

Evaluation of the Organ Donation (Deemed Consent) Act, 2019 in England

Final report

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Glossary of abbreviations

BACCN	British Association of Critical Care Nurses
BBN	Breaking Bad News
BMA	British Medical Association
CLOD	Clinical Lead – Organ Donation
DBD	Donation following Brain Death
DCD	Donation following Circulatory Death
DHSC	Department of Health and Social Care
ED	Emergency Department (or Accident and Emergency)
ESOT	European Society for Organ Transplantation
HCRW	Health and Care Research Wales
HRA	Health Research Authority
HTA	Human Tissue Authority
ICNARC	Intensive Care National Audit and Research Centre
ICU/ITU	Intensive Care Unit/Intensive Therapy Unit
IRAS	Integrated Research Application System
KPI	Key Performance Indicators
ME	Minority Ethnic
MRC	Medical Research Council
NHS	National Health Service
NHS CRN	National Health Service Clinical Research Network
NHS REC	National Health Service Research Ethic Committee
NHSBT	National Health Service Blood and Transplantation
NIHR	National Institute of Health Research
NOK	Next of Kin
NPT	Normalisation Process Theory
ODR	Organ Donor Register
ODT	Organ Donation and Transplantation
OID	Organisational Information Document
ONT	Organización Nacional de Transplant
PA	Programmed Activities
PDA	Potential Donor Audit
PI	Principal Investigator
PIRU	Policy Innovation and Evaluation Research Unit
PPIE	Patient and Public Involvement and Engagement
R-CLOD	Regional Clinical Lead for Organ Donation
RINTAG	Research, Innovations and Novel Technologies Advisory Group
R & D	Research and Development
SNOD	Specialist Nurse – Organ donation
SOP	Standard Operating Procedures
SR	Specialist Requester (for organ donation)
TC	Transplant Coordinator
UK	United Kingdom

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Executive summary



In the United Kingdom, as in most other developed countries, the demand for organ donation continues to exceed the supply of organs, leading to many dying each year whilst on an organ donation waiting list. England had been debating for some time whether to switch to an opt-out system of consent as a way to address this important yet complex issue. Following Wales, which had introduced a ‘soft’ opt-out policy into its National Health Service (NHS) in 2015, a bill was passed in England in 2019 creating a similar ‘soft’ opt-out system of consent to organ donation, thereby switching the default to one that, in theory, supports deceased organ donation for those who meet specific criteria. Alongside this, the role of the family changed. While families remain essential to deceased organ donation by providing information to health care professionals to maintain the safety and effectiveness of organs for transplant, they are no longer the decision makers. Instead, families are required to support the organ donation decision their relatives made in life. In May 2020, at the height of the COVID-19 pandemic, and constrained by circumstances at the time, the Act was implemented. As all services were dramatically reconfigured to manage the high number of critically ill COVID-19 patients, and the general public were preoccupied with digesting the multiple rules and guidance with regard to social distancing, plus trying to keep themselves and their loved ones safe, the planned public information campaign to support the law change was postponed indefinitely. In other respects, the law change was implemented in a staggered way (e.g. staff were retrained).

The Policy Innovation and Evaluation Research Unit, based at the London School of Hygiene & Tropical Medicine, in partnership with Bangor University, was commissioned before the pandemic to undertake an evaluation of the implementation of the changes. Despite the major changes made to the implementation plan and the complete redesign of health services during the pandemic, the evaluation was undertaken broadly as originally intended with additional components added to further understand the implementation of the law change as findings were emerging. The eventual mixed method evaluation comprised:

- a review of Parliamentary debates leading up to the law change;
- a media content analysis of the public’s responses to media articles ahead of the law change;
- analysis of intensive care and routine NHS Blood and Transplant (NHSBT) potential donor audit data;
- surveys and interviews with health care professionals involved to varying degrees with deceased organ donation;
- interviews with the public;
- interviews with relatives and close friends who had been approached about organ donation after their relative or friend had died; and
- a comparative analysis of Spain’s consent processes and documents.

Given the timing of the evaluation, all components looked at the impacts of COVID-19 on the organ donation and wider health care system.

Below is an overview of the main findings which are presented in greater detail in the report which follows. This summary broadly maps onto the structure of Chapter 10 (the discussion) which provides further detail of the policy recommendations.

How the law change came about (Chapter 3)

- Over 15 years of debate in Parliament, the narrative changed from one which looked at the evidence of likely effects towards a more positive overall attitude that, regardless of mixed evidence, deemed consent was viewed as the ‘right thing to do’.
- The experience of Wales, lobbying from patient groups, and UK media rhetoric all contributed to gaining extensive, cross-party support for a change in the law so that organ donation would become the default for citizens.
- While much weight was given to the perceived successful opt-out countries, especially Spain, analyses also revealed evidence of misconceptions in the debates as to how organ donation actually works in the UK, and therefore how the legislation was expected to work in practice.

Publicity and media coverage of the law change (Chapter 4)

- Complementary media campaigns to the government-led media campaign leading up to implementation predominately featured children – who are excluded from the Act – these campaigns created a dominant and consistent narrative that organ donation is a moral good.
- However, analysis of reader-generated content in response to media coverage was mixed towards organ donation in general, and mostly critical of the law change.
- New narratives were created in the readers’ comments such as concerns about the expanding role of the state, loss of individual freedoms and rights, the potential for the change in the law to be abused for financial gain, and uncertainty about how death is defined and verified.
- The discrepancies between the tone of the articles and the readers’ comments suggests that some members of the public were much less trusting and supportive of the law change than Parliamentarians and the mainstream mass media.

Trends in consent rates (Chapter 5)

- Analysis of trends in consent rates over time shows a steady upward trend in England in the 10 years prior to implementation of the Act, especially from 2014 to 2019.
- The consent rate in England, Scotland and Wales reduced from 68.3%, 63.0% and 63.6%, respectively, in April-June 2019 to 63.2%, 60.5% and 56.3%, respectively, in April-June 2023.
- It is very unlikely that the implementation of the law caused the decline in consent rates, since, in May 2020, at the start of implementation, England was between lockdowns, was experiencing ongoing variations in social distancing guidance, and policy makers were preoccupied with containing the pandemic and investigating therapies.
- At the same time, in order to keep transplantation in operation, at some low level, major changes were made to the organ donor system, including substantial changes to the criteria for assessment of potential organ donors, making discerning any impact of the law change on consent rates challenging.
- Nonetheless consent rates have still not returned to their pre-pandemic levels.

Views of the public with a focus on views among ethnic minorities and faith groups (Chapter 6)

- Changing the law has had little impact on the general public's support, in principle, for organ donation, which has remained high and stable at around 80%. Furthermore, it does not appear to have influenced people's willingness to become deceased organ donors, but this proportion is lower, at 56% of the population.
- The number of people registering on the organ donor register has stagnated.
- Of those registered, 89% have opted in and are predominately white; about 10% have opted out and are predominately non-white.
- The intention of the Act to give decisions to individuals to make while they are alive, is not straightforward in the context of some ethnic minority families where decisions are shared or delegated in a hierarchy.
- There is a very low level of understanding about what deceased organ donation is, how it comes about, and how this aligns with important end of life rituals and processes in some ethnic minority communities.
- Harmful misinformation campaigns targeted at certain ethnic minorities encouraged people to opt-out of organ donation, and created further uncertainty and mistrust about organ donation at especially turbulent times.
- We identified four subgroups of the general population in terms of their attitudes to organ donation and likely behaviour:
 - **co-operative donors**, the subgroup of the population who are the most supportive of organ donation (24%)
 - **non-donors**, the subgroup of the population who are the least supportive of organ donation (9%)
 - **sensitive donors**, the subgroup least aware of organ donation publicity and who displayed the most uncertainty about organ donation (22%)
 - **ambivalent donors**, the subgroup who would consider organ donation but who are less certain about the practicalities involved in retrieval (46%)
- Co-operative and non-donors are unlikely to change their views or respond (positively or negatively) to interventions designed to increase consent rates.
- Apart from co-operative donors, most in the other three groups had not discussed their views or preferences and may benefit from more opportunities to talk to their family (or people who will ensure their organ donation decision will be upheld), or register their organ donation decision.
- The presumption of consent left gaps in all people's knowledge. They wondered what they needed to do while alive, what would happen if they or their relative who died was eligible for organ donation and, critically, what they would do if they did not know what their relative who died had wanted.

Views of specialist and other NHS staff of the deceased organ donor system (Chapter 7)

- COVID-19 affected every aspect of implementation for staff. Many staff were redeployed or left their jobs. As a result, staff were not able to work collectively as intended for implementation.
- Although supportive in principle, many staff were unconvinced that legislative changes alone would increase consent rates.
- Staff received routine donor audit data suggesting that the law was yet to make a difference to consent rates, reducing their enthusiasm and commitment towards the law over time.

- Many felt that the continued requirement from NHSBT for NHS clinical staff not to mention organ donation to family members was harming the collective action needed to bring about organ donation.
- Despite receiving training in the approach to families, specialist NHSBT staff faced even more challenges than before the law change.
- The law gave the specialist nurses in organ donation and specialist requesters (SNODs/SRs) no new tools to navigate the complexities of speaking to the acutely bereaved or influencing family behaviours in regard to deceased organ donation.
- NHS clinicians too felt that NHSBT's standard operating procedures were not always helpful in what were often highly varied family contexts, and complex family discussions and negotiations.
- Nothing got any easier for staff managing complex and sensitive end of life care processes in a permanently overstretched and understaffed service as a result of the law change.

Experiences of family members approached about organ donation after the law change (Chapter 8)

- Irrespective of the deceased decision pathway (via the Organ Donor Register (ODR), expressed or deemed), most families still felt that they were the decision makers.
- The 'soft' opt-out system was not yet making decisions or experiences any easier for families at the bedside.
- Families did not see deemed consent as a genuine choice, unlike a decision on the organ donor register which was generally viewed as a positive decision in support of organ donation.
- Families struggled to comprehend the highly complex and multiple processes involved in organ donation that they were presented with at the bedside.
- SNODs/SRs were critical to supporting families through these confusing processes.
- Families most frequently asked themselves if their relative would have wanted to donate (i.e. have surgery) rather than whether the person who died wanted to save lives.
- Families frequently unpicked the decisions of the deceased and superimposed their own values, judgements and preferences to challenge and overturn the prior consent. They did this most often when there was potential to deem consent.
- Family members not supportive of deemed consent and of organ donation, in particular, believed that donation would cause them and their deceased relative additional harms. They opted for what they thought would benefit them or their family the most, rather than what would provide the maximum benefit to unknown others.
- Irrespective of whether the families supported the deceased's decision to donate made in life, most found the current process of organ donation very difficult to go through.
- Families consistently leaned on the SNODs/SRs for guidance, support and reassurance, and appreciated the high quality care that they provided.

Comparison of England with Spain as world leader in deceased organ donation (Chapter 9)

- Families are as involved in decision making in Spain as they are in England.
- The Spanish system has simpler and locally tailored consent documents, and the time taken for bereaved families to support organ donation is shorter, according to discussions with Spanish experts.

- There are more pathways leading to organ donation in the Spanish system, and more robust legal protections for the decisions of individuals made in life.
- The language used with family members and staff was also observed in the documents to be different in tone and meaning. England appeared more focussed on establishing last known decisions and SNODs/SRs are encouraged to remain impartial. The Spanish system aims to establish the willingness of the deceased in general to help others, as well as their willingness to donate their organs.
- Organ donation is more ingrained as an integral part of end-of-life care, with many health care professionals aware of it and encouraged to be involved in it in Spain.

Implications and recommendations for policy and practice

We have taken a whole system perspective and developed a series of recommendations which we think are needed to bring about the desired outcomes of the Act based on the findings of the evaluation. None of the recommendations for change should be interpreted as criticisms of any of the staff involved currently in deceased organ donation. The NHS (even before the COVID-19 pandemic) consistently operates above its maximum capacity. NHSBT and, in particular, the SNODs/SRs, who are essential to organ donation and whose work is consistently praised by the families of the deceased, are operating in a permanently overstretched and consistently understaffed system.

The recommendations are presented at the end of the report in Chapter 10 and in a detailed table. The recommendations are organised into short, medium and long-term changes, specifying the agency or agencies needed to bring about each change.

The Table 10.1 and final chapter cover recommendations on the organ donor register, media campaigns, considerations of inequalities and ethnic minorities, processes at the bedside for families, in particular related to consent, and the organ donor system, including the interfaces between NSHBT and the rest of the NHS.

The main recommendations are:

- To introduce new public ongoing media campaigns crafted to be more supportive of organ donation as a benefit to transplant recipients. Communications need to emphasise the changed role of the family as well as improving public understanding of the circumstances likely to bring about deceased organ donation and the processes involved.
- To add more organs, tissues and processes to the 2019 Act to help simplify and align policy and practices with the principle of deemed consent.
- To give decisions on the ODR greater legal status to further legitimise and protect individuals' decisions and increase support for the changed role of the family. There needs to be regular reminders embedded in day-to-day life to those on the ODR so that decisions are kept up-to-date, thereby helping SNODs/SRs in their roles.
- To shorten and simplify the documents and processes that the family have to complete so that they only cover the essentials in terms of ensuring the safety and effectiveness of transplanted organs.
- To provide further training and tools for SNODs/SRs to help them on a new mission of assent rather than consent to deceased donation.
- To clarify the concept of deemed consent and increase public understanding of the principle so that family members come to consider it as a legitimate pathway for their deceased relative.
- To replace the culture of risk aversion with a more positive philosophy, embedding organ donation in end of life care and developing practice more in line with the spirit of the opt-out legislation.

1

Introduction

Background

Organ donation is the supply of an organ or tissue to allow a lifesaving or life-changing transplant to be performed. Globally factors influencing availability of organs for transplant include: developed healthcare systems; (long) established and integrated donation and transplant programs; public attitudes towards organ donation; general health of the population; care and support for the acutely bereaved; availability of healthcare specialists including specialist nurses; end of life care policies; resources including hospital bed capacity; inequalities, and innovations and research to preserve and prolong (organ) life.[1] Although complex and multi-factorial, it is generally agreed that consent to deceased organ donation is one of the main barriers to making more organs available for transplant.[2] To address this, law makers have, over time, introduced various versions of opt-out systems of consent to deceased organ donation. Despite mixed evidence as to their effect, support for such systems have increased, and trends increasingly show more countries adapting to opt-out systems.[3] Versions of opt-out vary considerably but the underlying principle is the same, switching the default position of citizens (who meet specific inclusion criteria, normally a minimum of an adult with mental capacity) to one that supports organ donation.

Context

In the UK NHS Blood and Transplant (NHSBT) was established in 2008 as a Special Health Authority to address the need for more transplants, and has been working ever since “*managing the donation, storage and transplantation of blood and blood components, organs, tissues, bone marrow and stem cells, and researching new treatments and processes*”. [4] Special Health Authorities deliver services on a national, rather than local level and are created by the Secretary of State through secondary legislation. See **Box 1** for further details on the UK organ donation system.

Box 1: The UK organ donation system

The deceased organ donation system comprises services in 12 regions across the UK, with nine covering England.[5] Each region will have a minimum of a Regional Clinical Lead for Organ Donation (R-CLOD), a Regional Manager, Team Managers, SNODs, SRs, Professional Development Specialists, administration support with other roles co-opted as required depending on the region configuration, overall activity and priorities, e.g. education and paediatric leads. Each region will be responsible for a population size, a geographic area and a number of NHS hospital trusts. NHS hospital trusts provide secondary health services and are made up of a number of local hospital sites.

NSHBT operates a level one to four system in order to best allocate limited resources to where they are most needed in the context of deceased organ donation in hospital trusts. Levels are defined by the number of proceeding organ donors per year from level 1, n=12 or more to level 4 less than n=3 proceeding donors per year. Releveling normally takes place every five years. In 2023 the UK relevelled creating 36 level one, 51 level two, 31 level three and, 39 level four trusts/health boards.[8] Additional labels and resource considerations might be given for particular functions relevant to organ donation e.g. adult neuro centre, major trauma, paediatric, cardiothoracic or transplant but in simple terms the level label will determine the number and hours of embedded Special Nurse in Organ Donation (SNOD) time and the number of Programmed Activities (PA) time is made available for a local Clinical Lead in Organ Donation (CLOD) at each trust.

The promotion and management of deceased organ donation is the responsibility of NHSBT working with and through the NHS. This starts at a national level, with the National Organ Donation Committee,[9] (typically meeting three times a year), then a regional organ donation committee, (typically meeting monthly) and a local trust level committee, (typically meeting three times a year).[10] The make-up and priorities of local level committees will vary but normally have an overall focus on performance, education, policy and promotion. The chairs of the local committees are often voluntary and come from a wide variety of backgrounds, their main job is to work collaboratively with the CLODs and SNODs facilitating the organ donation agenda. A local trust organ donation committee will typically have multi-disciplinary representatives from each NHS site (clinicians and link nurses) and NHSBT (Team Managers, SNODs and SRs) including bereavement care and sometimes wider charity partner representatives.

Organ donation NHS healthcare professional training is delivered via a nationally co-ordinated simulation course,[11] supplemented by online resources and materials.[12] Locally the SNODs have a key role in raising awareness, sharing best practice and good case studies (e.g. where multiple lives were saved), supported by their CLODs and their committee members. Overall performance is managed via the Potential Donor Audit (PDA), a national database where local level NHS data are fed into, cleaned and used to measure performance throughout the UK. Key Performance Indicators (KPIs) include, referral, SNOD presence, Neurological Death Testing and consent.[13] KPIs are reported back at every committee meeting at the appropriate local, regional, and national level. In addition, a national performance team will attend regional committees (normally held every two months) and feedback national and regional performances; what issues might be coming up; and help address them.

The identification and consent of potential donors

The identification of a potential donor works on a manual referral system. Any patient with a severe brain injury, or a patient where decisions are being made to withdraw treatment, is considered a potential donor and should be referred as soon as possible via a national referral number.[6] In the UK people can become organ donors via donation via brain death (DBD), or donation via controlled circulatory death (DCD). Any member of clinical staff can call the referral line, which is operated via a pager system within NHSBT, who will make an assessment over the phone and collaboratively agree next steps. Once the patient is identified as potentially suitable for organ donation, NSHBT will mobilise an SR or SNOD, to the hospital site to progress the process. On arrival the SR will usually be met by the intensive care team. This process has, over time, become increasingly specialised with the implementation of the SR role and includes bespoke training with a focus on communication.

Despite major innovations, and a steady increase over time in consent, transplants and reductions to the waitlist, the UK can only be regarded as a middle-ranking performer in terms of deceased donor organ donation compared with other high-income countries (see Appendix 1 Figure 1). While the overall organ donation and transplant picture remains complex, consent to deceased organ donation has also been widely cited as the biggest single barrier to making more organs available for transplant in the UK. To address this issue between 2013 and 2023 each of the devolved nations and territories in the UK have moved to 'soft' opt-out systems of consent to deceased organ donation.[7]

Table 1 summarises the opt-out systems that were introduced in Wales, Scotland, Northern Ireland and England. In March 2019 The Organ Donation (Deemed Consent) Act 2019 received Royal Assent and came into effect in May 2020.

Table 1 Summary of opt-out systems in UK countries

UK Country	Title of Act relating to organ donation consent	Timeline	Summary of law relating to consent	Summary excluded groups where deemed consent does not apply	Organ Donation Acts the legislation amends/ adds to
England	Organ Donation (Deemed Consent) Act 2019 (England) Referred to as 'Max and Kiera's Law'	Introduced: July 2017 Passed: March 2019 Implemented: May 2020	<i>"The person concerned is to be deemed to have consented to the activity unless a person who stood in a qualifying relationship to the person concerned immediately before death provides information that would lead a reasonable person to conclude that the person concerned would not have consented."</i>	<ul style="list-style-type: none"> • Under 18 years • Short-term visitors or temporarily resident in England for less than 12 months immediately before dying • Those who: 'lack the capacity to fully understand the consequences of deemed consent for a significant period before dying • transplants that are currently rare or novel and many may not regard as normal to donate'. 	Amendment to Human Tissue Authority (HTA) Act 2004 (England/ Wales/ N.Ireland)
Scotland	Human Tissue (Authorisation) (Scotland) Act 2019	Introduced: 2018 Passed: 2019 Implemented March 2021	<i>"An adult is deemed to have authorised the removal and use of a part of the adult's body after the adult's death for transplantation where there is in force at the relevant time: (a) no express authorisation by the adult of removal and use of any part of the adult's body for transplantation, and</i>	<ul style="list-style-type: none"> • Under 16 years • Without the capacity to understand 'deemed authorisation' • Who have been living in Scotland for less than 12 months. 	Amendment to the Human Tissue (Scotland) Act 2006

UK Country	Title of Act relating to organ donation consent	Timeline	Summary of law relating to consent	Summary excluded groups where deemed consent does not apply	Organ Donation Acts the legislation amends/ adds to
Scotland			<i>(b) no opt-out declaration by the adult as respects removal and use of the part of the adult's body for transplantation."</i>		
Northern Ireland	Organ and Tissue Donation (Deemed Consent) (2022 Act) (Commencement) Order (Northern Ireland) 2023. Referred to as 'Daithi's Law'	Introduced: 2018 Passed: 2019 Implemented March 2021	Aligned with the updates to the HTA, <i>"The person concerned is to be deemed, for the purposes of subsection (6)(ba), to have consented to the activity unless a person who stood in a qualifying relationship to the person concerned immediately before death provides information that would lead a reasonable person to conclude that the person concerned would not have consented"</i> .	<ul style="list-style-type: none"> • Under 18 years • Those lacking capacity to understand the law • Visitors to Northern Ireland • Temporary residents • Added conditions for advertising to the public 	Amendment to Human Tissue Authority (HTA) Act 2004 (England/ Wales/ N.Ireland)
Wales	Human Transplantation (Wales) Act 2013	Introduced: 2012 Passed: Sept. 2013 Implemented: 1st December 2015	<i>"Consent is deemed to be given to the activity unless: (a) a relative or friend of long standing of the deceased objects on the basis of views held by the deceased, and (b) a reasonable person would conclude that the relative or friend knows that the most recent view of the deceased before death on consent for transplantation activities was that the deceased was opposed to consent being given."</i>	<ul style="list-style-type: none"> • Under 18 years • Those lacking capacity to understand law • Visitors to Wales and those not living in Wales voluntarily • Adults living in Wales less than 12 months before death 	Amendment to Human Tissue Authority (HTA) Act 2004 (England/ Wales/ N.Ireland)

The new system in England, a brief summary

Under the new system in England, all adults aged over 18 years are considered to have consented to organ donation (deemed consent), unless they indicated that they did not want to be a donor during their lifetime by registering an opt-out decision on the organ donor register, or by informing their family members, or were in one of the excluded categories. Only certain organs, tissues and their use were covered by the ‘soft’ opt-out system,^[14] excluded organs and tissues and their use still required family or another type of consent (e.g. first person). The law change was intended to be supplemented by a set of initiatives to complement the new system. These included media campaigns to raise awareness about the change; expansion of the workforce of staff responsible for obtaining consent to organ donation from family members and additional targeted training of NHS staff (Box 2).

