiesce in *any* donation, despite the deceased being on the organ donation register, are tiny: in internal figures from NHSBT provided to us in 2010, only two families in five years (0.2% of the total) had refused to follow the deceased's wish to donate their kidneys. In contrast, around 10% felt unable to donate the heart. We call on NHSBT to publish this detailed breakdown of the most recent figures (e.g. 2012-2017) to support a more informed debate about the role of families, and to encourage the exploration of how families can be better supported in these situations. Any suggestion that family concerns will be overridden could have serious consequences for 'medical mistrust' alluded to above, and have serious consequences for organ donation. In contrast, focusing efforts on even better and more skilled support for families and engaging seriously with their anxieties about donation will lead to better outcomes both for those families themselves, and for donation.

**Q8. Which of the following should not be included in the proposed new rules about organ donation?**

- **Children under 18 years old**
- **People who lack capacity**
- **Visitors to England**
- **People living in England for less than 12 months (for example, students from overseas, armed forces personnel)**

**Are there any other groups you think should not be included? Please say why you think this.**

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<sup>11</sup> Ibid., at paragraph 6.29.

<sup>12</sup> Ibid.

<sup>13</sup> Ibid, Introduction

- 19 The key ethical basis for donation is that it is in line with the wishes of the deceased. Where there is a risk that the person concerned has not opted out, but has not made an informed choice about this – for example, because of lack of knowledge of the system, or compromised capacity - it is unethical to assume their consent to donation. All of those listed above should therefore be excluded from the system.
- 20 Having said that, in relation to children under 18, a child of sufficient maturity and understanding, regardless of age, should be able to provide consent to organ donation. They should therefore be able to continue to ‘opt in’ to organ donation, as they can in the current system. However, we don’t believe they should be included in an opt-out system because it cannot be assumed that a child who has *not* opted out has made a clear decision with respect to donation. They might never have engaged with the question, or yet have the capacity to make an informed choice.

**Q9. Please tell us any opinions or evidence you have about opting out of organ donation.**

- 21 There is little evidence that changing the legal basis on which consent for organ donation should be documented or expressed increases the number of organs donated. We are very concerned about the way in which claims about possible lives to be saved by this legislative proposal have been presented.
- 22 Recent evidence from the Welsh Assembly Government shows that the introduction of opt-out has had no impact, yet, on the number of organ donors in Wales.<sup>14</sup> More evidence on the opt-out system for organ donation in Wales needs to be gathered over a longer period, given that Wales shares broadly the same donation infrastructure as England, and hence it will be easier to separate out what factors are most likely to underlie any changes.
- 23 A 2009 systematic review of opt-out studies, which showed five ‘before and after’ studies representing three countries that had reported an increase in donation rates after the introduction of ‘presumed consent’, concluded that “presumed consent alone is unlikely to explain the variation in organ donation rates between countries. Legislation, availability of donors, organisation and infrastructure of the transplantation service, wealth and investment in health care, and public attitudes to and awareness of organ donation may all play a part, but their relative importance is unclear”.<sup>15</sup>
- 24 A more recent review comparing international donation rates, found that countries classed as ‘opt-out’ had higher deceased organ donation rates (but

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<sup>14</sup> NHS Blood and Transplant (2017) *Organ donation and transplantation data: Wales*, available at <https://nhsbtdbe.blob.core.windows.net/umbraco-assets/1518/wales.pdf>.

<sup>15</sup> Rithalia A, McDaid C, Suekarran S, Myers L, and Sowden A (2009) Impact of presumed consent for organ donation on donation rates: a systematic review *BMJ* **338**.

lower living donation rates) than countries classed as 'opt-in'.<sup>16</sup> However, it is highly problematic to classify countries simply as 'opt-in' and 'opt-out' given the number of other factors that influence donation: a point reiterated by Rafael Matesanz, the leading figure of the Spanish transplantation system.<sup>17</sup> Spain, for example, is classed in this review as an opt-out country on the basis of its legislative position, even though it operates neither an opt-out register, nor any other means of registering objection, and relies entirely on family agreement for donation to take place.<sup>18</sup> The Department of Health's own impact assessment makes clear that the evidence in this area is highly ambiguous, and it is not possible to demonstrate a causative relationship between a change to an opt-out approach to consent and increased donation rates.<sup>19</sup>

- 25 However, there *is* good evidence regarding the role of a number of other factors in increasing the number of donated organs: raising public awareness; encouraging family discussion; and better support and communication between specialist nurses and bereaved families. The regular audits of donation in the UK, for example, show that the support of a SN-OD for bereaved families has a significant impact on organ donation. There is a need to expand and strengthen this network of specialist nurses, and for more training amongst staff and others involved in the organ donation process.
- 26 In summary, our *Human bodies* report takes the view that, in order to be ethical, opt-out systems must include a number of essential features, in brief that:
- people are well informed;
  - families are appropriately involved; and
  - trust in the organ donation system is not compromised.
- 27 We strongly encourage the Government, if going ahead with a change in the law in the absence of a secure evidence base to support its claimed benefits, ensures that this change is accompanied by positive action to ensure each of these three points are addressed.

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<sup>16</sup> Shepherd L, O'Carroll RE, and Ferguson E (2014) An international comparison of deceased and living organ donation / transplant rates in opt-in and opt-out systems: a panel study *BMC Medicine* **12**: 131.

<sup>17</sup> Fabre J, Murphy P, and Matesanz R (2010) Presumed consent: a distraction in the quest for increasing rates of organ donation *BMJ* **341**: c4973.

<sup>18</sup> *Ibid.*

<sup>19</sup> Department of Health (2017) *Consultation on an opt-out system of organ and tissue donation: impact assessment*, available at: <http://qna.files.parliament.uk/ws-attachments/804609/original/Organ%20Donation%20Opt-Out%20Consultation%20Impact%20Assessment.pdf>.