

Consultation on introducing 'opt-out' consent for organ and tissue donation in England

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

- Yes – there should be as many ways as possible to record a decision, including when people are doing other things, such as registering with a GP

Q2. What do you think are the advantages or disadvantages of including personal information on someone's organ donation decision?

A balance needs to be struck between having a straightforward, easy to access organ donation database and additional personal information which may have value if, for example, it provided the family members of a patient with confidence in the individual's decision. However, as time is such a critical factor in organ donation, the College would advise against a system which may cause excessive delay or bureaucracy.

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

A higher rate of organ donation will reflect increased public awareness, societal attitudinal change to donation, and improved clinical infrastructure. Considerable investment in terms of time and resource needs to be spent on continuing public education and improved infrastructure to support families and clinical teams, both in the current "opt in" authorisation system and in the circumstances of a move to "opt out".

The available international evidence supports the fact that 'opt out' legislation is associated with increased rates of deceased organ donation. However, **the legislation itself may not be the major determining factor** for organ donation as some countries with "opt in" systems still have higher organ donation rates than countries which have adopted "opt out" legislation. There are differing opinions within the medical profession and society at large regarding an 'opt out' system. Some believe that "opt out" legislation effectively means acquisition by the State of organs, and removal of the altruistic aspect of donation is of real concern to some of our Fellows, who feel that bereaved families take great solace from an active act of giving. These and other ethical issues have prevented the global adoption of presumed consent legislation. However, the higher rate of organ donation in 'opt out' jurisdictions persists even when the next of kin are still asked for their approval before retrieval (this is termed 'soft' opt out as opposed to 'hard' opt out when the relatives are not consulted).

The example of higher rates of organ donation in Spain has shown that improved clinical infrastructure with enthusiasm for transplantation is vital¹. Rafael Matesanz led the Spanish human transplant organisation change, and he has stated that the law change in 1979 had virtually no effect. The improved transplant coordination, however, came in 1989, and it was at that point that Spain saw the substantial increase in donation that they now experience. Conversations about donation are part of society in Spain and it is ensured that the public have awareness of organ donation through many different channels. Partnerships with schools and further and higher education will be important to embed the discussions around organ donation at an early stage.

Q4. If the law changes, would this affect your decision about organ donation?

- No – it would make no difference
- Yes – it would make me want to become an organ donor after my death
- Yes – it would make me want to opt out of being an organ donor after my death

If a free text box is available: *The College supports this move in principle, provided there is a parallel process of public education about the benefits of organ donation and improved infrastructure to support families and clinical teams at the time of organ donation. The College has sought the input of Fellows in a variety of medical specialties and a wide range of views have been submitted, and it is important to note that unanimity has not been reached on several issues.*

Some Fellows have expressed the view that there are a number of individuals who would be donors but have not made that view known before their death. The move to a soft opt out system would therefore likely make a small but real difference to the number of organs donated in England, when implemented alongside other initiatives.

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?

- Yes
- No
- Don't know

The publicity around the information campaign referred to would need to consider those unable to read; those with little or no English language and those who are less likely to engage with these issues due to personal circumstances.

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?

- Always – if someone has not opted out, their family should always be asked to make the final decision

Public confidence in a soft opt out system would be quickly undermined if family did not continue to play a key role in decision making. Clinicians could be placed in the very difficult position of harvesting organs in the face of explicit opposition from immediate family members and which could undermine confidence in medical teams. The family should always be consulted about the request to harvest organs and asked about the expressed wishes of the deceased.

Proceeding with organ or tissue donation against the wishes of grieving relatives in this situation would seem likely to lead to a very damaging breakdown in relationships and loss of trust between relatives and the public on the one hand, and the organ donation team and the wider medical profession on the other.

The role of the Specialist Nurse for Organ Donation (SNOD) is key in circumstances such as this to provide sensitive assistance and support to the potential donor's family and ensure that communication remains open and transparent.

If despite the best efforts of all involved, donation was to cause distress it should not go ahead – and this is probably the strongest argument for not changing the law, since the situation would in effect be little different from what happens now.

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?

- Yes – someone's family should always make the final decision, even if it is different to what the person decided

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

- 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.

The College is undecided on under 18s: there are shades of opinion on this issue given that patients under 18 are able to give informed consent for other medical procedures. However, a more explicit "opt in" approach may be helpful for those under 18, particularly as it is likely to be their parents who are asked for consent to harvest organs.

The general principles of capacity for consent should apply as in other situations, as covered by the mental capacity legislation introduced in England & Wales in 2005.

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

The College wishes to reiterate the view of our Fellows that a higher rate of organ donation will reflect increased public awareness, societal attitudinal change to donation, and improved clinical infrastructure.

In terms of infrastructure, for example, Fellows have described situations where there is a loss of potential donated organs due to surgical considerations. There are occasions where transplantation

is unable to proceed because there is a lack of retrieval or a transplant surgical team, because they are already operating on other patients. Some emphasis should therefore be placed on identifying areas of improvement on the transplant side.

ⁱ <http://blogs.bmj.com/medical-ethics/2017/09/25/organ-donation-presumed-consent-and-focusing-on-what-matters/>