Box 1: The (planned) Organ Donation Policy Package in England as described in 2019

Organ Donation (Deemed Consent Act) 2019: Change in the law introducing the concept of “deemed consent” from Spring 2020 – in the absence of a decision to donate or not donate, the presumption will be in favour of organ donation.

National communication campaign about law change: In April 2019, NHSBT started the national awareness campaign about the changes in the law from 2020. This focused on using social media, radio adverts, information available on NHSBT’s website etc and planned to ramp up in the new year with TV adverts ahead of May 2020.

Targeted communication campaign about law change: Alongside the national awareness campaign, NHSBT was targeting specific groups such as BAME, faith groups and those approaching 18.

NHS Organ Donor Register (ODR): NHS Database where someone records a decision about organ donation (to opt-in or opt-out). A key message of the communication campaign was to record a decision (as research shows that when families know what their relative would have wanted they are more likely to support their decision).

Specialist Nurses for Organ Donation/Specialist Requesters/Specialist Nurses – Tissue Donation (SNTD) – training: Specialist Nurses are trained to discuss organ donation with families if organ donation is a possibility for their relative and support them throughout the process by answering questions etc. The Specialist Nurses would have a key role in implementation.

NHS App: New NHS App making it possible to also access the ODR through it.

Government public consultations: Government consulted on two occasions on the move to an opt-in system – the first consultation received 17,000 responses and the second one 4000. Many stakeholders took a key interest in the new policy, including representatives of faith groups.

Code of Practice for healthcare professionals: Practical guidance to healthcare professionals. Updated guidance for healthcare professionals about how the system would work in practice. Issues to be covered will be how to establish if someone has made a decision, what is the role of the family, how to establish if someone is excluded from deemed consent etc.

Amending clinical protocols and procedures: NHSBT have a number of protocols and procedures in place about the donation process. Procedures and protocols have been updated to reflect the new system.

Training of NHSBT healthcare staff on the new system: NHSBT healthcare professionals are trained on issues around consent etc. This includes the Specialist Nurses, retrieval teams etc. Updated training to cover the new system. This would include faith training and development of resources in the form of a DAT, information leaflets and YouTube links. This ties in with person centred care and end of life and/or care after death practices.

Introduction of Specialist Requesters: New role for Specialist Requesters for organ donation, focussing on liaising with/ supporting the family rather than clinical activity. This was an existing programme rolled out to all teams after a successful pilot.

Changes to the Potential Donor Audit: Amendments to the Potential Donor Audit to collate data from Trusts about people dying in intensive care. The type and process for data collection was changing to support new initiatives.

National Call Centre capacity and training: To ensure that they can keep pace with increases in calls to the ODR call line, so that queries and registration requests are managed quickly and efficiently; and that the call centre team are aware.

The official goals of the law change in England were to:

- Increase the consent rate (the rate at which consent is given before or after death);
- Increase the number of deceased donors;
- Increase the number of transplants from deceased donors.

The Department of Health and Social Care (DHSC) commissioned the Policy Innovation and Evaluation Research Unit (PIRU), one of its NIHR-funded Policy Research Units, to undertake an evaluation of the implementation and impact of the Organ Donation (Deemed Consent) Act, 2019 in England.

References – Chapter 1

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2

Aim, objectives and methods of the evaluation as whole

The evaluation was broadly designed to investigate the impact of the changes on:

Consent rate – by type of death, given that consent rates are higher for Donation after Brain Death (DBD) than for Donation after Circulatory Death (DCD).

Number of deceased donors – by population sub-group in that BAME groups had much lower consent rates than the rest of the population and the Government would like to see this increase.

Number of transplants – overall and in relation to particular organs.

Public attitudes to organ donation – in particular:

- Awareness and understanding of the change (including how to opt-out and in, the role of the family, what organs/tissues are included).
- Impact on support for organ donation (support for the new policy, willingness to donate, trust in NHSBT/NHS).
- Impact of the communications campaign (did they see it; did they get enough information?).
- What action (if any) members of the public have taken since the introduction of the policy (did they change their decision, register, or speak to their family?).
- Whether they had used the NHS App to register a decision and if they found that route easy to use.
- Whether they think there are barriers to donation or to registering a decision, especially for particular ethnic groups.

Impact on families of potential donors, close friends and nominated representatives – in particular:

- Whether they understood the changes and their changed role.
- Whether the changes were well explained to them.
- Whether they had confidence in the new system.
- If they overrode the organ donation decision made by the deceased, why they did so.
- If they had enough support during and after the donation process.

Impact on NHSBT and other key NHS staff – in particular:

- Their understanding and awareness of the change, particularly related to the role of the family excluded materials, and the new Code of Practice.
- Whether they would feel confident explaining the new system to families or next of kin or directing them to information and, if not, what would assist them?

- Whether they support the new system and reasons why, if not.
- Whether they feel it has affected their work, including their conversations with families, negatively or positively.
- Whether they feel they have had sufficient support from NHSBT and other agencies (e.g. HTA, DHSC, NHSE), including sufficient training.

The research team developed a detailed evaluation plan in collaboration with the DHSC, NHSBT and the programme implementation board which included the overall design, methods, primary and secondary outcomes, work packages and dissemination plan. The detailed evaluation was approved via a National Institute of Health Research (NIHR) internal review process in June 2020, and began as planned in September 2020. The study received Health Research Authority (HRA) and Research Ethics Committee (REC) approvals. Full details including all of the data collection tools are available in the evaluation [protocol via the PIRU website](#). The only significant change (to that described above) was the addition of a COVID-19 component to the evaluation, adding the impacts of COVID-19 on the organ donation system and in the post-COVID-19 recovery period.

Aims

To evaluate the effects of the changes in the organ donation system associated with the Organ Donation (Deemed Consent) Act, 2019), with particular reference to deceased donor consent rates and to explain any changes observed by investigating:

- the behaviour and experiences of staff;
- the behaviour and experiences of relatives and nominated representatives of potential and actual deceased donors; and
- the influence of changes in the health care system, including those associated with the COVID-19 response and the NHS' recovery post-COVID.

Objectives

- To analyse trends in indicators of the performance of the transplant system in England before and after the law change compared with other parts of the UK with primary focus on consent rates;
- To capture the views, behaviour and experiences of relatives and nominated representatives of actual or potential deceased organ donors;
- To capture the views, behaviour, and experiences of specialist NHSBT, intensive care unit and other NHS local acute trust staff;
- To analyse the attitudes, views, and preferences of the wider public, including those involved in legislating for law change; and
- To capture the views, behaviour, and experiences of the public, relatives of the deceased, and NHS staff about the impact of COVID-19 on organ donation.

Methods

This was a mixed method design incorporating quantitative and qualitative methods in order to provide an impact and process evaluation of the law change and associated actions. This comprised of: secondary analysis of NHSBT commissioned public surveys of knowledge attitude and behaviour; case studies of two NHSBT regions including four NHS trusts; two

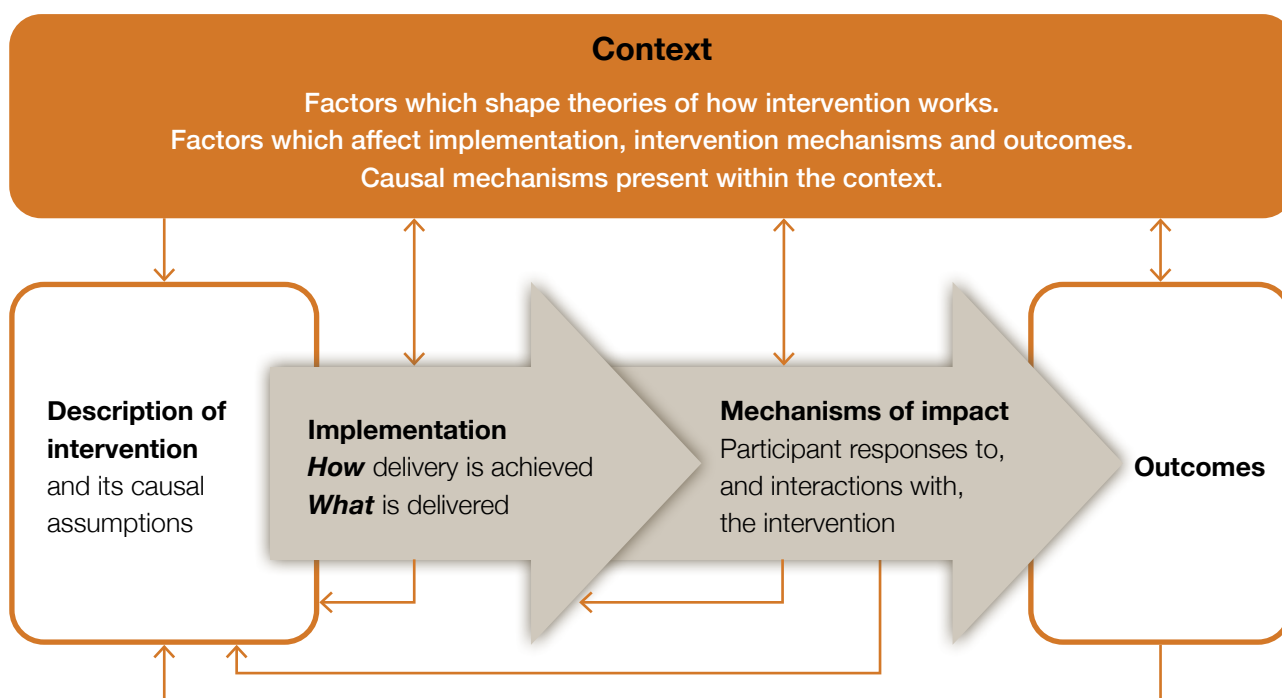
surveys of NHSBT/NHS staff involved in organ donation, 12-18 months apart; interviews with family members, close friends and nominated representatives of potential donors; analysis of organ donation routine data (e.g. donation consent rates) before and after law change; analysis of ICNARC data to identify trends and characteristics of organ donors in ICUs; public interviews (2 rounds 12-18 months apart) with a range of different population sub-groups with particular focus on minority ethnic groups. In addition to the original proposal, we undertook a media content analysis of newspaper articles leading up to implementation, a review of Hansard debates leading up to the law change, and a comparative analysis of consent processes and documents between Spain and England.

Theoretical framework

The research was guided by the Medical Research Council’s (MRC) Framework for Evaluating Complex Interventions [1, 2] (Figure 1).

Figure 1: Illustration of process evaluation of complex interventions

Adapted from Moore et al [3]



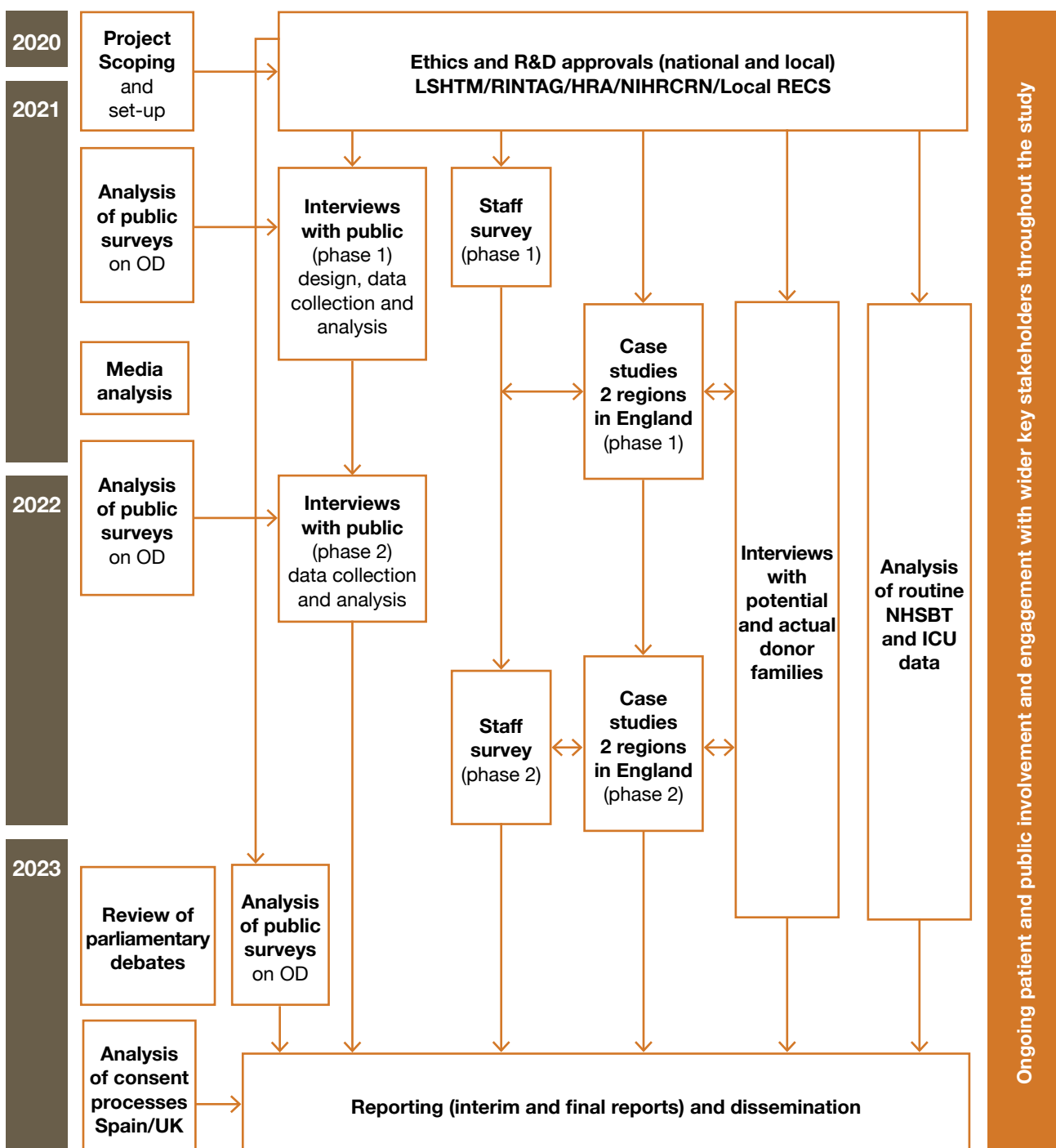
The intervention (law change and support package) was defined as complex, as it comprises of multiple components which interact together to produce change. We therefore incorporated a variety of theories to help conceptualise the study and interpret the evidence. This involved complexity theory as applied to health systems.[4] Complexity also relates to behaviours targeted by interventions and the number of, or organisational levels targeted and the range of outcomes.[5] We undertook a health systems perspective to help understand the wider system within which the intervention was implemented.[6] Using this as a guide, a logic model was developed to describe the intervention, depict processes and drivers in the organ donation system and describe the evaluation.[7] See an example of the Evaluation’s [logic model](#) in Supplementary File 1. We also developed a health systems’ map (Appendix 1 Figure 2) to illustrate the complexity of the system and the interface and interaction between the multiple systems, processes and actors. We used rational choice theory to underpin the analysis of the public and their behaviours.[9, 10] We used Normalisation Process Theory (NPT),[8] an action theory which seeks to understand what people do rather than

their attitude or beliefs to analyse and interpret healthcare professionals perspectives, and concepts associated with utilitarianism were used to frame the analysis of potential donor families behaviours and experiences.[14]. We also used Bereavement Support Frameworks, a framework to support ethical decision making, to guide our research with bereaved families. [12] These theories and their application are expanded in the relevant chapters of the report.

Overview of study

The evaluation comprised of several distinct but connected programmes of work carried out between 2020 to 2023. Figure 2 below provides a flow chart for the intended work programme and timeline.

Figure 2: Flow chart of evaluation



Project Advisory Group

The multi-disciplinary advisory group represented donor families, transplant recipients, professionals involved in organ donation (e.g. specialist nurses; intensive care specialists; transplant surgeons); Organ donation committee chairs, academics with expertise in ethics, organ donation and transplant and representatives from associated charities and third sector organisations (e.g. Kidney Care UK, British Heart Foundation). We also engaged with bereavement care services (e.g. CRUSE) and representatives supporting minority ethnic groups in organ donation (e.g. National BAME Transplant Alliance (NBTA) and Jain and Hindu Organ Donation Alliance (JHOD)).

Patient and Public Involvement and Engagement

We worked with a lay member as a core member of the research team throughout the evaluation. Additional Patient and Public Involvement and Engagement (PPIE) had a focus on involvement and engagement with minority ethnic groups, and perspectives less heard in research on organ donation. This was especially important in order to better understand the impact of the law changes on minority ethnic and under-represented groups in England. Additional groups and individuals we reached out to included the Race Equality Foundation, One Voice Blackburn, NHSBT Community Ambassadors, Indian Association Oldham, British Sikh Nurses, Action on Blood, Rehoboth, RAFFA (Renewal, Advancement, Financial, Freedom, Autonomy) and representatives from NHSBTs Community Investment Scheme. We followed the UK standards for public involvement throughout.[13]

Contents of the rest of this report

The material that follows covers all the outputs from the evaluation. To provide a comprehensive picture of the evaluation, the report includes material that have already been published in peer-reviewed journal form, the remaining chapters are currently either under review for peer reviewed journals or will soon be submitted. Given that each chapter is also a stand-alone academic article, there may be some repetition in places, although we have tried to minimise this wherever possible. The chapters are presented broadly as per their submitted academic paper heading and aim to follow a fairly linear timeline story covering: the lead up to implementation; what happened from multiple perspectives; learning from organ donation consent processes of other countries; a discussion and synthesis of results; and implications and recommendations for policy and practice.

Chapter 3: *‘Why did England change its law on deceased organ donation in 2019? The dynamic interplay between evidence and values’* examines the views and evidence that informed the decision to change the organ donation consent law in England, through an analysis of parliamentary debates before, during and immediately after the law change of 2019.

Chapter 4: *‘Analysis of content and online public responses to media articles that raise awareness of the opt-out system of consent to organ donation in England’* aims to identify the tone (positive, negative, neutral) of the media coverage related to organ donation and associated reader-generated comments in the year leading up to the implementation of the ‘soft’ opt-out system of organ donation in England and the 12 months after implementation.

Chapter 5: *‘Trends in organ donation in England, Scotland and Wales in the context of the COVID-19 pandemic and ‘opt-out’ legislation’* provides a descriptive analysis, using logistic regression and descriptive trend analysis, of changes in consent and transplant rates for deceased organ donation in England, Scotland and Wales. Data analysed were from the Intensive Care National Audit and Research Centre (ICNARC) in England from 1 April 2014 to 30 September 2021, and from the Potential Donor Audit for England, Scotland and Wales from April 2010 to June 2023.

Chapter 6: *‘Subgroup differences in public attitudes, preferences, and self-reported behaviour related to deceased organ donation before and after the introduction of the ‘soft’ opt-out consent system in England: a mixed-methods study’* employs secondary analysis of NHSBT commissioned public surveys of knowledge attitude and behaviour, and interviews with purposively selected members of the public, with the aim of understanding more about the impact of the law change on attitudes and views likely to be relevant to consent to deceased organ donation between different population subgroups.

Chapter 7: *‘Perceptions and experiences of healthcare professionals of implementing the organ donation (deemed consent) Act in England during the COVID-19 pandemic’* reports on the perceptions and experiences of staff (NHS and NHSBT) on the organ donation law change and its implementation in practice. This involved an analysis of staff surveys (one carried out earlier in the COVID-19 pandemic and one during the recovery period) and qualitative interviews with NHS/NHSBT staff working in selected case study sites within two regions in England (North West and London).

Chapter 8: *‘Potential donor families behaviours and experiences following implementation of the deemed consent Act 2019 to organ donation: a mixed method study’* presents a qualitative analysis of the experiences, behaviours and decisions of families who were approached about organ donation after their relative had died. Methods included semi-structured interviews with people involved in organ donation discussions, feedback from specialist nurses, stakeholder feedback and public involvement, findings were put into context with the overall consent rates.

Chapter 9: *‘A qualitative content and discourse analysis comparing the current consent systems for deceased organ donation in Spain and England’* identified differences and similarities in the consent policies, documents and procedures between England and Spain, and considered what works well in Spain, to see if there were opportunities to further increase the consent rate of organ donation and improve current practice in England and the rest of the UK.

In **Chapters 10** we include a discussion of our findings and overall synthesis of results, and present implications and recommendations in the form of a table, in terms of what we think needs to happen now to bring about the desired outcomes of the Act in the short, medium to long term in the UK.

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3

Why did England change its law on deceased organ donation in 2019? The dynamic interplay between evidence and values

Authors: Lorraine Williams, Jennifer Bostock, Jane Noyes, Leah McLaughlin, Stephen O'Neill, Mustafa Al-Haboubi, Paul Boadu and Nicholas Mays

Summary

Background

This chapter examined the views and evidence that informed the decision to change the law in England from one in which individuals were encouraged to express their consent for organ donation (opt-in), to one in which most adults are deemed to have given their consent for organ donation unless expressed otherwise, despite limited supportive evidence and opposition from significant health professional organisations such as the Intensive Care Society and the Royal College of Surgeons of England, through an analysis of the debates before, during and immediately after the law change of 2019.

Methods

Qualitative analyses of Parliamentary debates on organ donation was undertaken. A total of 23 transcripts of organ donation debates and meetings taking place in the House of Commons or the Lords between 2004 to 2022 were identified (via Hansard) and analysed.

