

Response from the Royal College of Anaesthetists to the Department of Health & Social Care consultation, 'Introducing 'opt-out' consent for organ and tissue donation in England

About the Royal College of Anaesthetists

- 16% of all hospital consultants are anaesthetists, making anaesthesia the single largest hospital specialty in the UK^{1,2,3}
- Anaesthetists play a critical role in the care of two-thirds of all hospital patients⁴ and 99% of patients would recommend their hospital's anaesthesia service to family and friends⁵
- With a combined membership of 22,000 fellows and members, representing the three specialties of anaesthesia, intensive care and pain medicine, the Royal College of Anaesthetists (RCoA) is the third largest Medical Royal College by UK membership.

If you have any questions regarding our submission, please contact Chris Woodhall, Head of Policy & Public Affairs, at cwoodhall@rcoa.ac.uk or on 020 7092 1690.

GENERAL COMMENTS

The restrictions put in place by the consultation timeframe do not allow for a full survey of our membership, and therefore we do not argue a position regarding support or opposition to the proposal – or indeed the ethical issues that arise. Instead, our response focusses on the demands on NHS staff, hospital capacity and the role of our membership in delivery of donation and transplant services.

As part of the extended surgical team, anaesthetists plays a vital role in organ and tissue donations, and we were pleased to see the role of anaesthetists and the development of anaesthetic practice in this area noted by NHS Blood and Transplant (NHSBT), in its collaborative four nations' strategy 'Taking Organ Transplantation to 2020: A detailed strategy'.⁶

The NHSBT strategy also notes that outcomes after a transplant are not as good as they should be. The RCoA is at the forefront of the development of perioperative medicine⁷, which is about ensuring patients are cared for either side of surgery – to be fit for surgery and supported through recovery and aftercare. In our perioperative medicine vision document, 'The pathway to better surgical care'⁸, a particular focus is placed on addressing high-risk patients and developing tailored pathways to risks which might lead to sub-optimal patient outcomes.

An example of perioperative medicine in action in this area, the vision document provides a case study on acute kidney injury (AKI) after major surgery, in response to the recognition of the step-wise deterioration in kidney function that can occur after an episode of AKI; and could lead to a transplant being required.

Staff time, service demand, and capacity

A recent story reported in the *Evening Standard* in February 2018⁹, regarding three liver transplants performed back-to-back at the Royal Free Hospital in London, demonstrated the need for the extended surgical teams, which include of surgeons, anaesthetists and intensivists – among others – to be available at short-notice in these centres of excellence.

The article highlighted that for the hospital to perform the three transplants, two of which were categorised as 'super urgent', a number of staff who were off-duty attended the

hospital to support the procedures. It is right these staff are celebrated – as the article does – but it cannot be the case that off-duty staff are needed to meet the demand on services.

The length of time taken for a transplant procedure is a key consideration. For example, a liver transplant usually takes up to 8 hours¹⁰ followed by a few days in an intensive care unit, then further time in a regular ward – for a total period of around two weeks.¹¹ Based on the Impact Assessment's (IA's) best estimate of an additional 93 liver transplants per annum¹² resulting from an 'opt-out' consent system, this will create the need for an additional 744 hours of theatre time and up to 1,302 additional bed days which will be divided – though not uniformly – between an intensive care unit then a standard hospital ward.^a

This means that the equivalent of 186 Programme Activity (PA) additional time in theatre would be demanded - based on a standard 10 PA per week contract for consultants in England.¹³ This figure will be multiplied by the number of staff needed per procedure as part of an extended surgical team (noted above). It cannot be expected that this additional staff capacity can be found within the existing workforce. In the short-term, this suggests that additional locum costs may be incurred and, in the longer-term, this strengthens the case for further investment to expand the numbers of students entering medical training.

A hip replacement – one of the most common surgeries – involves a procedure of around 60-90 minutes, followed by a hospital stay of three to five days.¹⁴ This time can be as short as one to three days if surgery was minimally invasive and the patient is able to access an enhanced recovery programme.¹⁵

Liver transplantation is a highly specialised service, with only around 600 transplants performed each year (in England).¹⁶ By comparison, there were 87,733 primary hip replacements performed in the UK.¹⁷ The indicative cost for a liver transplant is £56,100^{18,19} and for a primary hip replacement, it is £5,625.^{20,21}

Notwithstanding the evidence that suggests that many surgeries are financially advantageous to the health economy, for example, a kidney transplant is significantly cost effective compared dialysis²², an increase in the number of available organs will change demands on clinicians' time. Ensuring that a hospital/trust/foundation trust is not financially harmed by a shift in the caseload of procedures it is delivering must be a policy objective of the proposed changes. On current projections, the Nuffield Trust calculates that the 'optimistic' scenario for 2020/21 would see a gap between providers' recurrent income and expenditure of around £2 billion.²³

RESPONSES TO CONSULTATION QUESTIONS

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**
- **No – you should only be able to record your decision directly onto the NHS Organ Donor Register online or on the phone**

Response: Yes - We agree that there should be as many ways to record a decision about organ and tissue donation as possible. This should also extent to amend a previous decision.