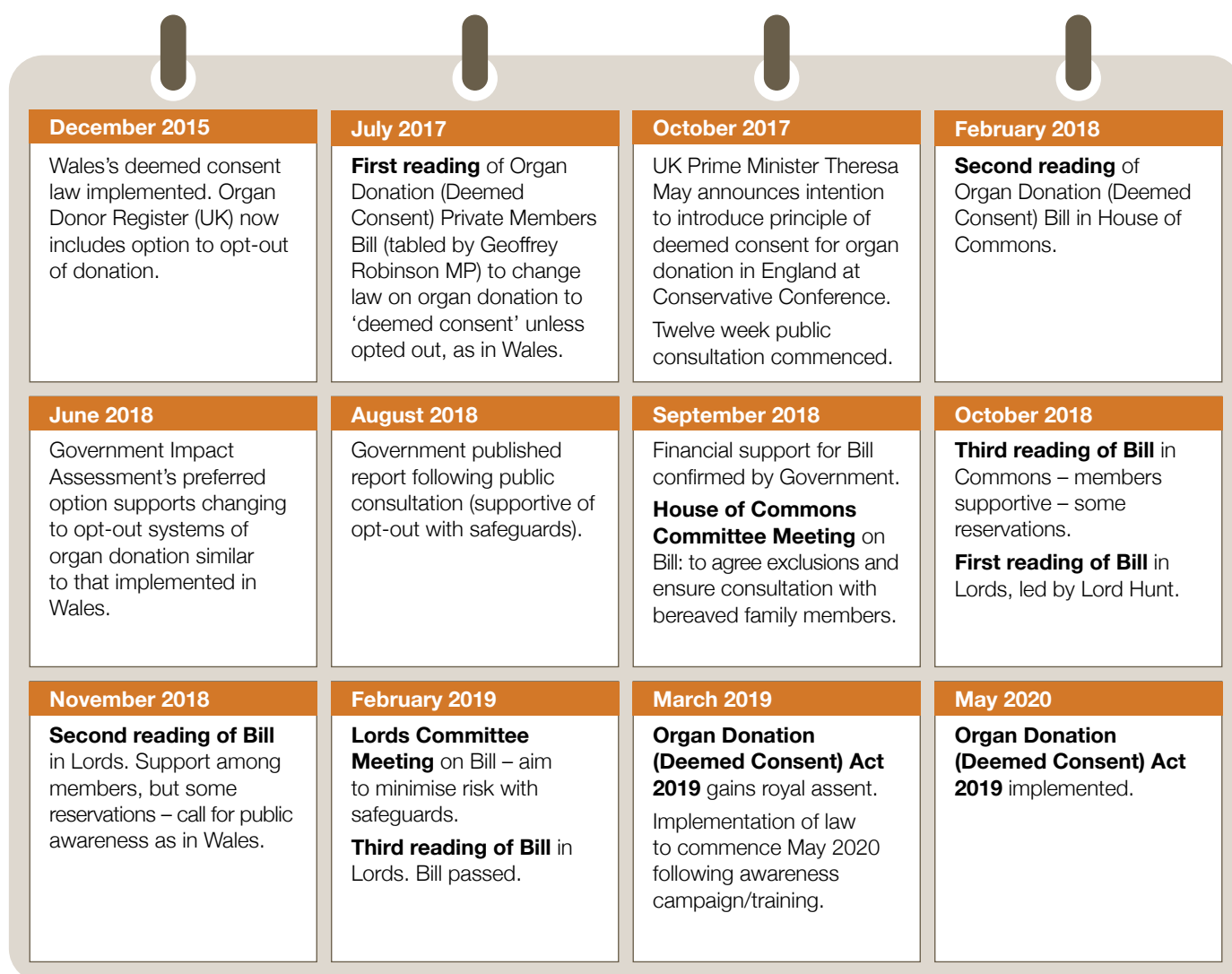
Findings

Analyses revealed a shift from a dominant position, which gave primacy to the evidence of likely effects, towards a more normative position in which the deemed consent option was viewed as the 'correct thing to do' and the limited and conflicting evidence viewed in a generally positive light. By 2017, following Wales's move to an opt-out system, together with continued lobbying for similar changes for England by the British Medical Association and patient groups; and sustained public popularity for organ donation, amplified by UK media rhetoric, the balance of opinion had shifted towards a system where deemed consent would become the default position for most adults, leading to little opposition and large cross-party support for the change in law.

Introduction

The Organ Donation (Deemed Consent) Act, England,[1] presented as a Private Members' Bill with cross-party support, was debated, passed in Parliament in 2019 and went live in May 2020. Scotland enacted a similar law change soon after, and Northern Ireland followed in 2023. Figure 1 illustrates the key dates and milestones of the passage of the law change in England, from its introduction 2017, to becoming law in 2019.

Figure 1: Passage of Organ Donation (deemed Consent) Bill in Parliament



This chapter examines the views and evidence that informed the decision to change the law in England from one in which individuals were encouraged to express their consent for organ donation (opt-in), to one in which most adults are deemed to have given their consent for organ donation unless expressed otherwise, despite limited supportive evidence and opposition from significant health professional organisations such as the Intensive Care Society and the Royal College of Surgeons of England, through an analysis of the debates before, during and immediately after the law change of 2019.

Methods

A search of the Westminster Parliament's official Hansard Reports [34] for all activity relating to organ donation between 2004-2022, including search terms such as organ donation opt-out, and presumed, or deemed consent, was conducted. A search of related documents and

reports, either mentioned in debates or through literature searches up to and at the time of the debate, for example systematic reviews, key papers and reports, was also carried out.

A total of 23 published transcripts of organ donation debates and meetings taking place in the House of Commons or the Lords between 2004 to 2022 were identified and analysed. These comprise: four readings of organ donation presumed consent Bills presented, but withdrawn, or which did not proceed beyond first or second readings in the House of Commons in 2004, 2009 and 2017; five debates on strategies to increase organ donation taking place in Westminster Hall and the Commons between 2008 and 2017; ten debates and meetings relating to the Private Members' Bill first presented in 2017 that became law in 2019; and four motions and questions about organ donation initiatives, regulations and strategies. 138 responses from 117 individuals were analysed, some contributing to more than one debate, representing those in favour of presumed consent/opt-out and those against, plus those who supported presumed consent in principle but who expressed some concerns or reservations. The debates are summarised in Table 1 below:

Table 1 Characteristics of debates, motions and questions relating to organ donation opt-out/deemed consent

Title of debate/ meeting	Date/lead	Transcripts analysed from Houses of Commons, Lords and Westminster Hall	Total	
			Docs	Total No. speaking
Organ Donation (Presumed Consent & Safeguards) Bill	2004 (Siobhan McDonagh – Lab)	Presentation and first reading in Commons (withdrawn after first reading)	1	2
Organ Donation (Presumed Consent) Bill	2009 (Jeremy Browne – LD)	First and second readings in Commons (did not continue to third reading)	2	4
Bill to enable persons in England to withhold consent for organ donation	2017 (Paul Flynn – Lab)	First reading in Commons – did not proceed to second reading due to prorogation and General Election	1	1
Organ Donation (Deemed Consent) Bill	2017 (Geoffrey Robinson – Lab)	Readings in Commons and Lords x 6; Committee meetings in Commons and Lords x 2; meeting in Commons to agree funding x1; Meeting in Commons to discuss impact assessment x1	10	82
Debates on opt-out system of organ donation	2008 (Dawn Primarolo) 2011 (Paul Uppal, Con) 2011 (Glyn Davies, Con) 2014 (Andrew Griffiths, Con) 2017 (Dan Jarvis, Lab)	2008 debate in Westminster Hall 2011 (Paul Uppal) in Commons 2011 (Glyn Davies) in Westminster Hall 2014 debate in Westminster Hall 2017 debate in Commons	5	40
Motions/questions on organ donation initiatives/strategy	2011 (Duncan Hames, LD) 2020 (Lord Bethel, Con) 2021 (Dan Jarvis, Lab) 2022 (Andrew Mangall, Con)	2011 Question on OD initiatives in Commons 2020 motion to approve OD regulations presented in Commons 2021 Question on success of OD law change in Commons 2022 Motion on OD strategy presented in Westminster Hall	4	9
			23	138*

* Responses from 117 individuals (82 from House of Commons, 35 House of Lords) – some individuals spoke on more than one occasion. Con = Conservative, Lab = Labour, LD = Liberal Democrats

Transcriptions of the Parliamentary debates and meetings were uploaded to a qualitative analysis software package (NVivo 12) and the data analysed using the Framework Method. Framework [30] is an approach to the analysis of qualitative data designed specifically for use in applied policy and practice research.[31] Transcripts were read and re-read to enable familiarisation of the data. A deductive approach to coding was used, using predefined categories and codes to capture the range of views expressed relating to whether and on what basis the law should be, or might be changed. These were then indexed and charted within an analytical matrix of cases and categories. Further interpretation and discussion within the research team was carried out to identify patterns, themes and relationships. Findings and interpretations were verified at an event in April 2023 with members of the Commons and Lords involved (e.g. those leading and speaking on organ donation debates), as well as other commentators, to reflect on the interim findings of the team's evaluation of the law. Participants were asked whether the findings were expected or not, given their previous positions on deemed consent and their opinions on the implications of the findings for future policy of deceased organ donation. The meeting was recorded with consent and ethical approval was obtained from the London School of Hygiene and Tropical Medicine's Research Ethics Committee (Ref: 26427 – 3. 17/02/23).

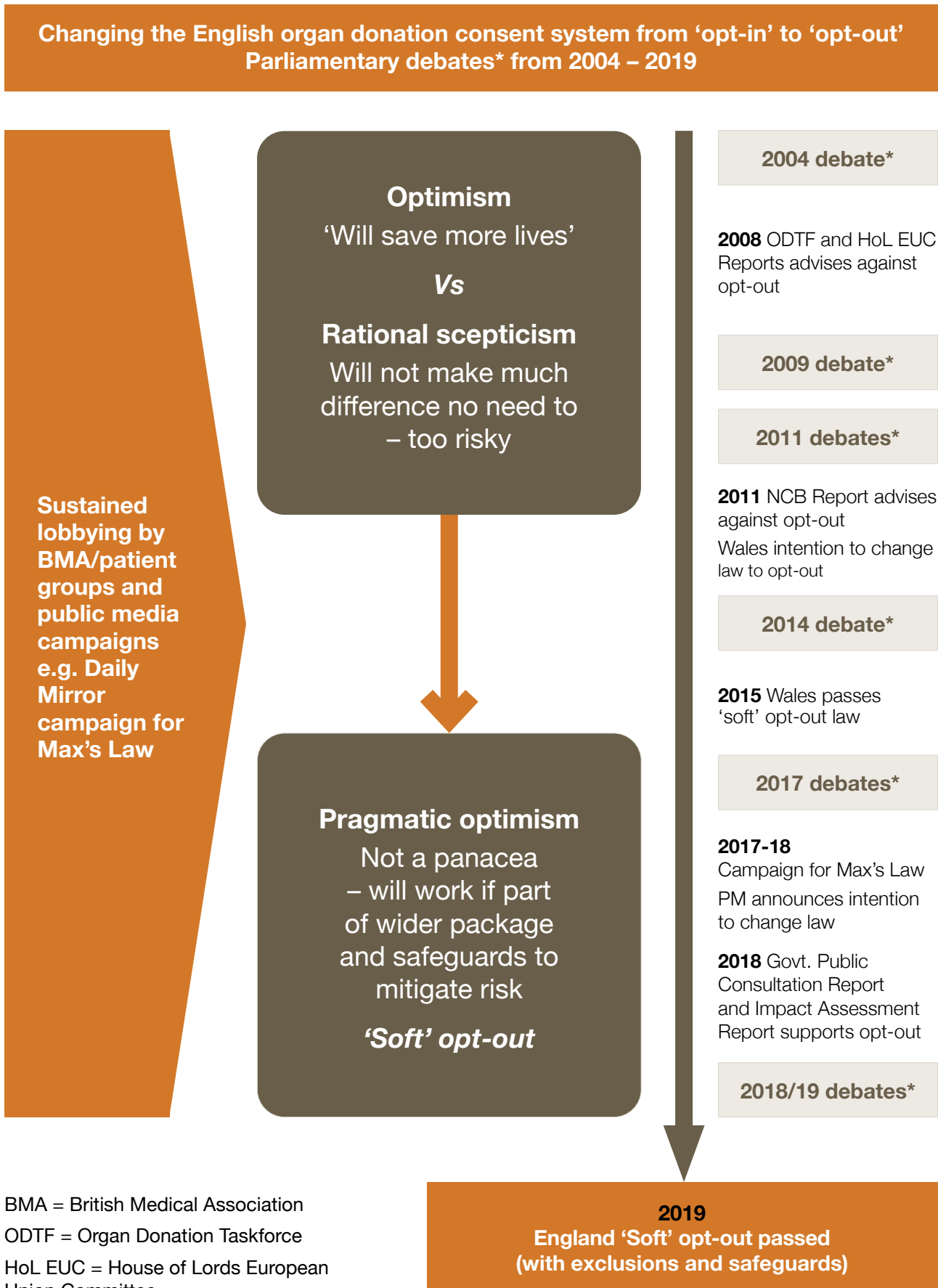
Findings

Three positions were identified among those debating opt-out systems of organ donation:

- 1. Optimism** – that the law change will save more lives;
- 2. Rational scepticism** – changing the law would be unlikely to make much difference to organ donation rates and would be too risky;
- 3. Pragmatic optimism** – agreement that the law change would not be a panacea on its own but would likely help to increase donation with other changes and safeguards.

Though all three positions were present in the debates from 2004 onwards, the first two (optimism and rational scepticism) came to characterise the debates in the lead up to the readings of the Bill in 2017. Thereafter, during meetings and debates in 2018 and 2019, the debate became more marked by those with a 'pragmatic optimist' view. According to this, objections to a change in the law could be accommodated as long as it was made clear that the law would be implemented in its 'soft' form; i.e. family members of the deceased would always be consulted to confirm and support their relative's organ donation decision; donation would not go ahead if the family objected; and other safeguards would be put in place to exclude the deemed option for specific organs and tissues, such as novel transplants, and groups, such as children, non-residents and those lacking capacity to consent. Figure 2 illustrates the three positions and key timelines of Parliamentary debates, significant reports and emerging evidence.

Figure 2: Debate on changing the law to an opt-out system, including an option of presumed consent



BMA = British Medical Association
 ODTF = Organ Donation Taskforce
 HoL EUC = House of Lords European Union Committee
 NCB = Nuffield Council for Bioethics
 PM = Prime Minister Theresa May

Optimism: deemed consent will save more lives

A central theme in the arguments in favour of an option of deemed consent was the belief that this would ‘save people’s lives’ as it would allow more organs to become available. Expressions such as ‘people are dying whilst waiting for an organ to become available’ and ‘demand for organs is outstripping supply’ were repeated regularly among members proposing and supporting a deemed consent option. The sense of duty to do something was strong among these speakers, using emotive language to illustrate their support.

In all debates, members spoke frequently of the evidence of a lack of organs available for donation and of high public support for organ donation – some members citing surveys where, despite up to 90% of people in favour of organ donation – this did not convert into a commensurately high level of willingness to ‘opt-in’ on the public register.[35] It was, as described by one MP, an opportunity for all politicians, from all parties, to work together to save lives:

*“For goodness’ sake, instead of going along as we are... serving the few rather than the many and talking about our various political differences, let us realise that this is an area in which we politicians **can save lives** and lift the burden of anxiety from families waiting for organs.”* (Paul Flynn MP, Westminster Debate on Organ Donation, Nov 2011)

For these parliamentarians, the current system of opt-in was viewed as not working, or not working well enough. It was also noted that similar countries with opt-out laws had better donation rates than the UK.[36, 37] There was a perception that, by moving to an opt-out system, the organ donation pool would increase as it was rationalised that people would be encouraged to actively indicate if they did not want to donate in life by telling their relatives and/or by opting out on the organ donation register. Doing neither would indicate implicit consent to donation.

However, for some parliamentarians, evidence of whether an opt-out system including presumed consent would increase organ donation was viewed as less important than it being the right thing to do. As one MP noted:

*“...logic tells us that, [with deemed consent], it is likely that more organs will be donated. **Even if that was not the case, and even if, as has been said, it made no difference whatever, are we not right to try?**”* (Kevin Brennan MP, Westminster Hall Debate on organ donation 2011)

Throughout debates, particularly during early readings of the Bill, parliamentarians reasoned that opt-out would better reflect the national sentiment, which was supportive of donating organs, signalling the UK as a ‘compassionate society’. Affective reasoning was frequently employed in arguments to support the change in law, such as by giving personal examples of how organ donation could help their constituents. Many of these were stories of the pain and privations individuals (often children and young adults) endure whilst waiting for a suitable donor, and of the benefit of organ donation to the recipient and their family. One Member, in a description of their young constituent’s experience on kidney dialysis, said:

“...this Facebook post hits home: ‘Today 1,608 days with total kidney failure. Today 19,296 hours spent on Dialysis. Today waiting for the precious call, a match has been found’ ...when we think of such children...it is very hard not to support the Bill today?” (Andrea Jenkins MP, House of Commons Second reading of the Bill Feb 2018)

This type of response was common in key debates, such as those on the second reading of the House of Commons Bill in February 2018, whereby members would have had the

opportunity to read Parliamentary briefings [18] and consider the evidence. Large proportions of members (in one reading 17 out of the 42 members speaking) presented examples of their constituents', friends' or family members' need for organ donation as sole statements of their support for the Bill. Many of those in support of deemed consent drew selectively on evidence that best supported their argument, particularly the evidence of opt-out systems working successfully to increase consent and donation in other similar countries. For many, the solution was simple and intuitive; changing the law to an opt-out system as in Wales *"would [likely] add thousands of names to the organ donation register", therefore potentially saving "hundreds of lives"* (Dan Jarvis, House of Commons Third Reading of Bill, Oct 2018), and would also have wide public support.

The lack of time to address the issue was a concern for many, appending their statements with 'we cannot afford to do nothing' as 'people were continuing to die' whilst on the organ donation waiting list. Even those who expressed some reservations, accepting that the evidence was promising but not wholly conclusive, were *"willing to go with an act of faith"* to address the problem (Julian Knight MP, House of Commons Third Reading of Bill 2018), or to forgo personal ethical concerns for the sake of the 'greater good', as expressed in this quotation:

"I'm not entirely comfortable with the principle of the state taking control of bodies without express permission, but I think that option is far less bad than the situation whereby hundreds of lives are unnecessarily lost every year effectively through inertia." (Mike Wood MP, House of Commons Second Reading of Bill, Feb 2008)

Rational scepticism: Law change unlikely to make much difference to rates of organ donation and a potential risk

A rational sceptic is defined as 'one who questions the validity of particular claims of knowledge by employing or calling for statements of fact to prove or disprove claims, as a tool for understanding causality'.^[38] Those arguing from this position focused mainly on two areas: that there was limited and conflicting evidence that this would lead to an increase in deceased donations; and that it could have negative outcomes by harming trust between the public and the medical profession. These arguments were more frequent during earlier debates, for example, those occurring in 2008, 2011 and 2014 – before the Readings of the Organ Donation (Deemed Consent) Bill 2017-19. See Table 2 on the following pages for a summary of the debates in both Houses from 2002-2022.

Table 2 Summary of debates carried out in the House of Commons and Lords relating to organ donation opt-out, including Draft Bills, motions, questions and statements

Date	Title of debate	Venue	Led by	Speakers for opt-out	Total no. speaking	Speakers against	Political party mix	Summary
20/3/2002	Organ Donation (Presumed Consent and Safeguards) First Reading	House of Commons	Tom Watson (Lab)	1	0	0	1 x L	Bill to introduce opt-out (presumed consent) first read in Parliament. Cited three quarters of population willing to donate yet 15% on ODR. Argued for Belgian system with register of non-donors and estimates change in law will increase donation by 20%. Did not make second reading.
3/2/2004	Organ Donation (presumed consent and safeguards) Bill (First Reading)	House of Commons	Siobhain McDonagh (Lab)	1	0	1	1 x L 1 x C	Bill read the First time; and ordered to be read a Second time on Friday 30 April. Withdrawn (reason not provided).
20/11/2008	Organ Donation debate	Westminster Hall	Dawn Primarolo – Minister health (Lab)	1	0	3	2 x L 1 x C 1 x LD	Debate following publication of OD Taskforce report with recommendations – working to improve system – against move to presumed consent at this time.
6/3/2009	Organ Donation (presumed consent) Bill – First reading	House of Commons	Jeremy Browne (LD)	n/a	n/a	n/a	n/a	Bill presented and printed.
13/3/2009	Organ Donation (presumed consent) Bill – Second reading	House of Commons	Jeremy Browne (LD)	4	0	2	3 x LD 2 x C 1 x L	Private members Bill presented by LD Browne – one full argument for (supported by 3 LD and L) and one against – Government response was to continue with current improvements/strategy and wait for evidence of increase in donor rates in 2013. Did not make third reading.
10/10/2011	Question in House on organ donation	House of Commons	Duncan Hames (LD)	n/a	n/a	n/a	3 x C 1 x L 1 x LD 1 x PC	Original question was put about new initiatives to encourage OD. Hywel Williams, Plaid Cymru (PC) asked Ann Milton (Secretary of State (SS) for Health) about plans for opt-out – response was: evidence not there and OD rates improving with current initiatives – minister urged Wales to look at evidence on opt-out before move to change law.

Date	Title of debate	Venue	Led by	Speakers for opt-out	Total no. speaking	Speakers against	Political party mix	Summary
9/11/2011	Debate on organ donation progress	House of Commons	Paul Uppal (Con)	3	5	3	8 x C 2 x LD 1 x L	Debate to address BME issue in OD and concern about numbers on OD wait list and lack of long-term strategy/leadership on OD. Opt-out not being pursued by government – on target to meet 2013 rates for OD (50% increase).
30/11/2011	Organ Donation Debate	Westminster Hall	Glyn Davies (Con)	7	5	3	7 x L 4 x C 2 x LD	Glyn Davies led debate – in response to Welsh Assembly indicating move to opt-out – large number of MPs representing Welsh regions (from L and LD). Government (Ann Milton PUSSH) response to keep under review – no change – urged Welsh Assembly to look more at evidence before voting.
17/6/2014	Organ Donor Register debate	Westminster Hall	Andrew Griffiths (Con)	3	2	2	3 x C 2 x DUP 1 x L 1 x SDLP	Debate on interventions to improve donation – including introducing register to opt-out. PUSSH Jane Ellison (Con) against changing law – to improve operational issues – make it easier to register etc.
17/1/2017	Bill to enable persons in England to withhold consent for organ donation (First Reading)	House of Commons	Paul Flynn (Lab)	1	0	0	1 x L	Bill read the First time; to be read a Second time on Friday 24 March, 2017 and to be printed (Bill 123). Did not reach second reading. Withdrawn due to prorogation and general election.
13/7/2017	Debate to consider introduction of an opt-out system for organ donation in England	House of Commons	Dan Jarvis (Lab)	6	1	2	0	Debate held as still lots on waitlist. Government (PUSSH) still on fence (Jackie Doyle Price) as saw presumed as useful tool but not panacea and concern how medical profession will deal with it. Geoffrey Robinson announced tabling private members bill for deemed consent in July.
19/7/2017	Organ Donation (Deemed Consent) Bill First reading	House of Commons	Geoffrey Robinson (Lab)	n/a	n/a	n/a	n/a	Bill presented to parliament – second reading scheduled for 23/2/18. Robinson announced that there is good cross-party support following during questions to Health Secretary on 10 October.

Date	Title of debate	Venue	Led by	Speakers for opt-out	Total no. speaking	Speakers against	Political party mix	Summary
19/12/2017	Discussion of Organ Donation (Deemed Consent) impact assessment	House of commons	Glyn Davies (Con)	1	3	1	3 x C 1 x L 1 x DUP	Discussed evidence base for decision of impact statement recently published prior to second reading of Bill. Parliamentary Under Secretary of State for Health (PUSSH) (Jackie Doyle-Price) said impact analysis suggests moving towards opt-out, as part of package of support – e.g. wraparound care from SNODs and public awareness campaign) can be associated with higher rates of donation – however further evidence is being requested.
23/2/18	Organ Donation (Deemed Consent) Bill Second reading	House of Commons	Geoffrey Robinson (Lab)	30	10	2	L x 25 C x 15 Ind x 1	Debated Bill – lots of support including some supporting with reservations – Most of fully support from Lab; most of those supporting but reservations from Cons (2).
13/6/2018	An opt-out system of organ and tissue donation. Impact Assessment	n/a	n/a	n/a	n/a	n/a	n/a	The Government’s Chief Scientific Advisor (CSA) advised with moderate certainty, that when introduced as part of a wider communication and logistical package, opt-out systems can be associated with higher donation rates.
11/9/2018	Organ Donation(Deemed Consent) Bill (Money)	House of Commons	Jackie Doyle-Price (PUSSH)	n/a	n/a	n/a	n/a	Jackie Doyle-Price (PUSSH) confirmed government support for Bill and authorised payment of money to support Bill (18 million for public campaign plus £20 billion over 10 years long term commitment for resources to support) Geoffrey Robinson (Lab) thanked House (“sailed through committee in record time”).
12/9/2018	Public Bill Committee on Organ Donation (Deemed Consent) Bill	House of Commons	Geoffrey Robinson (Lab)				5 x L 4 x C 1 x DUP	Very short committee (35 mins) Amendments included to define organs that don’t apply for deemed and requirement to consult family added. Good cross- party agreement – all speakers supporting opt-out.
26/10/2018	Organ Donation (Deemed Consent) Bill Third reading	House of Commons	Dan Jarvis (Lab)	11	5	0	12 x C 4 x L	Third reading – lots of support but significant numbers (all Con) supported with reservations – PUSH (Jackie Doyle-Price) said there is lots of nervousness – and concern about protecting family consent.
23/11/2018	Organ Donation (Deemed Consent) Bill Second reading	House of Lords	Lord Hunt	14	3		9 x C 4 x L 4 x CB 2 x LD	Second reading of Bill in HoL. (First reading 29 October presented by Lord Hunt) Lots of support but a few had reservations and wanted public engagement and awareness as in Wales – some said that it did not change things much as family have to be contacted to support/consent.

Date	Title of debate	Venue	Led by	Speakers for opt-out	Total no. speaking	Speakers against	Political party mix	Summary
26/10/2018	Organ Donation (Deemed Consent) Bill Third reading	House of Commons	Dan Jarvis (Lab)	11	5	0	12 x C 4 x L	Third reading – lots of support but significant numbers (all Con) supported with reservations – PUSSH (Jackie Doyle-Price) said there is lots of nervousness – and concern about protecting family consent.
1/2/2019	Public Bill Committee on Organ Donation (Deemed Consent) Bill	House of Lords	Lord McColl (Con)	7	2			Committee led by McColl who was initially against opt-out for poor evidence of working, money better spent elsewhere, reduces pool of donors and impact on public trust of system. Did not want to block Bill so supported. Aimed to minimise risk by strengthening safeguards/amendments.
26/2/2019	Organ Donation (Deemed Consent) Bill Third reading	House of Lords	Lord Hunt	1	0	0	1 x L	Bill read for third time by Lord Hunt – no further discussion or debate – Bill passed.
18/5/2020	Motion to approve regulations and permitted material	House of Commons	Lord Bethel (PUSSH)	n/a	n/a	n/a	n/a	Lord Bethell (PUSSH) explained draft regulation to Bill first read in July 2017 and became law in March 2019. Has had 3 public consultations – aim to become law May 2020. Would only apply to routine organs for transplant – novel would still require express consent.
May 2021	Question to House about success of law change	House of Commons	Dan Jarvis (Lab)	n/a	n/a	n/a	n/a	Question in House to mark one year since implementation of law change. Question from Dan Jarvis on how successful law change has been in increasing OD. Helen Whately (Minister for Care) said that opt-out system has increased number of organs available and saving ‘hundreds’ of lives (since law change 296 people have donation in England under the opt-out system accounting for 29% of donations that took place last year).
February 2022	Motion on organ donation and transplant strategy	Westminster Hall	Anthony Mangnall (Con)	n/a	n/a	n/a	n/a	30-minute debate on motion. Aim to congratulate Govt. on Bill, to encourage further awareness and education on OD and explore future steps on OD. Said that opt-out successful as more organs available and fewer opting out.

Those arguing against implementing a deemed consent option cited the evidence supplied by the review commissioned in 2008 by the Organ Donation Taskforce [39] which recommended against changing the law on the grounds that the evidence did not wholly support such a change or was conflicting (Figure 1). Members, including Government Ministers summarising organ donation debates prior to 2017, reasoned that the organ donation system changes that had been put into place in response to the Taskforce's recommendations in its first report,[26] such as setting up a dedicated national and regional team to promote and support organ donation, were already having some impact in meeting the 2013 target of a 50% organ donation increase. From this perspective, this group of Parliamentarians argued that any further changes to the system, such as a change in the law, were not necessary, would be expensive to implement, and could even be disruptive, for example, by giving the public the impression that the 'state was taking organs' rather than these being given as a gift. Some argued that this might even reduce the organ donation pool, through more people opting out via the register. Lord McColl, when reflecting on the position in Wales since introducing opt-out, argued that *"over 180,000 people, all of whom were previously potential donors, have now withdrawn and...lost to the system"* meaning that *"It is no longer possible for clinicians to talk to [some] families about donation, when previously they could all have been approached"* (Lord McColl, House of Lords Committee debate, Feb 2019). Improving current organ donation systems generally, as in the Task Force recommendations, was viewed to be the most appropriate way to increase donation rates, and members argued for this in debates, even those who had reservations, by supporting a 'wait and see' approach: *"let's get to 2013 then see where we are"* (Paul Uppal, 9th November 2011).

A concern for some was that the case for change was based on a misconception of how the current opt-in organ donation system worked in practice. The popular, although incorrect perception, leading to, as Members suggested, large public support for a change in the law, was that only those on the Organ Donor Register were approached for donation:

"Many people support presumed consent because they intuitively feel that it must make a difference. Opinion polls show support, and it is not surprising that they do. When people are going around saying that the change to presumed consent will increase the number of organs available, others will automatically say that they are in favour, but the reality is not what they think. There is a misconception that, if a citizen does not put their name on a centralised register, their organs can't be used for transplantation." (Glyn Davies, Westminster Hall Debate, Nov 2011)

Current practice in the opt-in system meant that health practitioners were encouraged to refer all potential candidates for donation, irrespective of their name being on the organ donation register. Thus, it was argued that changing the law would not necessarily change consent protocols and practice, though it might change the conversation with relatives. Here too it was argued that the change in conversation from 'consent' to 'support' risked alienating families. As one MP noted:

"... asking, 'Do you wish to object?' is no easier than asking 'Please may I do this?' but the latter is far kinder and gentler." (David Wilshire MP, House of Commons 2004)

Those arguing from this position stressed the importance of awareness raising (rather than law change), so that people would be encouraged to let their closest relatives and friends know of their organ donation decision so that this could be supported.

The risk of the law change damaging the relationship of trust between clinicians, patients and the public was discussed during all debates. One Minister suggested that this was more important than the potential for opt-out improving donation rates:

"... the Taskforce did not completely write off [deemed] consent. It noted that it 'may deliver real benefits', but the stronger concern, which outweighed that possibility, was that it 'carries a significant risk of making the current situation worse.'" (Dawn Primarolo, Minister of State for Public Health, House of Commons debate Nov 2008)

Pragmatic optimism: law change is on balance worth pursuing, but will not be a panacea, will not work on its own and will need safeguards

Later debates (2018 onwards) a compromise position gained support as arguments on both sides of the debate became more open to a middle of the road position, and a sort of pragmatic consensus emerged. There was acceptance that changing the law to include a deemed consent option, while not a silver bullet on its own, might help address organ donation shortages if implemented as part of a package of measures designed to raise awareness and develop a culture in which organ donation would become the norm. Concerns of potential risks, identified and debated previously, were largely mitigated through a series of suggested safeguards, such as a requirement to include the deceased's family and close friends in any decision making, to ensure adequate staff training and regulations to ensure ethical practice of the medical profession so that public trust was maintained. Creating a culture of acceptance of organ donation was viewed as particularly important:

"... how we can make sure that the Bill is as successful as it can be... making sure that we educate people from a very young age, so that they see organ donation as a positive thing that they want to do... to help other people." (Michelle Donelan, House of Commons Second Reading of Bill 2018)

Evidence of perceived success of the Welsh opt-out system with consent rates continuing to rise following implementation was also deployed in favour of an English law change. The reported public response in Wales, and the fact that there had not been the predicted public backlash, were listed as reasons for supporting the Bill, even among those who had expressed reservations in earlier debates:

"I used to be sceptical about opt-out systems but the proposal in this legislation, which has been demonstrated to work in Wales, strikes the right balance, giving people power and control while making sure that they can make a positive choice if they are well informed." (Lord O'Shaughnessy, House of Lords Committee, Feb 2019)

Some members, concerned about the continued lack of organs to meet demand, framed their support as a step towards creating a compassionate culture where organ donation would become normalised. These Parliamentarians viewed the law change, with its accompanying communication campaigns, as a means to stimulating debate on organ donation and, as one member pointed out, *"will do absolutely no harm"* (Dame Cherry Gillan, House of Commons Second Reading Feb 23, 2018). Others, who in earlier debates had been concerned that this might adversely affect faith groups, particularly those that require 'bodily integrity' after death, softened their concerns and supported the Bill after assurances that any expressed decisions to opt-out would be respected, and that families of the deceased potential donor would always be consulted. One Peer quoted a letter presented by the Parliamentary Under Secretary of State for Mental Health and Suicide Prevention, Jackie Doyle-Price, assuring faith groups that a faith option would be included within the organ donation register which would include the text:

"I would like NHS staff to speak to my family and anyone else appropriate about how organ donation can go ahead in line with my faith or beliefs"; and that "appropriate agencies will engage with faith and minority communities in developing guidance that addresses those concerns." (Baroness Deech, House of Lords Second Reading Nov 2018)

The letter also confirmed that, if family members could not be contacted, donation would not take place (even in cases where the deceased had opted in on the register). However, others questioned whether this commitment should be contained within the legislation rather than in a 'side letter'.

‘Making it work’ coming to a consensus supporting a soft approach

During the various debates, participants began to influence one another over time and identify ways that could conceivably make an opt-out system work alongside the current opt-in system in England, given that both systems needed to operate simultaneously as not all potential donors would meet the eligibility criteria for deemed/presumed consent. Figure 1 and summary of debates (Table 2) illustrate the shift in the dominant Parliamentary narrative. Before the introduction of the 2017 Bill, there had been eleven Parliamentary debates, motions, and questions on changing the organ donation law to an opt-out/deemed consent system for adults who met the eligibility criteria since Tom Watson had introduced his Bill in 2002. These discussions were first introduced to Parliament via a number of Private Members’ Bills and related debates but had remained largely binary, based on conflicting ethics and evidence. Parliamentarians discussed the pros and cons of changing the law to an opt-out system, using rival interpretations of the evidence. Those supporting opt-out would refer to the evidence of higher donation rates in other countries with opt-out laws. Those against, or expressing concerns, would highlight the evidence of other opt-in countries with higher donation rates than England (e.g. the US) and the fact that Spain’s apparent success was not necessarily attributable to its opt-out laws, rather its improved organ donation system. Participants in later debates, from 2017 onwards, described by many as having strong cross-party support, appeared more accepting of the case for the law change. As one commentator noted, they exhibited more ‘reluctant acceptance’ [40] of the principle of the law change for eligible adults and its limitations, for example, agreeing that it would not be a quick fix and would need to be supported by a strong and continuous public awareness campaign, as well as other safeguards.

“... it is absolutely right to say that this Bill, in itself, is not a panacea, but it is an important contribution. It will help start the debate and deliver – in the way that has been shown in Wales – profound changes, we hope, in levels of donation.” (Lord Oates, House of Lords Second Reading, Nov 2018)

Some questioned or refuted interpretations of the evidence of the Organ Donation Taskforce Report, stressing the ambiguity of the term ‘may’ as used in its findings, suggesting that opt-out could have the potential to be effective if implemented alongside other supportive measures. This was further supported by updated evidence reviews and reports, which favoured a soft form of opt-out for England and Scotland.[41-44] Even those who were vocal in their opposition in earlier debates reluctantly accepted the popularity of the Bill within the House, and its likelihood of passing, so, whilst expressing their reservations, did not oppose it, but instead argued for system improvements as part of a reform package alongside law change:

“... we accept fully the head of steam, as it were, behind the Bill and will certainly not oppose it. Nonetheless, we ask that...three very important considerations are taken into account... there should be very good communication...adequate resources should be made available for the implementation of this new system...[and] more effective use should be made of potential donors, in ways highlighted by the transplant pathway. Only then do we believe that the pressing need for more organ donations will be met.” (The Lord Bishop of Carlisle, House of Lords Second Reading, Nov 2018)

Discussions with some of those involved in the Lords debates confirmed that their intention were to make the law change work through providing greater clarity around persons, organs and tissues that fell under the law (and any that were excluded). They relied on advice from the Department of Health officials and lawyers to ensure this *“... so as far as possible, you know, the Bill should be watertight”* (Lord Hunt, meeting to reflect on law change, April 2023).

Interpretations of the successes of the law change

After implementation, Ministers made statements on the impact of the law change, particularly in light of its enactment during a global pandemic. It was initially viewed very positively, as families were seen to be supporting deemed consent. For example, around the first anniversary of the law change, Matt Hancock, the then Secretary of State for Health and Social Care, announced that it was *“already having an impact”* [45] and the Minister for Care announced that the opt-out donation system *“is saving hundreds of lives ... as [deemed consent] accounted for 29% of the 1,021 donations that took place last year.”* (Helen Whately, House of Commons, May 2021). In 2022, similar statistics were presented to the public as a success,[46] despite the fact that many of the deemed consents would have appeared as ‘family consent’ under the previous opt-in system, so were not necessarily a reliable indicator of the impact of the new law. However, in the same year, Ministers began to frame success differently as ‘more people ‘opting in’ on the Organ Donor Register and a ‘less than anticipated’ number opting out’.[47] Overall consent/authorisation rates for deceased donors were, in fact, down from 69% in 2021 to 66% in 2022.[4] This was likely to be why Government Ministers became more cautious, reporting family consent rates as being *“a good figure – much better than where we were – but there is still a lot of room for improvement”* (Maria Caulfield, Parliamentary Under-Secretary of State for Health and Social Care, House of Commons, Feb 2022,[4] also see summary of debates (Table 2).

Discussion

For approximately 15 years (from 2002 until 2017), the issue of whether England should change from an opt-in to an opt-out system of deceased organ donation was debated in a range of Parliamentary fora, until, in 2017, the Government notified its intention to implement a ‘soft’ opt-out system by backing a Private Members’ Bill to make amendments to the Human Tissue Act (2004) in relation to consent. The current analysis has shown that this came about through a gradual shift from more binary arguments in early debates, based principally on conflicting ethics and evidence, to an emerging consensus around what could be termed a position of ‘pragmatic optimism’ in support of a ‘soft’ opt-out system of deceased organ donation consent. This pragmatic position recognised that the law change was only likely to be acceptable and workable in a ‘soft’ form: that is, by continuing to involve families of the deceased in any organ donation decisions, and by minimising potential risks by excluding certain groups and ‘novel’ organs, where family consent would still be required. The change was not seen by its supporters as a panacea but would need to be underpinned by a package of measures, especially greater publicity. It was also understood that the law change would likely take some time to have effect.

A number of external factors can be identified that help to explain this shift among Parliamentarians, notably: the example presented by Wales’s decision to move to ‘soft’ opt-out (despite it being difficult to interpret trends in the Welsh data due to small numbers); and public and media support for the principle of default opt-in.

The knowledge that Wales was intending to implement its own opt-out law change from 2011 was a key factor in shifting the debate in England (and other UK countries) towards considering the same. The apparent increase in organ donation consent rates in Wales after the law change was referenced by the English media and in Parliamentary debates in 2017, despite small numbers limiting interpretability and the absence of any sign of an increase in organ donation or transplant rates (an example of framing effect bias, see below). In addition, public support for the law change in Wales remained high, and there was no public backlash, a reassurance to those concerned about this anticipated risk.

Public and media support for the change in law was clearly highly influential with Parliamentarians. Faherty and colleagues, in their recent analysis of English media portrayal of organ donation at the time, found that most popular press coverage, namely online content of UK national and local newspapers and specialist publications, were supportive of organ donation and of changing the law, emotively portraying organ donors and recipients as superheroes worthy of full public support.[48] There was a clear shift in Government rhetoric and activity following the Mirror Group's campaign for opt-out, framing the debate as 'saving Max's life', even though deemed consent would not apply to children under 18. The Daily Mirror, a popular UK tabloid newspaper, claimed the law change, named 'Max and Kieras law' after the child recipient and donor, as its own victory,[31] winning awards for its efforts, and inspiring other UK countries to follow suit. For example, Northern Ireland named their opt-out law as Dáithí's Law, after a five-year-old child on a heart transplant waiting list. The attendance of both Max's and Kiera's family at significant Parliamentary debates on both the second and third readings of the Bill in the Commons and Lords, may have introduced additional pressure on sceptical Parliamentarians not to speak against the Bill, due to the sensitivities of those present.

It is also clear that participants in debates were more likely to accept and deploy evidence that supported their general position and to refute evidence that contradicted it. There were clear signs of confirmation bias in the debates, especially among those arguing in favour of the opt-out. There was little or no dispute among participants on the evidence of the need for more organs; all agreed that donation rates were not rising fast enough to meet demand. The differences lay in how a greater number of organs could be achieved, with some arguing for the continuation of measures aimed at strengthening the donation system and raising public awareness (the 'wait and see' approach that prevailed until 2014) and others supporting a change to the law on consent. The 'pragmatic optimistic' position that emerged later was an amalgam of the two.

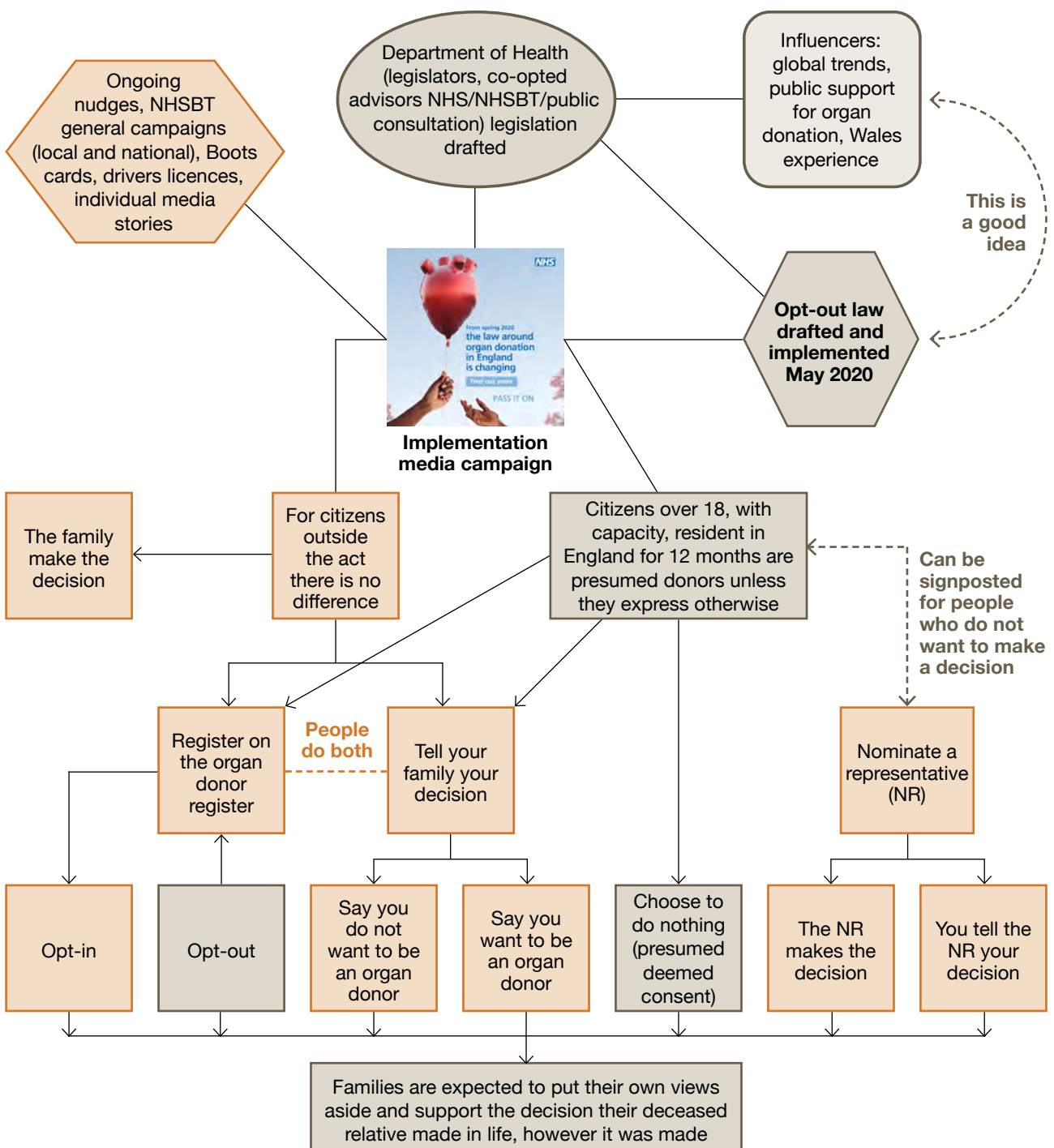
The debates also display evidence of framing effect bias.[49] This is when decisions are influenced by the way the information is presented, or framed, in a positive or negative way, leading to an emotional response. Glyn Davies, MP, (among others) pointed this out during one of the early debates in November 2011, arguing that people would intuitively be more likely support the option of deemed consent if it was presented simply as being about 'saving more lives.' Similarly, later debates consisted largely of members expressing their support for organ donation per se (largely equating supporting organ donation in general as automatically supporting the law change), with very little discussion of the likely effectiveness of changing the law or of any possible negative effects. This is evident in statements of those leading the debates and from Ministers commenting and summing up.

Another rather different explanation for the law change relates to an occupational bias among Parliamentarians in favour of using legislation to solve problems, since they are familiar with, and can control legislative change. Those arguing strongly for the law change recounted their experiences of organ donation, as either advocates for their constituents or others on waiting lists for transplants or having personal experiences of donation or transplant. This was particularly noticeable in supporting statements in both Houses on second readings of the Deemed Consent Bill where members declared their involvement with patient groups, especially groups benefitting from more deceased organ availability, and/or individuals lobbying for law change. The evidence presented in support favoured other countries who had better donation rates on the assumption that these were the result of opt-out systems, highlighting the level of public support for change.