^a This is based on a calculation of 8 hours multiplied by the 93 additional liver transplants indicated in the impact assessment would result from the introduction of an opt-out consent system. That same figure of 93 is then separately multiplied by 14 days to give an estimate of additional bed days

Due consideration should be given to ensure the accessibility of methods to record a decision about organ and tissue donation, including non-electronic forms which can then be transferred to e-records.

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

Response: The complexity of recording personal information is a consideration, notwithstanding the increased staff and funding that the IA notes would be required by NHSBT to administrate the introduction of a new opt-out system.

It might also be the case that providing personal information deters individuals from giving consent and we would encourage that the Department of Health & Social Care (DHSC) to speak with counterparts in Wales to explore this hypothesis further.

The opportunity to provide personal information when recording a decision may help family members to understand a donor's decision, which could mitigate delays to a transplant and reduce distress for relatives – and clinicians. Collecting characteristics including age and ethnicity may also help to inform targeted marketing campaigns to improve donor numbers among certain groups.

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

Response: This will require public-facing marketing, similar to recent behavioural change campaigns on issues such as smoking in cars when children are present²⁴, eating habits among people (Change4Life)²⁵ and Stay Well This Winter²⁶ - aimed at increasing flu vaccination uptake.

NHSBT has had success in delivering creative, public-facing campaigns, which have generated a significant uplift in blood donations. The 'Missing Type' campaign led to a record 30,000 people registering as blood donors within 10 days of the campaign being launched, indicating the potential impact that marketing could have on increasing organ donations.²⁷

A recent survey from the British Heart Foundation found that there is public support for an 'opt-out' organ consent system, with almost three quarters (74%) of survey respondents backing the proposal.²⁸ However, there is a risk that the modest impact of 'opt-out' systems introduced in other countries could undermine public opinion. For example, media reports have noted that the introduction of an 'opt-out' system in Wales – on which many of the assumptions in this consultation's IA are based – has led to an increase of just 20 donors.²⁹

While the evidence is inconclusive, it should not be intended or expected for an 'opt-out' system to be a 'silver bullet' to increase the number of available donor organs. It will be important that this message be clearly communicated to the public as part of the rollout of any new system.

As part of the RCoA's Anaesthesia, Research, Innovation, Education, and Scientific (ARIES) talk series, Dr Paul Murphy discussed the topic of 'Changing the way we think about organ donation'.³⁰ In this talk, Dr Murphy highlights the UK's leading role in donations after circulatory death, which has been the result of initiatives undertaken over the past 20 years. In order to capitalise on this leading role, facilitated by clinical innovation and delivery, it will

be crucial for the DHSC, along with other national NHS organisations, to ensure that NHS staff feel that they will get the support, resources and backing of leadership to respond to any significant uplift in organ donations.

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**

Response: This question is not applicable as this response represents the views of an organisation, not an individual.

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**

Response: We do not have any evidence to inform a response to this question.

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**
- **Sometimes – there are some circumstances where someone's family should make the final decision**
- **No – if someone has not opted out, donation should always go ahead**
- **Other (please give details)**

Response: Regardless of the decision that is taken by the DHSC in response to this consultation process, our main concern is to ensure that all clinicians and healthcare staff involved in the organ donation and transplant pathways are given clear, timely and consistent guidance on this point.

We would also like to draw attention to the 2008 independent report from the Organ Donation Taskforce³¹ that noted:

5.2. 'Presumed consent' is something of a misnomer in medical care because consent is in fact an active process in which permission is given by a patient for a procedure to be carried out of their body, thereby avoiding any possibility of clinical staff being guilty of an assault on the patient. Should a patient lack capacity and be unable to give consent for vital invasive procedures, doctors act on their judgement of the patient's 'best interests', not on a 'presumption of consent'.

The IA accompanying the consultation uses the term 'presumed consent' without making the clear distinction between this and the term 'opt-out'. The sensitivity of this area demands robust policy making and language must be consistent to help, not hinder, clinicians.

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?

- **No – someone’s family should never be able to make a different decision about organ donation**
- **Sometimes – there are some circumstances where someone’s family should be able to make a different decision**
- **Yes – someone’s family should always make the final decision, even if it is different to what the person decided**

Response: Please refer to our answer to Q6.

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)**

Response: We believe that the proposed groups should not be included in the new rules about organ donation, with the following amendments and clarification:

- Under current arrangements, you will be offered to join the organ donor register when applying for a driving license.³² Applicants may be as young as 17 years old and it may therefore be appropriate for the exclusion to apply for those under the age of 17, not 18
- The definition of ‘capacity’ to make this decision must be clearly defined and be consistently applied.

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

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

A consultation-stage impact assessment examines the evidence base for moving to an opt-out system of consent and provides additional information on:

- **whether an opt-out system would change the organ donation consent rate**
- **whether higher consent rates increase the number of transplants**
- **whether implementing an opt-out policy is a good use of health system resources**

The Department of Health would welcome any further quantitative evidence you have on the following areas:

- **for people who have received a transplant: o any evidence on the financial costs of this to the health system and wider society**
o **the quality of life of the individual and those around them**

- **for people who would benefit from a transplant but have not had a transplant: o any evidence on the financial costs to the health system and wider society**
o **the quality of life of the individual and those around them**

- **any other factors that have not been considered in the consultation analysis, which could impact on the desired outcome to increase the number of organs for transplant in England, or which could have other considerable costs/benefits**

Response: The IA notes that one of its key assumptions (under Option 1) is that ‘Both NHSBT and NHS England have the capacity to deal with any additional donors that might arise from the reform so will not incur any additional cost – this is far from certain’.

The consultation document noted that over the last 10 years, the number of organ donors has increased by 75% and deceased transplants have increased by 56%. Against this backdrop the workforce pressures on the specialty of anaesthesia – as a key component in the organ donation and transplant pathway – requires particular scrutiny.

Overall anaesthesia (and critical care) numbers remain robust in comparison to other specialties.³³ However, since 2015 the fill rate at for the specialty training programme (ST3) has fallen by more than 7.5% which indicates a concerning trend.³⁴ In addition, these UK-wide figures hide the significant geographic variation in fill rates that has proven a persistent issue in many areas. For example, the fill rate at ST3 was just 50% in Yorkshire & the Humber and 66.67% in the North East of England, but in a number of areas, including London and the South West of England, the rate has been stable at 100%.

The Chief Executive of NHS England, Simon Stevens, has suggested that incentives may be offered to encourage an increased uptake of posts (across all specialties) in areas where it has proven difficult to attract doctors in training.³⁵

Notwithstanding the conclusions of the IA, which indicate that there is insufficient evidence as to whether a move to an 'opt-out' system will increase donation consent rates, increasing the annual number and quality of organs transplanted is the objective of this policy intervention. Therefore, any decision to proceed with the introduction of an 'opt-out' consent system must be coupled with a comprehensive projection of the impact of service capacity and workload.

We agree that an increase in consent rates and a proportionate increase in organ transplants would represent good value for money, but the latter claim that 'any additional transplants will result in an increased cost to the health system' is incomplete. Paragraph 20 of the IA highlights:

'It should be noted that there is a significant risk associated with [assumptions regarding capacity] as it is unclear if the transplant infrastructure will not be able to cope with a significant increase in the number of transplants without further funding'

However, the IA does not address the following considerations that will need to be assessed in advance of any move to a new 'opt-out' system:

- What will be the service impact on anaesthetists and intensivists who provide organ support for brain dead donors and the post-operative care for transplanted patients?
- What will be the impact on the capacity required for solid organ transplantation in terms of theatre time and for support services such as radiology and pathology?
- Patients in need of an organ transplant are, by definition, at end stage disease, which is invariably complex. These patients will require consultant input for preoperative and postoperative management, which will create an increase demand on consultant and support staff time.