There was also some misconception and misinterpretation of what was proposed in the Bill and the evidence to support it which may have contributed to the votes in favour of changing the law. Some Parliamentarians alluded to this by reminding their colleagues that not all deceased organs were obtained from those on the opt-in register, pointing out that a wider group of families of potential donors were already approached under the opt-in system. Another

misconception shown by some participants and potentially influential was the framing of the law change as a complete shift from an opt-in system to an opt-out system, thereby ignoring the fact that, in practice, the law change would provide an additional deemed consent pathway, alongside other previous consent processes. This was encouraged by the title of the Bill which included ‘deemed consent’. This may well have contributed to the incorrect impression that there would be a single route to deceased donation with opt-out replacing opt-in. In reality, the 2019 Act introduced a dual ‘opt-in and opt-out’ system in which family members would have a potential veto whichever route was involved. Thus, instead of making the system easier to navigate, it probably made it more complex for those requesting and taking consent. Figure 3 illustrates the consent pathways after the law change, showing deemed consent, in grey, as one of seven potential pathways.

Figure 3: Illustration of organ donation consent pathways in England



One could argue that these specifics were not necessarily intended for debate as there had been Government led consultation with stakeholders before the main legislative debate, as well as assessment of any impact the law change would have on the donation system as a whole. Parliamentarians were therefore deliberating primarily on the principle and ethics of England moving towards a system whereby deemed consent for deceased organ donation would become the default position for adults who had not indicated otherwise. The perceived ‘successes’ of recent opt-out systems such as that in Wales, in terms of numbers of consents deemed, clearly influenced the debates but were not fully interrogated. For example, there was no counterfactual evidence available to show whether family members would be more likely to consent in a system of deemed consent than in an opt-in system.

There was, especially in later debates, some greater recognition of the imperfect nature of the empirical evidence supporting an opt-out system but members were still able to rationalise their support for changing the law as something that they ‘couldn’t afford not to do’ as people were dying on waiting lists – it ‘being right to try’; and something they, as Parliamentarians, could do now in the belief that it would, in time, be helpful. Action bias, a tendency favour action over inaction (including legislating), even without sufficient reasoning in support, may have been a factor. This bias towards intervening was also likely to have been bolstered by the ‘high confidence’ with which the Government’s Chief Scientific Advisor presented his judgement in the official Impact Assessment [44] that the law change, in any event, would not reduce organ donation rates.

In his analysis focused on the extent to which the law change was evidence-based, medical ethicist Parsons reaches similar broad conclusions to the current analysis, arguing that, in his view, whilst the law change can be seen as ethically defensible from a logical perspective – in that moving to a default position of deemed consent would best reflect the in-principle attitude of the majority of the population – there was not enough good evidence of likely benefit to support the law change.[50] Our findings support Parsons’s high-level thesis but illustrate the nuances involved in the debates. While there was highly imperfect evidence throughout, it was interpreted and deployed differently over time. This was accompanied by some misconceptions and cognitive biases which mainly worked in favour of the law change. The identification of safeguards associated with a ‘soft’ opt-out helped alleviate the concerns of sceptics sufficiently to enable the Bill to pass on the grounds that it could do no harm and might conceivably be beneficial.

Conclusion

The above analysis of Parliamentary debates has revealed the shift from a dominant position, which gave primacy to the evidence of likely effects, towards a more normative position in which the deemed consent option was viewed as the ‘correct thing to do’, and the limited and conflicting evidence viewed in a generally positive light. By 2017, the balance of opinion had shifted towards a system where consent to donate organs would become the default position for most adults, leading to little opposition and large cross-party support for the change in law. There are a number of reasons why this shift took place despite imperfect evidence of likely benefit in terms of increasing consent rates, and considerable scepticism from medical experts. At one level, it was to ensure that the law better reflected popular opinion: that most people would be happy to donate their organs after death. This was amplified by UK media rhetoric. On another level, it was to demonstrate a response to the pressing need for more organs for donation, and therefore reflected an underlying belief that it would somehow save more lives, even though the evidence for this was always unclear. Much weight was given to perceived ‘successful’ opt-out countries such as Spain, signalling a degree of cognitive bias and confusion between correlation and causation. The argument that the law change ‘would not make the situation worse’, thereby being a quick win and

'good news story', with minimal risk if implemented as a 'soft' 'opt-out' appeared to be influential in gradually growing support for change among Parliamentarians. For those initially opposed to the law change because of insufficient evidence of its likelihood of increasing consent and donation rates, this indicated a shift to a position of reluctant or pragmatic acceptance. Others were more hopeful, viewing the law change as one step towards creating a more positive culture towards donation.

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4

Analysis of content and online public responses to medial articles that raise awareness of the opt-out system of consent to organ donation

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Summary

Background

Preceded by a national media campaign, in May 2020, England switched to a ‘soft’ opt-out system of organ donation which rests on the assumption that individuals meeting specific criteria have consented to organ donation unless they have expressed otherwise. We aimed to learn more about how the changes were communicated, how people responded and any discrepancies between key messages and how they were interpreted by the public.

Methods

Summative content analysis of 286 stories and related reader-generated comments in leading UK online news sources (April 2019 to May 2021). Further detailed thematic analysis of 21 articles with reader-generated content, complemented by thematic content analysis coding of all 286 stories.

Results

Most media coverage on both organ donation and the law change was positive, with little variation over time or between publications. The importance of organ donation, benefits of the law change, and emotive stories (often involving children) of those who had donated an organ described as “superheroes” or those who had received organs as benefiting from a “miracle” were frequently cited. In contrast, reader-generated comments were markedly more negative, for example, focusing on loss of individual freedom and lack of trust in the organ donation system. Commentators wished to be able to choose who their organs were donated to, were dismissive and blaming towards minority ethnic groups, including undermining legitimate worries about the compatibility of organ donation with religious beliefs and end of life cultural norms, understanding and acceptance of brain-stem death and systemic racism. Misinformation including use of inflammatory language was common.

Conclusion

The portrayal of donors and recipients as extraordinary is unlikely to help to normalise organ donation. Undermining legitimate concerns, in particular those from ethnic minorities, can alienate and encourage harmful misinformation in underrepresented groups. The

discrepancies between the tone of the articles and the readers comments suggests a lack of trust across the public, health, policy and media outlets. Easily accessible, ongoing and tailored sources are needed to mitigate misinformation and disinformation and ensure key messages are better understood and accepted in order to realise the ambitions of ‘soft’ opt-out organ donation policies.

Aim and objectives

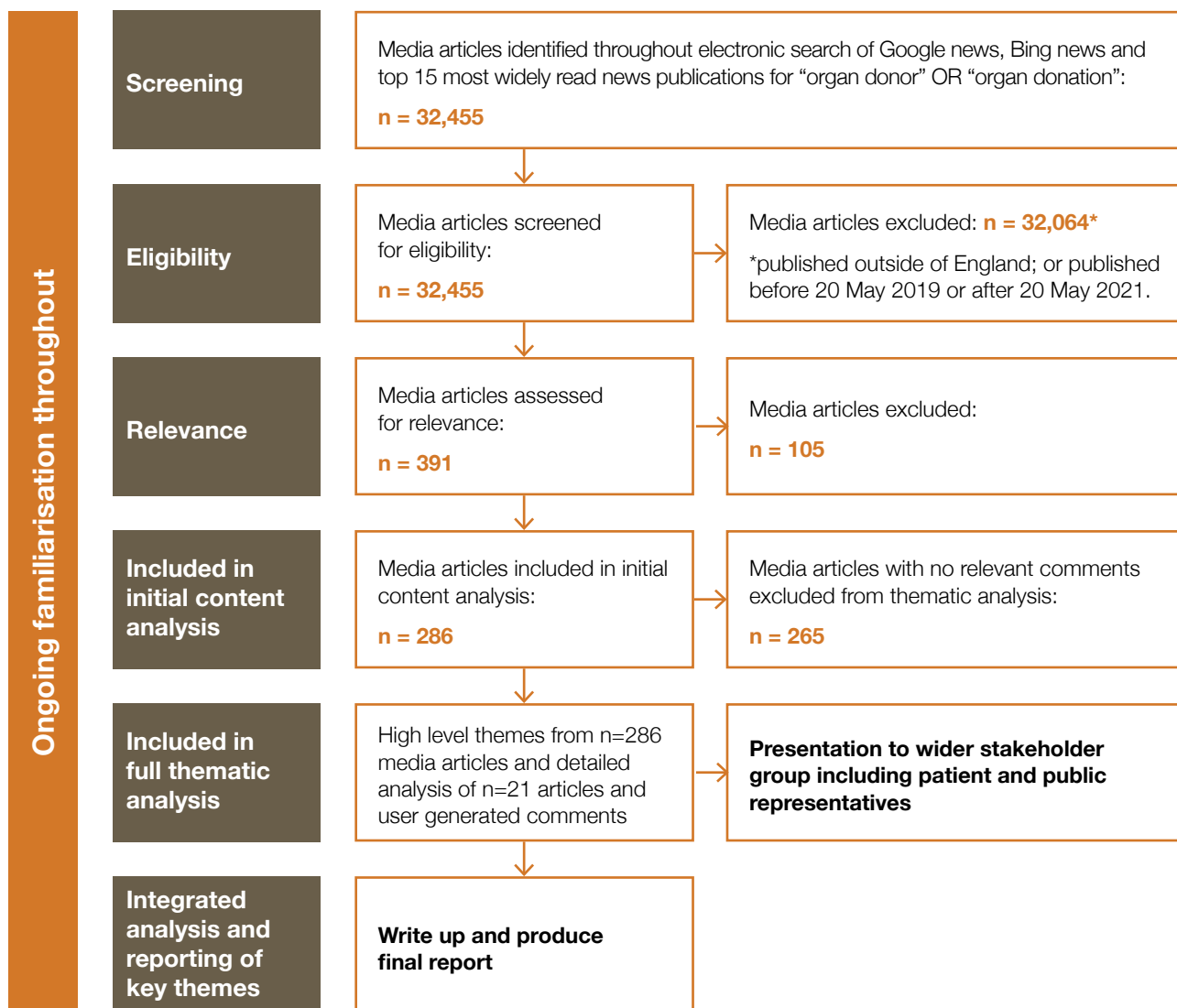
To undertake an analysis of media articles and associated online public responses about organ donation and the ‘soft’ opt-out system of organ donation in the year leading up to the change and one year afterwards (20 May 2019 to 20 May 2021) in order to explore:

- How the law change was communicated by news media; including whether the tone was positive, neutral, or negative, how the change was framed, whether the reporting was accurate, and whether there were differences between publications, or over time;
- How the public responded; whether the change was well understood, whether reactions were positive, neutral or negative, and whether there were differences between readers of different publications, or over time;
- Any differences in how issues relating to organ donation were presented by policy makers, communicated by the media, and discussed by readers; and the possible implications of this for the relationship between these groups;
- Other themes relating to public understanding and attitudes to the change to a “soft’ opt-out system; including how these may have been affected by the COVID-19 pandemic.

Methods

We used Powell and van Velthoven’s (2020) guidance on collecting and analysing digital data.[21] Two methods of analysis were used – summative content analysis (Hsieh and Shannon, 2005) and thematic analysis (Braun and Clarke 2006).[22, 23] The stages are presented in Figure 1 and described in further detail below.

Figure 1: Study flow diagram



Search strategy

A purposive sampling approach was used to identify news media articles and reader-generated comments available online that referred to organ donation and were published between 20 May 2019 and 20 May 2021. Media sources were identified according to their reach and readership. Google news, Bing news and 15 individual news websites with the highest levels of readership in England (Appendix 3.1) were searched for the terms “organ donor” OR “organ donation”. The initial search returned 32,455 results. After the exclusion of articles which did not meet the inclusion criteria and duplicate articles, 286 remained.

Inclusion and exclusion criteria

Articles were excluded from initial summative content analysis if they did not meet the following inclusion criteria:

- Published between 20 May 2019 and 20 May 2021. These dates were chosen to include coverage for one year before the law change, and one year after its implementation. The dates also align closely with NHSBTs media campaign, ‘Pass it on’, which was launched on 25 April 2019.
- Published by news media organisations based in England and aimed at an English audience.
- Contained relevant subject matter relating to deceased organ donation and/or the change in the law in England.

Data analysis

Once all relevant articles that met the inclusion criteria were identified, pdf copies were obtained and downloaded, and then imported into NVivo software (v12) for further analysis.[24] Articles were labelled by the date and newspaper of publication. As the articles were downloaded and imported, they were read again to ensure the article was relevant, to become more familiar with the content, and to make initial observations.

Summative content analysis

Initial summative content analysis was undertaken for all 286 articles including the 21 articles which had accompanying reader-generated comments (Table 1).[22] Each article and any relevant reader-generated comments were reviewed and coded according to whether their tone was interpreted by the researcher as positive, neutral, or negative in relation to organ donation, and separately whether the tone was interpreted as positive, neutral, or negative in relation to the law change. In order to ensure reliability of interpretation, a second researcher reviewed a purposive sample of 10 articles representing discussions about organ donation, the law change, from a variety of sources and with markedly different headlines and content and were initially coded as positive, negative or neutral, to check for agreement and consistency in the approach to coding. There was 100% agreement between researchers about the tone of articles and the emerging themes, demonstrating strong inter-rater reliability. The number of positive, negative and neutral articles and comments were then summarised and analysed to determine any patterns such as: changes in tone over time; differences between the tone of articles and that of reader-generated comments; and differences between the tone of reporting in different publications.

Assessing article influence

In order to account for the different influence of diverse publications on the public, two measures were used. First, the annual number of views for each news website was obtained from Similarweb to determine how many times each website was visited over the last year. Second, an engagement score was obtained from Alexa Analytics, which is defined as total engagement (number of Twitter retweets, Twitter replies, Twitter likes, Reddit comments and Reddit votes) divided by the total number of articles published.[25, 26] This can help to determine which sites have a highly engaged audience who are sharing or engaging with content. Both measures have limitations: the annual number of views includes views from people outside the UK, and is a measure of total views, rather than unique visitors. The engagement score does not include engagement via social media sites such as Facebook, or Instagram, and does not include comments directly posted to news websites. Both measures were therefore used independently to provide separate adjustments for influence in the summative content analysis.

Thematic analysis

At the end of the summative content analysis, the researcher was familiar with the entire dataset of 286 articles and their content. This familiarity enabled notes and memos to be made on emerging patterns and themes across the entire dataset. This information was then used to support the generation of initial codes and themes for a more detailed thematic analysis of the 21 articles with associated reader-generated comments. These 21 articles with relevant reader-generated comments were read again and where appropriate annotated and coded using NVivo. Additional codes were added as the inductive analysis progressed (Appendix 3.3). Codes were subsequently grouped and combined to create broader themes, reflecting patterns and ideas within the data. NVivo software automatically grouped together extracts of media articles with the same code, and a thematic map (Appendix 3.4) was created in order to visualise this. Themes were further defined and refined and complemented by coding from the previously undertaken content analysis of all 286 articles to understand the key ideas which underpinned them. Analysis was undertaken for each individual theme to identify what was being communicated by the news media and reader-generated content. Names for each theme were then finalised and articles were reviewed again to identify appropriate extracts for inclusion.

Integrating themes with key findings from the summative content analysis

Where relevant, we juxtaposed relevant key findings from the summative content analysis alongside the thematic analysis to develop an overall interpretation.

Reflexivity, reliability and rigour

The first author had no prior experience of research on organ donation but had expertise in public health and mixed-methods analysis. The other five co-authors had expertise in organ donation, health systems and services, public health and policy research and qualitative data analysis, thus bringing different perspectives to the analysis. Co-authors made transparent their positioning and any potential biases. A protocol was developed that included a high level of systematic processing. Decisions were discussed and agreed. Data and emerging findings were shared and discussed among the authors and presented to patient and public representatives who provided additional perspectives and input into the analysis.

Findings

Summative content analysis: media stories

Of the 286 articles analysed, 240 (85%) had a positive tone in relation to organ donation, 25 (9%) were neutral, and 18 (6%) were negative. When articles were weighted based on the annual number of online views for the publication or based on engagement score, the proportion with a positive tone increased (Table 1).

One hundred and fifty-five (54%) of the 286 articles mentioned the law change to a ‘soft’ opt-out system. Of these 119 (76%) had a positive tone in relation to the change in law, 29 (19%) were neutral, and 7 (5%) were negative. When articles were weighted according to online views, or according to engagement score, the proportion with a positive tone also increased (Table 1). Further detail of all media articles identified, and their tone is available in Table 2.

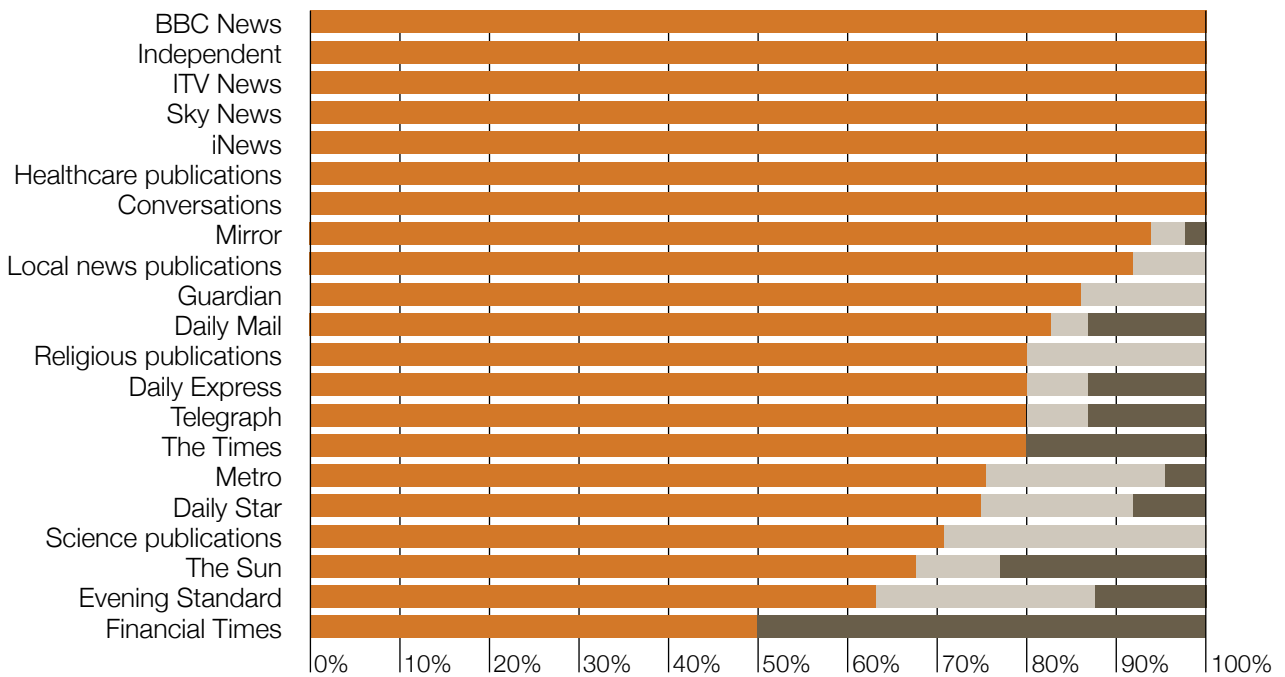
Table 1 Summary of content analysis of all media articles & reader-generated comments

Summary of content analysis of all media articles			
Tone	Organ donation	After adjustment for annual views	After adjustment for engagement score
Positive	85%	91%	88%
Neutral	9%	4%	6%
Negative	6%	5%	6%
Law change			
Positive	76%	84%	79%
Neutral	19%	12%	14%
Negative	5%	4%	7%
Summary of content analysis of all reader-generated comments			
Tone	Organ donation	After adjustment for annual views	After adjustment for engagement score
Positive	61%	57%	61%
Neutral	3%	3%	3%
Negative	36%	40%	36%
Law change			
Positive	34%	27%	33%
Neutral	1%	1%	1%
Negative	65%	72%	66%

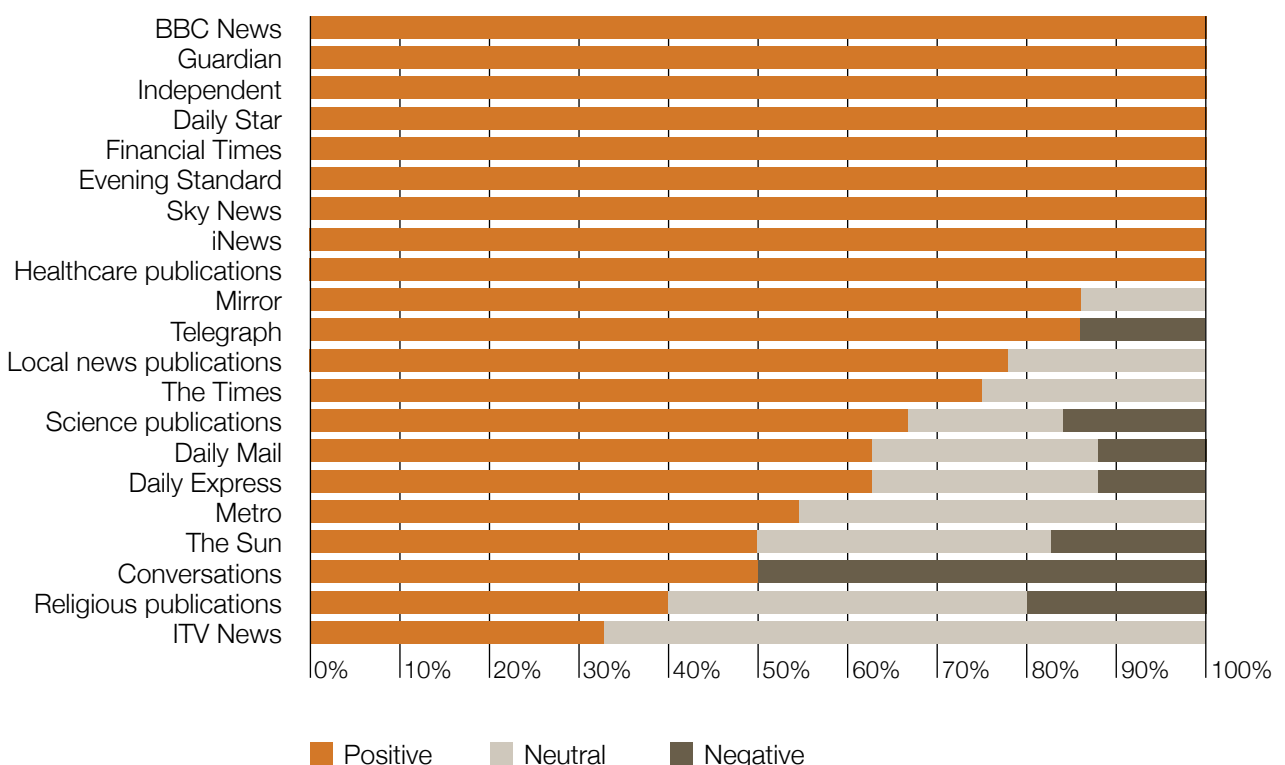
A comparison of the tone of articles by publication found some variation, particularly in relation to the law change. All articles published by BBC news, The Guardian, The Independent, Daily Star, Financial Times, Evening Standard, Sky News, iNews and healthcare-related publications conveyed a positive tone in relation to the law change, compared to less than half of articles by religious publications and ITV news. Figure 2 shows variation in the tone of articles by publication.

Figure 2 Organ donation and law change sentiment by publication

Organ donation sentiment by publication



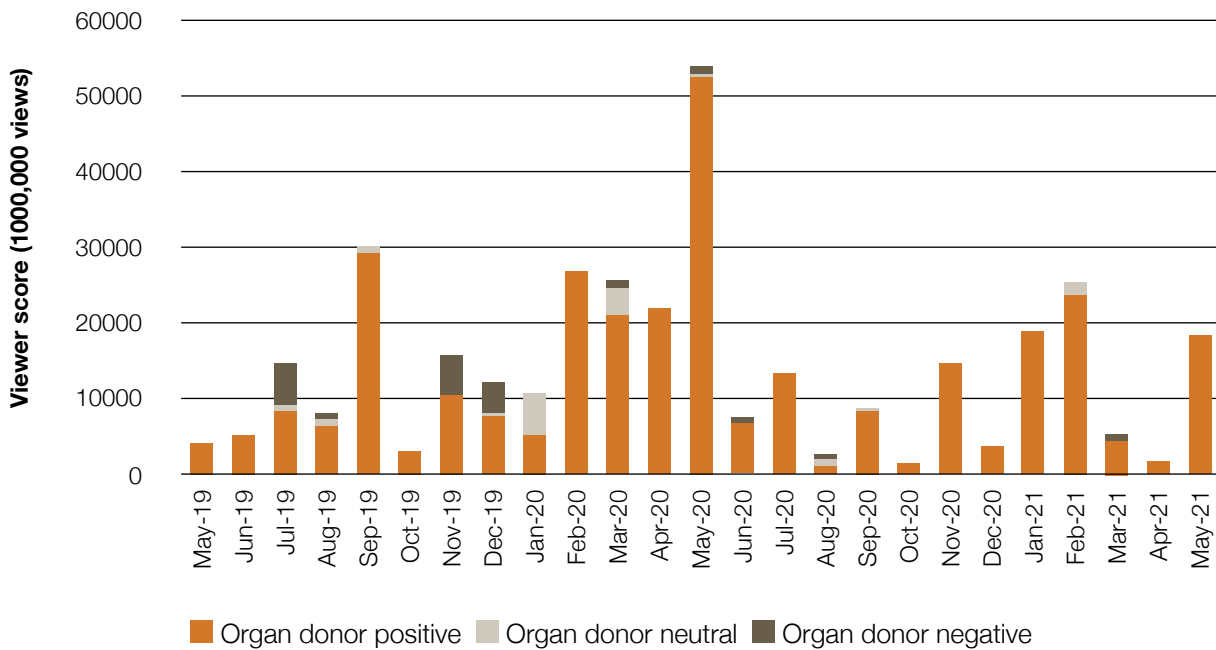
Law change sentiment by publication



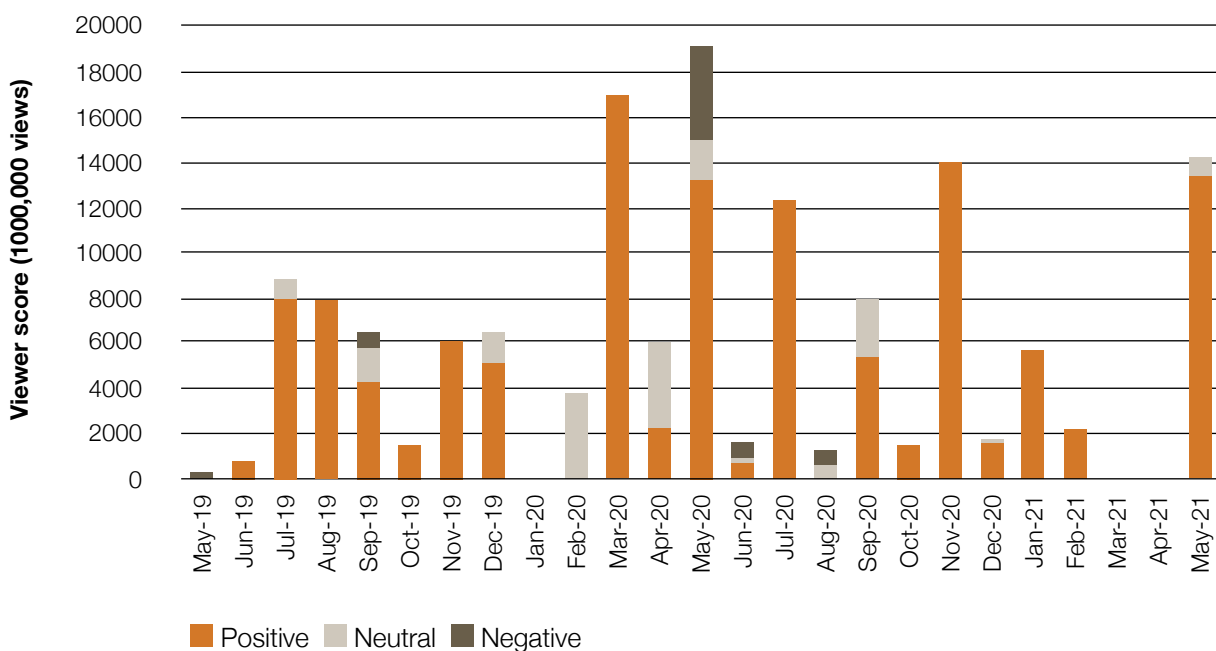
The proportion of positive, neutral and negative stories remained fairly consistent, both in relation to organ donation and in relation to the law change over the period of analysis (20 May 2019 to 20 May 2021). Figure 3 shows the variation in the quantity and tone of articles over time.

Figure 3. Organ donation and law change sentiment over time weighted by annual views

Organ donation sentiment over time weighted by annual views



Law change sentiment over time weighted by annual views

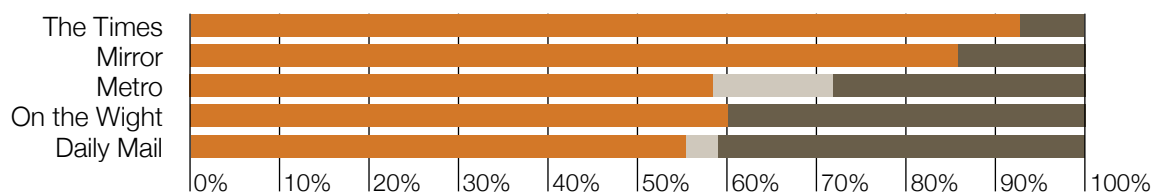


Summative content analysis: reader-generated comments

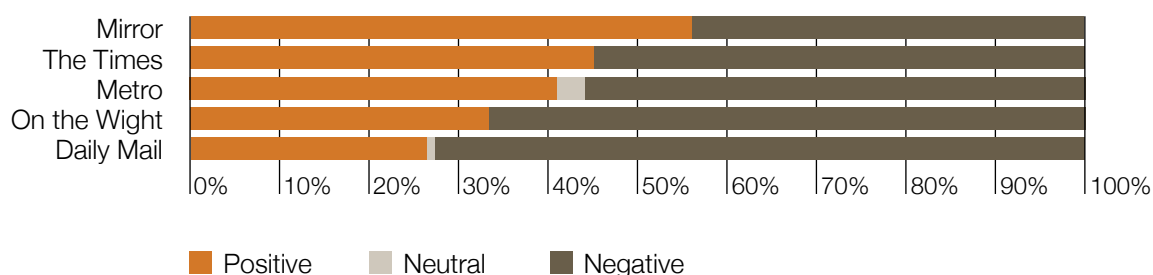
Twenty-one of the 286 articles were accompanied by relevant reader-generated comments. In relation to organ donation, 189 (61%) comments had a positive tone, 10 (3%) were neutral while 110 (36%) were negative (Figure 4).

Figure 4 Tone of reader-generated comments – organ donation and law change

Tone of reader-generated comments – organ donation



Tone of reader-generated comments – law change



These proportions were unchanged when adjusting for engagement score. When comments were adjusted for average number of views per publication, 57% had a positive tone in relation to organ donation, 3% were neutral, and 40% were negative. Three hundred and twenty-one of the relevant reader-generated comments mentioned or referred to the law change. Of these, 109 (34%) had a positive tone in relation to the law change, 3 (1%) were neutral, and 209 (65%) were negative. When comments were adjusted for annual views per publication and engagement score, the proportion with a positive tone fell, suggesting comments accompanying the most influential publications were more negative (Table 2). Further details of all reader-generated comments identified, and their tone is available in Appendix 3.2.

Table 2 Content analysis of reader-generated comments by publication

	Daily Mail	Metro	On the Wight	The Times	The Mirror	Total
Organ donation tone						
Positive	56%	59%	60%	93%	86%	61%
Neutral	3%	13%	0%	0%	0%	3%
Negative	41%	28%	40%	7%	14%	36%
Law change tone						
Positive	26%	41%	33%	45%	56%	34%
Neutral	1%	2%	0%	0%	0%	1%
Negative	73%	57%	67%	55%	44%	65%

The proportion of positive and negative comments varied depending on the publication. Of comments published by the Times, 93% were positive in relation to organ donation, and 7% were negative, while only 56% of comments published by the Daily Mail were positive in relation to organ donation, and 41% were negative. Similarly, of comments published in relation to the change in law, 56% were positive and 44% were negative in The Mirror, while in the Daily Mail, only 26% were positive and 73% were negative (Table 2).

Thematic analysis (complemented by coded data from the content analysis)

Six themes were developed from the data:

1. The importance of organ donation for recipients and donor families;
2. Inequalities;
3. The quality of organs which become available;
4. An NHS under pressure;
5. ‘Scientists playing God’; and
6. Tensions between the rights of individuals and those of the state.

Theme 1. The importance of organ donation for recipients and donor families

The majority of media stories emphasised the importance of deceased organ donation, both for recipients and for families of donors. At least 115/286 (40%) of articles featured personal stories about people who were waiting for, or who had received, an organ transplant. These stories were typically highly emotive. They almost exclusively featured babies, children, young people or parents of young children. Media stories typically emphasised the rare or unusual circumstances of both donors and recipients, describing the death of a donor as a “freak” or “tragic” accident (The Sun, 27 July 2019), while potential recipients were described as suffering from “rare” and often “genetic” conditions (The Mirror, 30 Dec 2019). In addition, emotive language was inserted throughout the stories, describing circumstances as “heart breaking” (Guardian, 29 June 2019), and families waiting for organs as “desperate” (Mirror, 14 Sep 2019). Organ donation was also frequently described as a “miracle” (Manchester Evening News, 04 June 2020), while organ donors and their families were depicted as “brave”, “selfless”, and “heroic” (The Guardian, 13 Nov 2019).

Reader-generated comments in response

Reader-generated comments on the whole supported the sentiments described in the media stories but there was more emphasis on, and preference for, choice in terms of who organs were donated to, as seen in this comment:

“I am happy for them to have mine but...I would like a say in who has them. I would be against say [my] liver going to an alcoholic or lungs going to a smoker and would rather somebody with an illness which isn't self-inflicted gets them.” (Disillusioned me, Daily Mail, 2020)

Integrated analysis of this theme

These stories emphasised the potential for organ donation to save and improve quality of life, and to provide pride and comfort for the families of deceased relatives. By focusing on children and young people, as well as those with rare or genetic conditions, such articles could inadvertently create a dichotomy between those who are considered to “deserve” an organ (children, suffering from a rare genetic condition that cannot be prevented), and those who do not (older people with chronic conditions, which may be exacerbated by behaviours such as drinking alcohol or smoking).

In addition, by characterising those who donate organs as “superheroes”, and the process of organ donation itself as a “miracle”, organ donors and organ donation were presented as exceptional or unusual and often glamorised.

While emphasising the benefits of organ donation for both donor families and recipients is helpful in framing organ donation as a positive act, the volume of media stories which

emphasised the extraordinary qualities of both donor families and recipients did not necessarily contribute to normalising organ donation and may support a more divisive narrative framed in terms of “deserving” and “undeserving” recipients of organs.

Theme 2. Inequalities

38/286 (13%) articles mentioned the disparity in rates of organ donation between different ethnic groups, highlighting both that people from minority ethnic communities are more likely to need an organ, and that there are fewer minority ethnic organ donors, resulting in poorer outcomes for people from minority ethnic communities. The impact of social and cultural norms was highlighted as a key contributor to this.

“Ashley Asomani, 39, known as Ace, the BBC Radio 1 XTRA DJ, is waiting for a kidney and said that his mother, who is of Ghanaian heritage, told him as a teenager “we don’t do” organ donation... He said the topic was “really taboo” in his family.” (The Times, 11 Sep 2020)

Religion was also cited as a factor contributing to inequalities by several media publications, although the Metro (13 Sep 2020), Daily Mail (02 Jan 2021) and Religion News (10 Feb 2020), attempted to counter the narrative that religious beliefs were a barrier to organ donation by providing examples of religions or religious leaders that permitted and endorsed organ donation.

“On our website you can see references from well-respected Islamic scholars from Egypt to Singapore, and from USA to the Netherlands, all of which say that organ donation in Islam is allowed. In 2019 a fatwa was even written in the UK by an Imam with 20+ years as a hospital chaplain, which states that organ donation is permissible.” (Metro, 13 Sep 2020)

“Some believe, wrongly, that their religion expressly forbids organ donation.” (Daily Mail, 02 Jan 2021)

“For the Sikh community, the concept of seva or selfless service is a fundamental principle of the faith... our fundamental faith encourages us to spend all our life becoming detached from our body... in our faith, once you’ve left your body, it’s just an empty vessel that’s going to decay in the ground or be cremated.” (Religion News, 10 Feb 2020)

Similarly, the Jewish Chronicle ran with a headline in May 2020 that the Chief Rabbi backs new organ donation system in England, and many news stories over the period emphasised that religious beliefs would be taken into account when decisions about organ donations were made.

Reader-generated comments in response

The reader-generated comments that accompanied such articles sometimes directed blame towards minority ethnic communities for longer waits and poorer outcomes, dismissed the concerns of minority ethnic groups and individuals as “superstitious”, and emphasised the concept of reciprocity:

“It has been understood that the [Black, Asian and Minority Ethnic] BAME do not act as donors generally. This is possibly due to religion or other superstition, unfortunately.” (Bolter, Daily Mail, 2020)

“Things should change within the BAME community. If anyone is willing to accept an organ then they must be willing to donate theirs; or not accept a donation, ever.” (Overlaxed, Daily Mail, 2020)

Media responses to the shortage of minority ethnic donors, and reader-generated comments also highlighted misinformation about organ donation and lack of trust in information, in the government, and in the healthcare system both in the UK and supposed country of origin.

Structural racism was described as an important factor in eroding trust and generating fear, which in turn appeared to contribute to a greater proportion of people from minority ethnic communities deciding to opt-out and declining deceased organ donation:

“Misinformation abounds and individuals from communities with reason to feel vulnerable enough already from unconscious bias within healthcare and institutional racism feel they have to take extraordinary measures to protect themselves.” (Ekd, The Times, 2020)

“Older South Asians often have hesitations and questions about the prospect of donation: Will the nurses look after me if I’m ill and dying, or will they just be interested in getting my organs?... Many immigrants from India, familiar with corruption in the medical system and stories of organ donation and trafficking there, also fear organ donation in Britain.” (Religion news, 2020)

Integrated analysis of this theme

The volume and nature of the coverage in relation to inequalities and organ donation helped raise the profile of the gap in organ transplant availability and health outcomes and acted as a call to action for people from minority ethnic communities to discuss organ donation and consider donating their organs. The coverage was wide-ranging and mostly nuanced, emphasising not only the impact of religious beliefs and cultural norms, but also the role of misinformation, lack of trust and systemic racism, although some media stories and comments potentially exacerbated the situation by blaming minority ethnic communities and dismissing their concerns.

Theme 3. The quality of organs which become available

32/286 (11%) media stories referenced the impact of age or health conditions (including obesity and COVID-19) on the quality of available organs. In most instances, these issues were mentioned briefly and sensitively, and were discussed as part of a wider picture of organ donation and transplant rates. However, there were some notable examples where the quality of available organs was presented in a more sensationalist way, such as:

People dying fatter and older is ‘reducing the numbers of useable donated organs’ as NHS reveals one in SIX body parts now get rejected by doctors, (Daily Mail, 18 July 2019).

New figures reveal one in five organ transplants come from drug users, (Daily Mail and Daily Express, 07th & 10th July 2019).

Woman died of HIV from donor’s kidney, (The Times, 10 July 2019).

Woman dies after receiving ‘double lung transplant from donor with COVID-19’, report finds, (The Evening Standard, 24 Feb 2021).

One NHS patient died, and another left seriously ill after receiving infected donor organs, (The Sun, 21 Nov 2019).

Reader-generated comments in response

Comments in responses to stories around the quality of organs were frequently indignant.

“Well pardon me for not being healthy enough for you to harvest my body.” (Fourfifteen, Daily Mail, 2019)

In response to the headline that organs frequently come from drug users, some felt that by transplanting organs perceived to be lower quality, clinical best practice and decision making were abandoned in favour of not wasting organs, time and resources.

Integrated analysis of this theme

These headlines spread concern among the public as to the quality of some of the organs being transplanted, and suggests that organs are sometimes coming from people with ‘bad’ habits (e.g. obesity, drug users).

Theme 4. An NHS under pressure

The overwhelming wave of public support for the NHS during the period of analysis due to COVID-19 meant that media coverage relating to organ donation focused primarily on the pressure the NHS was under and the cancellation of organ transplant operations. 23/286(8%) articles mentioned the drop in number of transplants taking place.

Exclusive: NHS trusts suspend life-saving organ transplants, (Health Service Journal, 02 April 2020).

NHS bosses admit ALL organ transplants could be scrapped ‘within days’ over fears patients will catch coronavirus as outbreak overwhelms intensive care units, (Daily Mail, 03 April 2020).

Coronavirus pressures ‘put organ transplants at risk’, (BBC News, 09 April 2020).

Reader-generated comments in response

Commenters reacted with anger and frustration, both towards the NHS itself, ‘shame on the NHS’ (Daily Mail, 03 April 2020), and towards the government for not providing adequate funding, ‘this whole crisis just shows how terribly underfunded and uncoordinated the NHS is.’ (Daily Mail, 03 April 2020).

Integrated analysis of this theme

The media created a picture of a Health Service unable to cope with demand, failing to meet the needs of people who were sick and collapsing while those in power sat back and watched it happen. The initial support for the NHS quickly turned to annoyance and even resentment that despite the sacrifices people were making or had made, COVID-19 did not go away, and the NHS was still in crisis.

Theme 5. ‘Scientists playing God’

Twenty-one (7%) of the 286 articles described technological advances in the field of organ donation. Around half of these advances were described in a positive way, using terms such as ‘major breakthrough’:

Scientists develop a machine that can keep a donated human liver alive for a week outside the body, (Daily Mail, 13 Jan 2020).

However, the others developed different narratives and used graphic images and terms such as ‘mutant’ and ‘science fiction’:

Plot to create human-animal hybrids using controversial gene editing science approved, (The Sun, 30 July 2019).

World’s first human head transplant could happen in the next 10 years, (Daily Mail, 20 Dec 2019).

Reader-generated comments in response

Although some recognized the potential of research to save and improve lives:

“A real breakthrough that should save many more patients.” (Dave444, Daily Mail, 2020)

Other comments reflected the sentiments in the articles with multiple references to ‘Frankenstein’ and ‘scientists playing God’:

“Frankenstein will become a reality.” (FarmerGeorge, Daily Mail, 2019)

“Death is traumatic. Grief never goes away, we just learn to cope with it. Yet it is nature, it happens to everyone. Our time is different for everyone, but allowing nature to take its course is better than inserting organs from dead people and playing God. What if the child you save then goes on to suffer horrific events afterwards, that death would have spared them from experiencing, who is to blame then?” (LizJ, Daily Mail, 2021)

Although some interpreted developments in research as progressive others saw such technological innovations as being unnatural and unwelcome. Others felt that novel technologies were ultimately dehumanizing by taking away the natural order of death and dying.

Theme 6. Tensions between the rights of individuals and those of the state

A few media stories explicitly referenced tension between the rights of individuals and those of the state, but the rights and responsibilities of individuals and the government represented a significant source of discussion and contention within the reader-generated comments.

Reader-generated comments in response to this theme

One hundred and sixty-five comments (over 50% of those that referred to the change in the law) remarked on one or more of four aspects of the tension between the individual and the state. They were:

- a. Objection to the change from opt-in to opt-out on principle,
- b. Concern that the law change diminishes the altruistic aspect of organ donation,
- c. A lack of trust in the state and questioning of government motivations,
- d. Understanding and accepting of criteria for brain death and associated terminology.

a. Objection to the change from opt-in to opt-out on principle

One article, published by the Daily Mail in February 2020, with a new opt-out donation law weeks away, Dr Martin Scurr and Dr Max Pemberton question if the NHS should have the right to take our organs, put forward two different perspectives on the law change, one of which said that:

“The scheme runs the risk of removing organs from those who did not want this to happen but had not registered their objection. This would seriously damage public confidence, and also represents further state intrusion into our lives.” (Daily Mail, 17 Feb 2020)

These sentiments were echoed by a number of comments made in response to stories across all publications, with many commenters declaring that they would now opt-out “on principle” as a result of the change, having previously opted-in:

“I was on the Organ Donor Register right until “deemed consent” came in. Now I have removed myself. I cannot think of anything more unacceptable than “deemed consent”. The state does not own me.” (LibertarianVoice, Mirror, 2020)

“Having in the past registered as a potential donor, I shall now register as a refusenik. The NHS has no right to assume it owns my body parts.” (Mary Rathke, The Times, 2020)

b. Concern that the law change diminishes the altruistic aspect of organ donation

The change in the nature of organ donation from a ‘gift’ to an ‘expectation’ was also widely discussed by readers, even though this was rarely mentioned by the media. Most mainstream media continued to conceptualise organ donors as “heroes” and “selfless”, and the process of organ donation as the “ultimate gift of life” throughout this period, reflecting the key messages in NHSBT’s ‘Pass it on’ media campaign. One exception to this was an article by Vatican News, published in May 2020, which stated that the Lead Bishop for Healthcare in England supported organ donation in general but did not support the change in the law because:

“It is important that there is a sense of the gift and there can be a sense of intrusion of the state taking over what should primarily be a gift from one person to another.” (Vatican News, 23 May 2020)

Other comments included:

“For decades I carried a donor card. I always thought it should remain a gift after I have gone. Now it is no longer a gift but a demand. I withdrew my consent weeks before the deadline.” (AnonymousMe, Daily Mail, 2020)

“A donated organ is a gift, not a right.” (Crazywitchlady, Daily Mail, 2020)

c. A lack of trust in the state and questioning of government motivations

Another common concern, also not mentioned in the media, was the suggestion that the law change on organ donation was the start of a “slippery slope” to further state control, and towards the creation of a totalitarian or dystopian society focussed on financial incentives and social cleansing.