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- ¹ NHS Digital. [NHS Hospital & Community Health Service \(HCHS\) monthly workforce statistics - Provisional Statistics](#). July 2017.
 - ² Stats Wales. [Medical and dental staff by specialty and year](#). March 2017.
 - ³ Information Services Division Scotland. [HSHS Medical and Dental Staff by Specialty](#). December 2016.
 - ⁴ Audit Commission. *Anaesthesia under examination: The efficiency and effectiveness of anaesthesia and pain relief services in England and Wales*, National report, 1998.
 - ⁵ EMK Walker, M Bell, TM Cook, MPW Grocott, and SR Moonesinghe for the SNAP-1 investigators. Patient reported outcome of adult perioperative anaesthesia in the United Kingdom: a cross-sectional observational study. [British Journal of Anaesthesia 2016](#)
 - ⁶ NHS Blood and Transplant. [Taking Organ Transplantation to 2020: A detailed strategy](#). January 2013.
 - ⁷ Getting It Right First Time (GIRFT). Anaesthesia and perioperative medicine. Accessed on 1 March 2018 at <http://gettingitrightfirsttime.co.uk/medical-specialties/anaesthesia-perioperative-medicine/>
 - ⁸ The Royal College of Anaesthetists. [Perioperative Medicine – The Pathway to Better Surgical Care](#). 2014
 - ⁹ Ross Lydall. Evening Standard. [Extraordinary! Hero Royal Free medics who swapped three livers in 18 hours](#). 8 February 2018
 - ¹⁰ NHS Choices. [Liver transplant](#). Accessed 13 February 2018
 - ¹¹ NHS Choices. [Liver transplant](#). Accessed 13 February 2018
 - ¹² Department for Health & Social Care. Introducing 'opt-out' consent for organ and tissue donation in England. [Impact Assessment: organ donation opt-out](#). 12 December 2017
 - ¹³ British Medical Association. Consultant contract in England. [Model contract for consultants in England 2003](#). Accessed on 28 February 2018 at <https://www.bma.org.uk/advice/employment/contracts/consultant-contracts/consultants-england>
 - ¹⁴ NHS Choices. [Hip Replacement](#). Accessed 13 February 2018
 - ¹⁵ NHS Choices. [Enhanced Recovery](#). Accessed 13 February 2018
 - ¹⁶ National Audit Office. Department of Health and NHS England: The commissioning of specialised services in the NHS. [HC 950: Session 2015-16](#). April 2016
 - ¹⁷ National Joint Registry. [14th Annual Report 2017](#). National Joint Registry for England, Wales and Northern Ireland and the Isle of Man.
 - ¹⁸ NHS Scotland. [Commissioning Transplantation to 2020](#). Subgroup of the National Specialist Services Committee. Final Report. July 2015
 - ¹⁹Table 17 Actual and forecast cost per case by service. 2013/14 data is used as this is the latest 'actual' cost, as subsequent years are 'forecast'. Data is from Scotland and is provided to be indicative only as transplantation surgery has no national tariff price in England (treatment function code 120) and prices are set locally.
 - ²⁰ NHS Improvement. National tariff payment system 2017/18 and 2018/19. [Annex A: The national prices and national tariff workbook](#)
 - ²¹ HRG code HN12E – Very Major Hip Procedures for Non-Trauma with CC Score 2-3: 2017/18 best practice tariff price is £5,625
 - ²² NHS Blood and Transplant. Factsheet 7: Cost-effectiveness of transplantation. Accessed on 28 February 2018 at [https://nhsbtmediaservices.blob.core.windows.net/organ-donation-assets/pdfs/Organ Donation Registry Fact Sheet 7 21337.pdf](https://nhsbtmediaservices.blob.core.windows.net/organ-donation-assets/pdfs/Organ%20Donation%20Registry%20Fact%20Sheet%207%2021337.pdf)
 - ²³ Gainsbury, S. The bottom line: Understanding the NHS deficit and why it won't go away. Nuffield Trust. August 2017
 - ²⁴ Public Health England. [Secondhand smoke campaign launch coincides with vote ending smoking in cars with children](#). 11 February 2015
 - ²⁵ Public Health England. [PHE launches Change4Life campaign around children's snacking](#). 2 January 2018
 - ²⁶ Public Health England. [PHE urges those at highest risk of flu to get vaccinated](#). 12 October 2017
 - ²⁷ PR Week. PR Week Awards finalists. Missing Type: MHP Communications, Engine / NHS Blood and Transplant. Accessed on 27 February 2018 at <http://www.prweekawards.com/finalists/missing-type/>
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 - ²⁹ Bodkin, H. ['Opt-out' organ donations won't solve waiting lists deaths, says NHS chief](#). The Telegraph. 15 February 2018
 - ³⁰ Royal College of Anaesthetists' YouTube Channel. [RCoA Aries Talk: Changing the way we think about Organ Donation by Paul Murphy](#). 23 January 2018
 - ³¹ The Organ Donation Taskforce. [The potential impact of an opt out system for organ donation in the UK](#). November 2008
 - ³² NHS Organ Donation. Organ Donor Register. Accessed on 27 February 2018 at <https://www.organdonation.nhs.uk/faq/organ-donor-register/>
 - ³³ Moberly, T. [Specialty training vacancies increase by 30% in a year](#). BMJ Careers. 19 Jul 2017
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 - ³⁵ Lintern, S. Health Service Journal. [Stevens: Higher pay needed to help recruitment in unpopular regions](#). 31 October 2017