“When the state effectively takes ownership of our bodies then we should be worried. I am a donor already, but this is going too far.” (Michael Organ, Metro, 2020)

“Sinister legislation. Keep your hands off my intestines.” (Maximus Glutimus, Daily Mail, 2020)

“Turning every human being into spare body parts for others isn’t progress however well intentioned – it’s positively chilling... The timing is cynical. Our collective attention is elsewhere. We need to push back against this Orwellian development.” (Bailey, The Times, 2020)

“Look good? Oops, didn’t recover after all. Then there are the religions/cultures that put little or no value on females, will there be ‘accidental’ deaths of mothers/sisters if a valued son needs an organ transplant? The law is Orwellian and open to abuse and temptation... in so many ways.” (Dorsetmaid, Daily Mail, 2020)

“50,000 to save the life of someone hurt in an accident or 100,000 or more profit made in selling organs to the highest bidder. Schemes started with altruistic intentions have a habit of being hijacked by money-making schemers. The rich will live, and the poor will supply parts to keep them going.” (Daily Mail, 2020)

d. Understanding and accepting of criteria for brain death and associated terminology

The view of both the government, and the process of organ donation as something sinister which cannot be trusted, was given further weight by a media article which described a situation in which a teenager who was “certified dead”, “began breathing” again after family consent had been given for organ donation (Mirror, 30 March 2021). Further examples of similar occurrences were echoed by commenters, which highlighted a perceived challenge in accurately defining death and contributed to an overall vision of a government which could not be trusted to prioritise saving lives over ‘harvesting’ organs:

“Friend of mine died recently aged 72. When he was 17 he was involved in a horrendous road accident and was in a coma for over a year. His parents were told he was brain dead and should switch off life support and allow certain organs for transplant. He survived, worked as an accountant, married and raised a family. Brain dead? How many times will this happen?” (Jolleyman, Daily Mail, 2020)

“A person’s organs are of no use when their body is completely dead. I think the criterion is brain death which is a condition that cannot always be ascertained with absolute certainty. Several studies have consistently shown the physician’s lack of ability to accurately discuss, define and recognise brain death.” (I am David, The Times, 2020)

“OK, as long as the definition of “death” doesn’t subsequently get revised for the purpose of ensuring the harvested organs are just that little bit fresher.” (Alexander More, The Times, 2020)

Integrated analysis of this theme

Implicit in this theme is the idea that the law change was undemocratic and that the timing of its implementation during the COVID-19 pandemic was problematic, as individuals had not had an adequate opportunity to opt-out and make their wishes known. These comments also suggested a lack of trust in the government, with words such as “sinister”, “chilling” and “cynical” hinting that the government must have had an ulterior motive for introducing the legislation, such as to sell organs for money or to save the lives of those members of society considered to be most ‘valuable’.

The use of the word ‘harvested’ is known to be dehumanising, with connotations of farming and cultivating individual organs deliberately for donation. The word ‘harvest’ is rarely used in connection with organ donation by the mainstream media but was mentioned in 69 comments. These differences in use of language reflect further differences in the tone, subject matter and concerns between those published by the media and those written ‘below the line’ by readers. While debate about the role of the state, fears about loss of rights, questions about government motivation and loss of trust in the government and NHS were rarely mentioned by the news media, such issues were dominant within the associated reader-generated comments.

Discussion

The role of news media in shaping as well as reflecting public opinion is well established. Human interest stories, news about policy changes and new technologies, and opinion pieces from a wide spectrum of publications can influence the way politicians, policymakers and the public view and understand organ donation. This in turn can create and propagate social norms which encourage individuals and families to consent (or not) to deceased organ donation. These analyses show that media messaging on organ donation and the change in the law from May 2019 to May 2021 was largely positive, and that this was consistent across different kinds of publications and over time. Positive stories about the importance of organ donation, accurate reporting of the change in law and its benefits, frequent references to widespread public support for organ donation, emotive human-interest stories, and relatively nuanced reporting of the importance of increasing rates of organ donation in ethnic minority communities created a dominant narrative. This narrative suggested that deceased organ donation is a moral good, as are any measures that help to increase organ donation rates, including the change in the law.

However, in order to increase deceased organ donation rates, the change in the law needed not only to be successfully communicated and supported by the media, but also correctly understood and supported by the public. An important part of this is the changed role of the family to one that supports organ donation decisions rather than makes them. Reader-generated content in the form of online comments ‘below the line’ of news articles was different from the articles themselves: attitudes towards organ donation were mixed and those in response to the change in the law were largely negative. Concerns about the expanding role of the state, loss of individual freedoms and rights, the potential for the change in the law to be abused for financial gain, and uncertainty about how death is defined and verified created a counter-narrative to that expressed by the mainstream news media. This narrative suggested that neither the government, nor the NHS could be trusted to act in the best interests of individual patients.

Meaning of this study in relation to other studies

The majority of coverage by news media in relation to both organ donation and the change in the law was positive, especially when adjusted for the annual number of views, with little change during the period of analysis. This differs from the tone towards the Welsh opt-out policy observed in a similar analysis carried out in 2015-2017 which found that the tone of coverage became more supportive of the Welsh policy over time.[12] This difference may be explained, at least in part, by changes in attitudes towards the ‘soft opt-out’ law during the intervening period. The introduction of the policy in Wales may have contributed to a positive discourse on the law change, and partial normalisation of the ‘soft opt-out’ policy in media reporting across the UK, which may have been further enhanced when early successes from the policy in Wales were reported.[27] The move towards more positive attitudes to organ donation is likely to have been supported by The Mirror’s ‘Change the Law for Life’ campaign, which championed the benefits of an opt-out law for several years, telling the stories of two children, Keira and Max, and presenting a positive view of organ donation. This particular campaign also indicates that the overall intention of the media was to focus on the benefits of organ donation rather than trying to explain or promote a change to a ‘soft’ opt-out system of organ donation as the law change does not include children.

The carefully crafted NHSBT communications campaign worked in that the majority of articles communicated the law change accurately, with similar content found across multiple publications, and frequently reiterated content from NHSBT’s ‘Pass it on’ campaign, suggesting a strong relationship between official sources including the NHS and media reporting.

However, while content and messages were relatively consistent across media articles, the tone of reader-generated comments was markedly different: only 27% of comments had a positive tone in relation to the law change, after adjustment for annual views of the publication. This pattern was sustained across publications and was observed even when comments were responding to positive articles. The disparity between the tone of articles and reader-generated comments may be in part a reaction against the overwhelmingly positive coverage of the change to the law in the mainstream media, which may foster a view that the media is acting as the mouthpiece of the state and provoke a negative reaction among commenters. In addition, there is evidence that people are more likely to comment on content they disagree with, and so positive coverage may have been more likely to incite a negative response.[28] However, the presence of such comments is likely to alter the perception of other readers about public opinion of the law change and may also affect perception of the news itself.[29] This may in turn influence wider public views and thus undermine the aims of both NHSBT and the mainstream media in normalising organ donation following the introduction of the ‘soft’ opt-out policy. Recent research by Ferguson et al. (2020) found that even those who may initially wish to co-operate with becoming an organ donor by default and feel encouraged by the law change, may also be strongly affected by individuals or “lone wolves” who publicly and vocally declare their decision to opt-out, suggesting the impact of comments which do not support organ donation or the change in law may be significant.[30]

Strengths and limitations

Media stories were identified from a wide range of sources, including national and local newspapers, and specialist publications. The volume and variety of coverage identified provided an opportunity to analyse trends over time, identify differences between publications and gain an overview of the tone and content in relation both to organ donation, and the change in the law. The analysis of reader-generated comments, as well as media stories, also facilitated comparisons between media and reader-generated content, and enabled further analysis of how the law change was understood and supported by the public.

The use of a mixed-methods approach, undertaking a summative content analysis across a wide range of articles and a thematic analysis provided an opportunity to gain a broad

perspective on the totality of media coverage, while also exploring the themes, language and framing of individual articles and reader-generated comments in more depth. Taking an inductive approach to thematic analysis allowed themes to emerge, rather than imposing pre-conceived ideas which may have constrained the analysis. The use of a second researcher to verify sentiment and coding of a sample of articles also strengthened the reliability of the findings, while weighting the media articles according to views and engagement ensured the results were largely representative of their likely influence on the population.

While the volume of media articles provided a rich view of media sentiment during the period of analysis, reader-generated comments observed are unlikely to be representative of the general public and cannot be interpreted as a proxy for overall public attitudes towards organ donation or the change in the law. This is because those who post comments in response to articles online are likely to differ systematically from the wider population in a number of important ways. First, people are more likely to comment online if they disagree with the sentiment or content of a news story,[28] and as the majority of news coverage was positive, those with negative views are likely to be disproportionately represented ‘below the line’. Second, people posting online comments may hold stronger views than the general population, since they are motivated to respond. Third, people posting comments online may be influenced by the physical distance and relative anonymity of the online environment, leading to some commenters posting deliberately provocative content (which they may or may not completely agree with) or posting multiple comments under different names to deliberately undermine public health messages.[31] Fourth, comments analysed were from a limited range of publications, with a significant number from the Daily Mail, whose readership is unlikely to be representative of the overall population. In addition, most articles did not contain any online comments, either because there was no facility to comment or comments had been disabled, it was possible to comment but no one had done so, or online comments had been removed by the publication by the time of the search. Nonetheless overall we did see a tendency for the below the line comments in setting a tone and subsequent narrative which did have the capacity to influence other people.

Finally, the COVID-19 pandemic affected media reporting and public responses during the period of analysis. The final stages of the NHSBT media campaign to inform the public about the change in the law were cancelled and NHSBT worked closely with the media to limit the promotion of organ donation at the height of the pandemic. This is likely to have affected coverage and public awareness of the law change, and limited media stories as well as the public’s response to them across mainstream media. For example, stories which included COVID-19 in the narrative and painting a picture of a health system in such disarray were especially likely to stoke fear and anxiety and likely contributed to undermining confidence not just in organ donation, but in the wider NHS health system.

Implications for policy and practice

The current analysis shows that despite carefully crafted positive messaging, divisive narratives and misinformation dominated the reader-generated content during this time, alongside legitimate concerns about the potentially expanded scope of state involvement in decisions about deceased organ donation.

Recommendations and further research

We were unable to undertake any detailed analysis of comments, threads and discussion posted on social media sites in connection with the media stories included here. We identify this as a gap and an area for future study, namely the impact of social media on interventions designed to increase number of organs available for transplant and to establish the influence of social media posts on wider public sentiment around living and deceased organ donation. Finally we note an overall lack of evidence speaking to the effectiveness of mass organ donation media campaigns and encourage robust evaluations capable of measuring what matters to the multiple stakeholders are built into future communication planning.[32]

Conclusion

The way the public disseminate and consume information has changed rapidly in recent years. Reader-generated comments have an increasing capacity and capability to shape narratives and understanding of media content, even when these discourses are unreconcilable with the source story. Organ donation remains sensitive and poorly understood across large parts of the general public. The views represented in online comments reveal an important alternative viewpoint to those presented by the mainstream media in relation to organ donation and ‘soft’ opt-out policies designed to increase the number of organs available for transplant. These views are likely to influence the interpretation and understanding of other readers although we do not yet fully understand how these relationships work, their interdependencies, and the full impact on public attitudes and behaviour in relation to organ donation. Additional tailored interventions are needed (e.g. evidence-based community centred approaches, targeted messaging to reflect local reality and social identities and education to minimize communications which may promote fear, avoidance or denial), alongside future media campaigns, to address mis- and dis-information and ensure that the public continue to have access to trustworthy sources and reliable guidance which are likely to vary for different subgroups.

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5

Trends in organ donation in England, Scotland and Wales in the context of the COVID-19 pandemic and opt-out legislation

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Summary

Background

In May 2020, England implemented soft 'opt-out' or 'deemed consent' for deceased donation with the intention of raising consent rates. However, this coincided with the COVID-19 pandemic, making it difficult to assess the early impact of the law change. Wales and Scotland changed their organ donation legislation to implement 'soft' opt-out systems in 2015 and 2021 respectively. This chapter provides a descriptive analysis of changes in consent and transplant rates for deceased organ donation in England, Scotland and Wales.

Methods

Logistic regression and descriptive trend analysis were employed to assess the probability of a patient who died in critical care becoming a donor, and to report consent rates using data, respectively, from the Intensive Care National Audit and Research Centre (ICNARC) in England from 1 April 2014 to 30 September 2021, and from the Potential Donor Audit for England, Scotland and Wales from April 2010 to June 2023.

Results

The number of eligible donors in April-June 2020 were 56.5%, 59.3% and 57.6% lower in England, Scotland and Wales relative to April-June 2019 (pre-pandemic). By April-June 2023, the number of eligible donors had recovered to 87.4%, 64.2% and 110.3%, respectively, of their levels in 2019. The consent rate in England, Scotland and Wales reduced from 68.3%, 63.0% and 63.6% in April-June 2019 to 63.2%, 60.5% and 56.3% in April-June 2023.

Conclusions

While the UK organ donation system shows signs of recovery from the COVID-19 pandemic, the number of eligible potential donors and consent rates remain below their pre-pandemic levels.

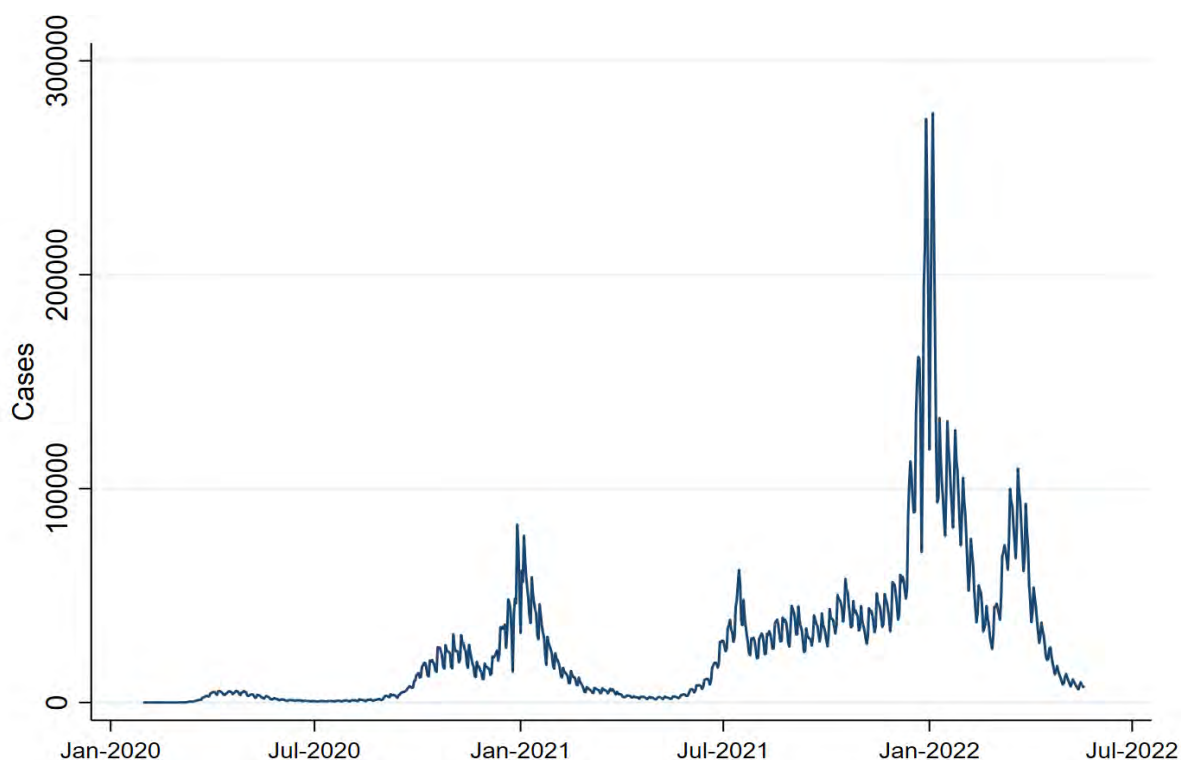
Introduction

Since 2015, different parts of the UK have been moving at different pace towards systems of organ donation consent based on the concept of ‘deemed consent’ (see Table 1 in Chapter 1 of this report for a summary of the UK countries organ donation laws). Below, we focus on England, Scotland and Wales. This sequence of similar law changes in the three countries at different times offers a natural experiment with the potential to assess the impact of deemed consent for the first time in a wider UK context.

The COVID-19 pandemic

Unfortunately, analysing the impact of the move to deemed consent in England and Scotland following the law change in Wales is challenging as the effects were conflated with the effects of the COVID-19 pandemic. The COVID-19 pandemic significantly affected healthcare systems worldwide, leading to concerns about the availability of donor organs and the ability to perform transplant surgery. Aubert and colleagues [1] report that, across 22 countries, the overall number of kidney, liver, lung, and heart transplants from human donors fell by 16% during the first wave of COVID-19. Figure A1 shows the daily number of COVID-19 cases over time for context.

Figure A1: Daily number of COVID-19 cases, by specimen date



Source: <https://coronavirus.data.gov.uk/details/cases> accessed 4th April 2023.

Manara and colleagues [2] report a reduction in trauma and other emergency department admissions in the UK of over 50% during the first lockdown (23rd March to 10th May 2020). However, despite the pandemic, deceased donation (transplant) activity was reportedly sustained at 75% of normal levels in 2020/21 (NHS Organ Donation, 2021). Plummer and colleagues [3] used national audit data from NHS Blood and Transplant (NHSBT) to compare the first 12 months after the pandemic (11th March 2020 and 10th March 2021) with the corresponding 12 months immediately pre-pandemic. They report that during the first wave (11th March to 1st September 2020) of the pandemic, referrals to NHSBT of potential

organ donors were inversely related to the number of people with COVID-19 undergoing mechanical ventilation in intensive care. However, in the second wave (2nd September 2020 to 10th March 2021), this was reversed, with a positive relationship observed. Overall, there were fewer eligible donors and a lower total number of donations when compared with the pre-pandemic period, but the proportion of eligible donors who proceeded to donation (27%) was unchanged.

The introduction of deemed consent aimed to increase the number of organs available for transplant by increasing the consent rates within the potential donor pool, providing an associated increase in the number of organs available for transplantation and in donation rates. However, increases in the consent rate may not necessarily lead to increases in the transplant rate, since a consented donor does not always proceed to donation as some families withdraw consent, some DCD donors do not die in a suitable timeframe to allow donation to occur and some donors may not have any organs deemed suitable for transplantation. The conversion of potential donors to successful donation tends to be low – a recent study suggested that less than 20% of patients identified as eligible donors went on to donate successfully.[4]

Existing evidence

A number of studies have analysed the short term effects of the earliest UK introduction of deemed consent, that in Wales. An early evaluation of the effects of the Welsh legislation change reported that while consent rates had increased in Wales after the law change, they had also increased similarly in the rest of the UK, so the Welsh increase could not be attributed specifically to the legislation change, while the number of deceased donors remained largely unchanged.[5] Albertsen [6] compared Wales with the UK as a whole using a difference-in-differences approach, and reported that concerns expressed by sceptics that deemed consent might even decrease both living and deceased donation rates had not materialised. More recently, Madden and colleagues,[7] using a longer follow up period (33 months), concluded that consent rates in Wales had been positively impacted. For England, very early reports indicated that the law change was associated with little change to the consent rates, or organ donations numbers, albeit changes may take longer to manifest or be confounded by the effects of the pandemic.[8]

Here we do not seek to disentangle the causal effect of the law changes and the pandemic, but rather conduct a descriptive analysis of changes in consent rates and transplant rates over time in England, Scotland and Wales, focussing on deceased donor consent rates before and after the law changes in each country, and before and after the initial wave of COVID-19.

Methods

Critical care – ICNARC data analysis

Data from ICNARC on admissions to critical care of patients aged between 20 and 80 years to NHS units in England between 1 April 2014 and 30 September 2021 were used. We reported the total number of reported admissions, deaths, and deaths leading to any organ or tissue donation, by quarterly time periods. Patient characteristics of age group, sex, ethnicity (collected using standard NHS categories and grouped as White; Mixed; Asian; Black; Other; Not stated) and primary reason for admission to critical care (grouped as trauma, cardiovascular, gastrointestinal, neurological, genito-urinary, endothermic, metabolic, thermoregulation and poisoning, haematological or immunological, other) were reported as counts and percentages, for all deaths and by donation status. A logistic model was fitted to estimate the probability of a patient who died in critical care becoming an organ or tissue donor,

adjusting for variables previously identified as affecting this decision (age, sex, ethnicity, reason for admission), and for date of admission (grouped into quarters). The adjusted odds ratio for each quarter (with 95% CI) compared to the starting period of April-June 2014 was calculated., to determine whether changing percentages of organ donations were driven solely by changes in the characteristics of patients dying in critical care, or by other factors not measured in these data. Each variable in the logistic model was separately tested for an interaction with quarter, to determine whether or not the association between that variable and the probability of donation remained constant over time, despite the pandemic and law change.

Potential Donor Audit (PDA)

The PDA is a continuous national audit of all patients aged ≤ 80 years who die within an intensive care or emergency department in a UK hospital. For this analysis, we obtained access to anonymised data from NHSBT captured in the PDA for England, Scotland and Wales. Potential donors are defined as those deceased patients who could be solid organ donors. The PDA data include data on both DCD and DBD donors. For DBD, deceased donors' intensive care treatments are continued after death is confirmed to preserve organs until they can be retrieved, whereas for DCD, organ donation takes place following the diagnosis of death using circulatory criteria. In the UK, the average number of transplantable organs retrieved from DCD donors (2.8) is similar to that from DBD donors (3.2), while DCD donors represented 44% of all deceased organ donors in 2021/22.[9]

The PDA reflects the pool of potential deceased donors whose families may be contacted for consent. Both potential DBD donors and DCD donors may be excluded before being approached due to a number of absolute contraindications (ACI) which clinically preclude organ donation as per NHSBT criteria (POL188).[10] In addition, potential DCD donors without absolute contraindications may also be excluded due to the DCD screening process before families are approached. Thus, these potential donors will not be captured in the NHSBT data on donor family consent. We exclude live donors and limit analysis to individuals aged 20 to 80 years, as in the ICNARC analysis.

We use simple trend analysis to describe variation over time in the rate of consent, defined as the percentage of eligible donor families approached for organ donation discussion where consent/authorisation for donation was ascertained, and the transplant rate, defined as the number of transplants divided by the number consented donors from whom at least one organ was transplanted. Outcomes are defined on a quarterly basis to reduce variability in the measurement, given the relatively low number of eligible donors in Wales and Scotland. While the pandemic is an important confounder preventing reliable estimation of the causal effects of the move towards deemed consent, especially in England and Scotland – to the extent that changes coincide across the nations, we can infer these are more plausibly attributed to the pandemic than to the similar law changes, and conversely where changes are nation-specific, we may infer that these are potentially attributable to the law changes unless countries adapted their organ donation system differently in face of the pandemic which is unlikely since NHSBT operates similarly across the UK.

Data from the PDA were available for 94,598 patients referred to the organ donation service for consideration of organ donation over 53 quarters of data running from Q2 2010 (i.e. April-June 2010) to Q2 2023 (April-June 2023). Of these, 65,411 were deemed to be eligible DBD or DCD donors, with 61,142 aged between 20 and 80. Unless otherwise stated, analysis was limited to the 36,038 (England = 31,576; Scotland= 2,633; Wales = 1,829) eligible potential donors aged between 20 and 80 years where the family was approached for discussion of organ donation. Consent was provided for 22,634 (England = 19,863; Scotland= 1,629; Wales = 1,132) of these potential donors.

Results

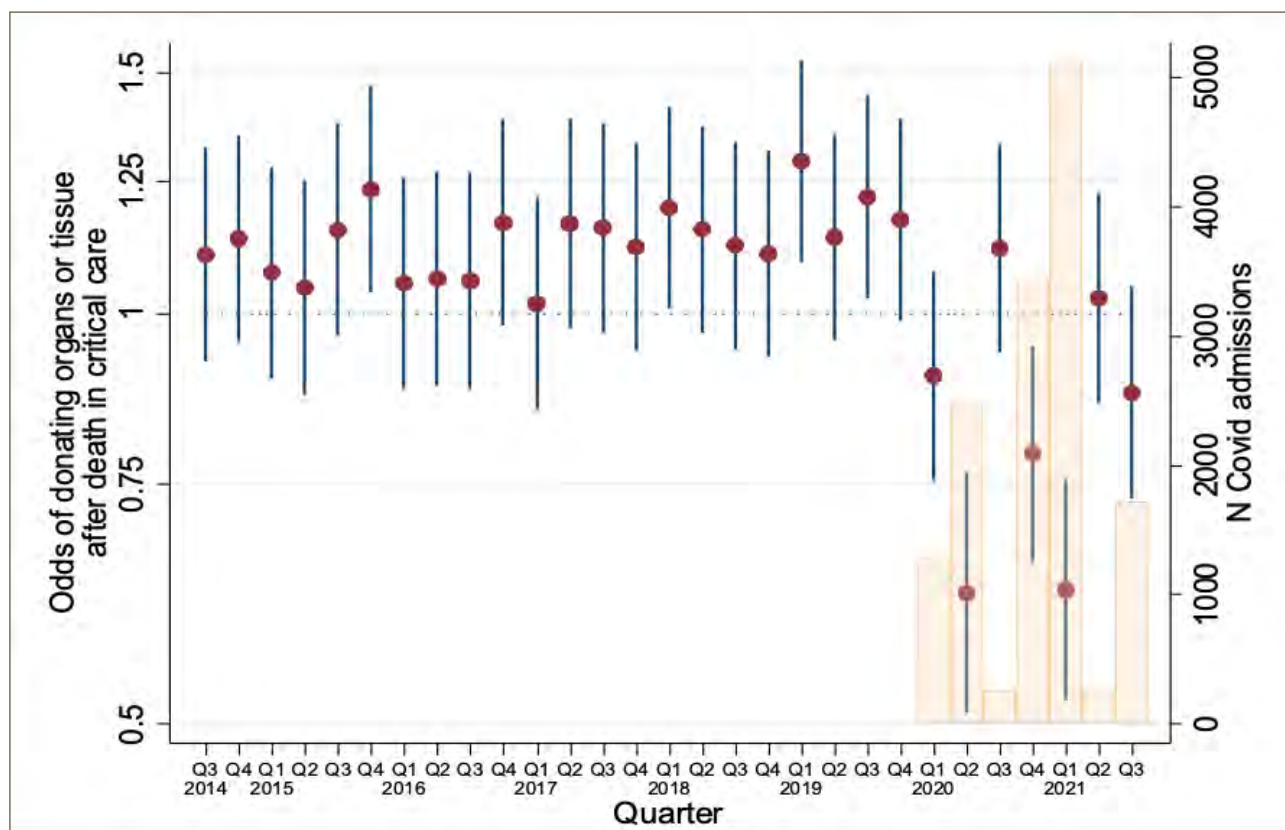
Critical care – ICNARC data analysis

Table 1 Admission, deaths, and donation rates by time period based on ICNARC data

Quarter	Admissions		Deaths			Organ and/or tissue donation	
	All (N)	Covid (N)	All (N)	% of admissions	Covid (N)	N	% of deaths
2014 q2	33,208	0	4,174	12.6	0	278	6.7
2014 q3	34,955	0	4,397	12.6	0	309	7
2014 q4	37,073	0	4,988	13.5	0	352	7.1
2015 q1	35,547	0	4,923	13.8	0	326	6.6
2015 q2	37,269	0	4,483	12	0	309	6.9
2015 q3	37,728	0	4,337	11.5	0	317	7.3
2015 q4	38,860	0	4,961	12.8	0	362	7.3
2016 q1	39,301	0	5,474	13.9	0	321	5.9
2016 q2	39,596	0	4,752	12	0	308	6.5
2016 q3	40,756	0	4,515	11.1	0	297	6.6
2016 q4	41,788	0	5,154	12.3	0	363	7
2017 q1	41,181	0	5,068	12.3	0	313	6.2
2017 q2	41,638	0	4,707	11.3	0	348	7.4
2017 q3	41,707	0	4,691	11.2	0	339	7.2
2017 q4	43,734	0	5,324	12.2	0	358	6.7
2018 q1	43,593	0	5,738	13.2	0	405	7.1
2018 q2	44,811	0	4,936	11	0	362	7.3
2018 q3	44,622	0	4,661	10.4	0	350	7.5
2018 q4	45,112	0	4,952	11	0	366	7.4
2019 q1	44,173	0	5,250	11.9	0	413	7.9
2019 q2	45,403	0	4,784	10.5	0	361	7.5
2019 q3	46,100	1	4,923	10.7	0	393	8
2019 q4	45,853	1	5,284	11.5	0	399	7.6
2020 q1	43,181	3,322	6,103	14.1	1,270	318	5.2
2020 q2	33,586	7,846	5,597	16.7	2,476	184	3.3
2020 q3	40,489	965	4,546	11.2	259	361	7.9
2020 q4	43,451	10,593	7,235	16.7	3,427	282	3.9
2021 q1	42,596	16,080	8,494	19.9	5,120	242	2.8
2021 q2	41,337	1,213	4,666	11.3	254	325	7
2021 q3	40,552	6,457	5,771	14.2	1,716	301	5.2

Overall, organ or tissue donations made up 6.4% of all deaths in adult critical care recorded over the time period, and 0.8% of all admissions, or 7.1% if we consider only the pre-COVID-19 period (prior to Q1 2020) (Table 1). Donation rates, defined as the proportion of deaths leading to organ and/or tissue donation, varied over time but with an overall rising trend between 2014 and 2019 (also seen in the PDA analysis, below), which was then followed by major fluctuations during the pandemic. This pattern remained after adjusting for patient characteristics known to affect donation rates, suggesting these changes were driven by something other than changes in the recorded patient characteristics (Figure 1).

Figure 1: Adjusted odds ratio (with number of COVID-19 admission) of donating organ tissue after death in critical care over time



The influence of recorded patient characteristics on likelihood of donation remained consistent over time for ethnicity and sex, but changed for age and presence of significant medical history, likely reflecting changes in eligibility during the pandemic rather than in decisions made by next of kin (Table 3). In the COVID-19 era (post-2020 Q1) death rates tended to be higher than in the pre-COVID-19 era, while conversely the number and proportion of deaths that led to organ and/or tissue donation, tended to be lower. Of the deaths in critical care units, those that became donors were more likely to be male, less than 60 years of age, White, be admitted for trauma or neurological (including eyes) reasons and less likely to have a history of severe conditions (Tables 2 and 3).

Table 2 Characteristics of deaths in critical care units, by organ donation status based on ICNARC data

	Donors (N = 9,962)	Non-donors (N = 144,917)	All deaths (N = 154,879)
Male, n (%)	(N = 9,962)	(N = 144,917)	(N = 154,879)
Age, median (IQR)	57 (46, 67)	66 (55, 73)	65 (55, 73)
Age, n (%)			
<50	3186 (32.0)	22937 (15.8)	26123 (16.9)
50-59	2489 (25.0)	26299 (18.1)	28788 (18.6)
60-69	2412 (24.2)	41523 (28.7)	43935 (28.4)
70-79	1811 (18.2)	50134 (34.6)	51945 (33.5)
80+	64 (0.6)	4024 (2.8)	4088 (2.6)
Ethnicity, n (%)			
White	8840 (88.7)	120185 (82.9)	129025 (83.3)
Mixed	49 (0.5)	890 (0.6)	939 (0.6)
Asian	235 (2.4)	9686 (6.7)	9921 (6.4)
Black	111 (1.1)	4149 (2.9)	4260 (2.8)
Other	206 (2.1)	3230 (2.2)	3436 (2.2)
Not stated	521 (5.2)	6777 (4.7)	7298 (4.7)
Any history of severe conditions, n (%)	628 (6.3)	32880 (22.7)	33508 (21.6)
Primary system affected/reason for admission			
Trauma	1450 (14.6)	7765 (5.4)	9215 (6.0)
Cardiovascular	1965 (19.7)	35242 (24.3)	37207 (24.0)
Gastrointestinal	272 (2.7)	20445 (14.1)	20717 (13.4)
Neurological (including eyes)	5108 (51.3)	16847 (11.6)	21955 (14.2)
Genito-urinary	57 (0.6)	6960 (4.8)	7017 (4.5)
Endocrine, Metabolic, Thermoregulation & Poisoning	125 (1.3)	3644 (2.5)	3769 (2.4)
Haematological/Immunological	20 (0.2)	3074 (2.1)	3094 (2.0)
Other	16 (0.2)	2281 (1.6)	2297 (1.5)

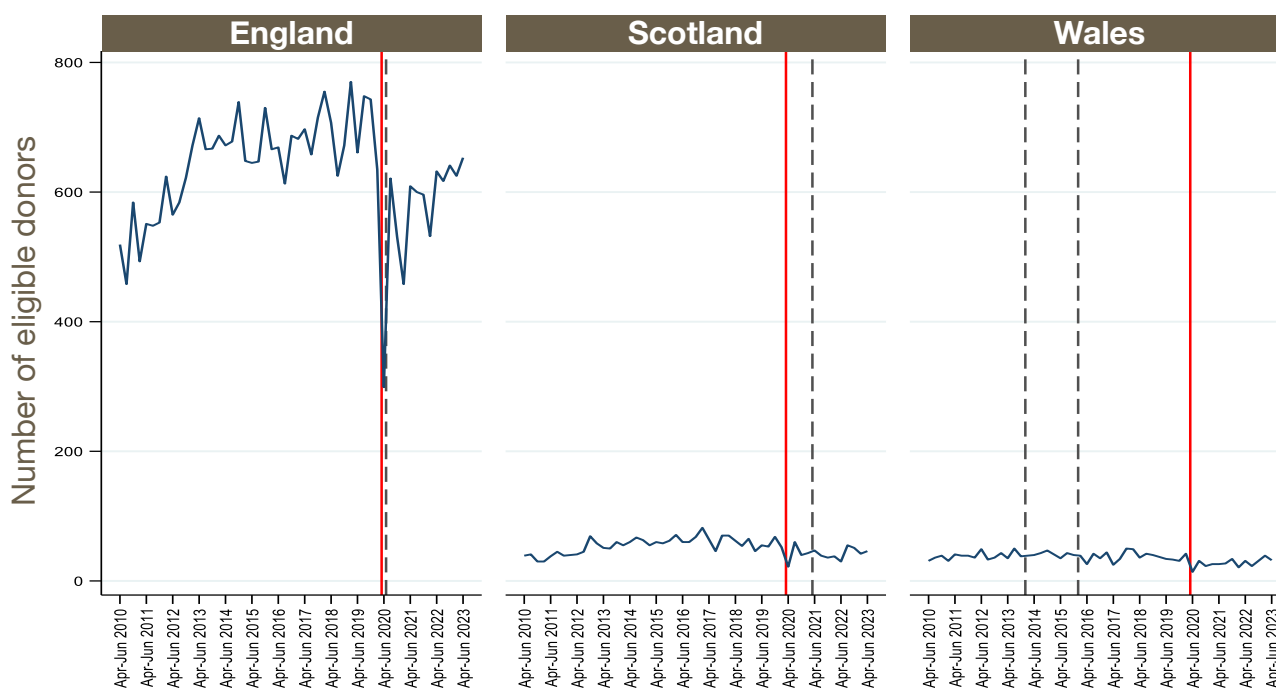
Table 3 Multivariable logistic model for probability of a death in critical care resulting in donation based on ICNARC data

Variable	Odds Ratio (95% CI)		p-value from test of interaction with quarter
Age (in years)	0.97	(0.97, 0.97)	0.0001
Male sex	0.88	(0.84, 0.92)	0.1868
Ethnic group			
White	1		0.3287
Mixed	0.59	0.43, 0.8)	
Asian	0.31	0.27, 0.35)	
Black	0.27	(0.22, 0.33)	
Other	0.64	(0.55, 0.74)	
Not stated	0.86	(0.78, 0.95)	
Any significant medical history	0.32	(0.3, 0.35)	0.0163
Primary system affected/reason for admission			n/a*
Cardiovascular	2.35	(2.17, 2.55)	* Not calculated because of small sample sizes within admission groups
Gastrointestinal	0.62	(0.54, 0.71)	
Neurological (including eyes)	11.15	(10.36, 12)	
Genito-urinary	0.40	(0.31, 0.53)	
Endocrine, Metabolic, Thermoregulation & Poisoning	1.17	(0.96, 1.41)	
Haematological/Immunological	0.38	(0.24, 0.59)	
Trauma	6.59	(6.04, 7.2)	
Other	0.28	(0.17, 0.46)	
Quarter:			
2014 q2	1		
2014 q3	1.10	(0.92, 1.32)	
2014 q4	1.13	(0.95, 1.35)	
2015 q1	1.07	(0.9, 1.28)	
2015 q2	1.04	(0.87, 1.25)	
2015 q3	1.15	(0.96, 1.38)	
2015 q4	1.23	(1.03, 1.47)	
2016 q1	1.05	(0.88, 1.26)	
2016 q2	1.06	(0.88, 1.27)	
2016 q3	1.06	(0.88, 1.27)	
2016 q4	1.16	(0.98, 1.39)	
2017 q1	1.02	(0.85, 1.21)	
2017 q2	1.16	(0.97, 1.39)	
2017 q3	1.15	(0.97, 1.38)	
2017 q4	1.12	(0.94, 1.33)	

Variable	Odds Ratio (95% CI)		p-value from test of interaction with quarter
Quarter:			
2018 q1	1.19	(1.01, 1.42)	
2018 q2	1.15	(0.97, 1.37)	
2018 q3	1.12	(0.94, 1.34)	
2018 q4	1.10	(0.93, 1.31)	
2019 q1	1.29	(1.09, 1.53)	
2019 q2	1.14	(0.95, 1.35)	
2019 q3	1.22	(1.02, 1.44)	
2019 q4	1.17	(0.99, 1.39)	
2020 q1	0.90	(0.75, 1.07)	
2020 q2	0.62	(0.51, 0.76)	
2020 q3	1.11	(0.94, 1.33)	
2020 q4	0.79	(0.66, 0.95)	
2021 q1	0.63	(0.52, 0.76)	
2021 q2	1.02	(0.86, 1.22)	
2021 q3	0.87	(0.73, 1.05)	

Potential Donor Audit

Figure 2: Number of eligible donors by country and quarter



KEY: Red line: COVID-19 pandemic Dashed line: implementation of opt-out legislation

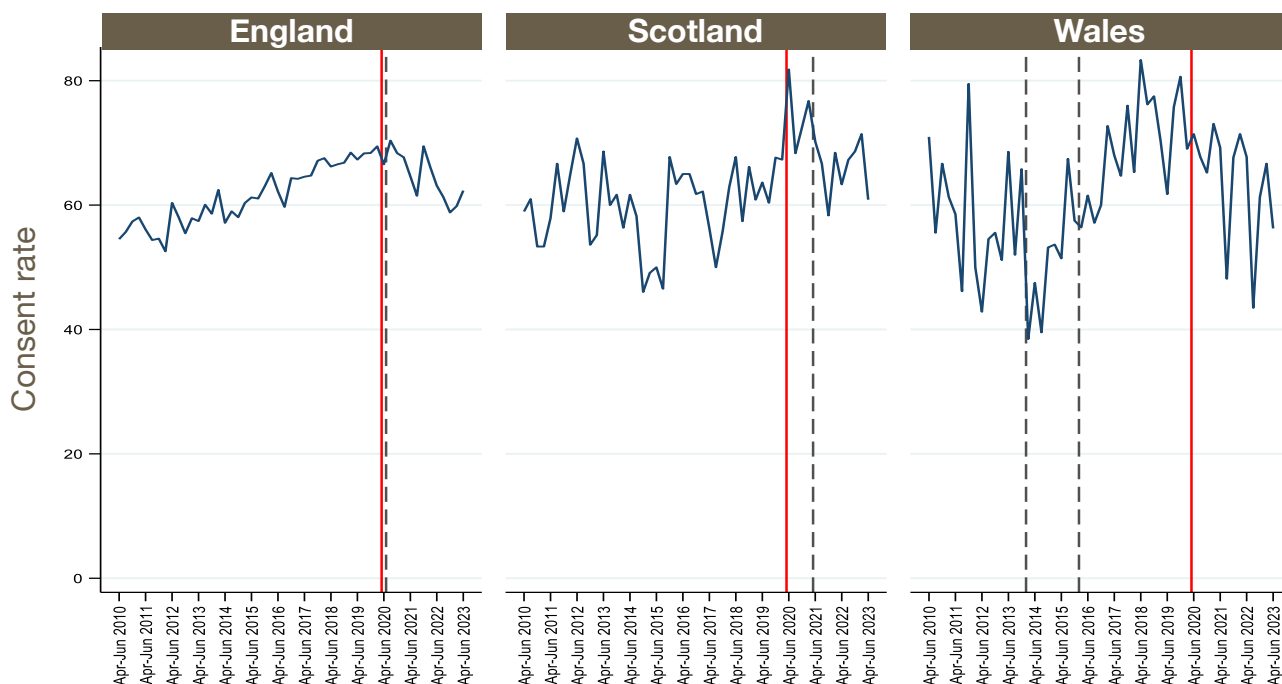
Figure 2 shows that most eligible donors are residents of England which is unsurprising given the disparity in population sizes. Hence, other reported values (e.g. consent rates) for Scotland and Wales tend to be more variable than for England. The number of eligible donors was increasing in England from 2010 to 2013, but was fairly stable thereafter. There was a large drop in the number of eligible donors during the first wave of COVID-19. Given the population size, the absolute drop was smaller in Scotland and Wales. However, in percentage terms relative to 12 months previously (i.e. preceding the pandemic), the changes in the number of eligible donors in Q2 of 2020 were more similar: 56.5% lower in England compared to 59.3% and 57.6% lower for Scotland and Wales, respectively. By the last period included in the analysis (April-June 2023), the number of eligible donors had recovered to 87.4%, 64.2% and 110.3% of their levels pre-pandemic in England, Scotland and Wales, respectively, albeit the absolute numbers were small (<50) in the latter two countries meaning that percentage changes should be interpreted with great care. NHS Blood and Transplant (NHSBT) commenced screening for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in deceased organ donors on 19 March 2020, and also revised its organ donation acceptance criteria, prioritising DBD over DCD and younger donors.[3] As shown in Table A4, this resulted in a change in the age composition of consented donors (See Table 1 in (3)) for details on age acceptance criteria).

Table A4 Proportion of eligible potential donors whose family were approached and for whom consent was given within each age group

Age group	January to March 2020	April to June 2020	July to September 2020	October to December 2020
Less than 20	5.3%	5.3%	5.4%	5.4%
20 to 25	4.1%	3.5%	2.2%	2.7%
25 to 30	3.4%	9.7%	4.4%	2.2%
30 to 35	4.7%	6.2%	6.6%	4.2%
35 to 40	5.1%	8.4%	5.0%	5.4%
40 to 45	6.7%	8.8%	5.8%	6.1%
45 to 50	8.7%	11.9%	10.0%	7.1%
50 to 55	10.1%	18.5%	12.6%	12.7%
55 to 60	11.4%	11.0%	15.6%	14.5%
60 to 65	12.6%	7.9%	12.0%	12.0%
65 to 70	11.2%	4.8%	9.4%	11.8%
70 to 75	9.1%	4.0%	8.4%	10.5%
75 to 80	7.1%	0.0%	2.4%	5.1%
80 to 85	0.4%	0.0%	0.2%	0.2%
All ages	100%	100%	100%	100%

The number of donors consenting broadly tracks the number of eligible donors, with a large drop in the peak pandemic period followed by a recovery (not shown). However, while the consent rate dropped in the COVID-19 era (Figure 3), the drop is not as stark as for the number of eligible donors. The consent rate in Scotland has returned close to the level pre-COVID-19, while this has not occurred in England or Wales (Figure 3). The dashed lines in Figure 3 correspond to the introduction of the respective ‘deemed consent’ Acts. For Wales, the leftmost dashed line indicates the media campaign run by the Welsh Government and NHSBT for two years preceding full implementation on 1 December 2015.

Figure 3: Consent rate by country and quarter



KEY: Red line: COVID-19 pandemic Dashed line: implementation of opt-out legislation

In England, the consent rate had been increasing over the decade before the pandemic and the law change (Figure 3; left panel). While consent rates dropped following the introduction of the Act, since similar drops were also seen in Scotland (Figure 3; middle panel) and Wales (Figure 3; right panel). Thus, we attribute this drop to the pandemic, rather than the Act. In Scotland and Wales, consent rates are volatile due to the lower number of eligible donors (driven by population size). In Scotland, following its legislation, there has been a drop in consent rates, but there are similar patterns in the other countries so this cannot be attributed to the Scottish law change. In Wales, following the initial period of the media campaign in 2013/14, there was a decrease in consent rates [leftmost dashed line]. However, this cannot be directly attributable to the law change since it preceded it or the media campaign since it also coincided with adverse media coverage of a particular adverse event where two recipients died from a kidney donor who was infected with meningitis, the first ever case in the UK. There was an increase in consent rates following the Act’s implementation [rightmost dashed line], but there was also an increase over this period in England and Scotland, so, again, this cannot be confidently attributed to the legislative change in Wales.

Table A1 reports the consent rate by age group for each nation, and overall. For England, consent rates are broadly similar by age group, while more variation is observed for Wales and Scotland, given the smaller number of eligible potential donors aged between 20 and 80 years where the family was approached for discussion of organ donation.

Table A1 Consent rate by age group for each nation

Age	England (N=31,576) %	Scotland (N=2,633) %	Wales (N=1,829) %	Total (N=36,038) %
20 to 25	64.3	62.2	67.3	64.3
25 to 30	65.8	68.7	69.0	66.2
30 to 35	61.5	64.1	68.8	62.1
35 to 40	64.6	70.8	67.5	65.2
40 to 45	63.1	68.6	65.4	63.6
45 to 50	63.7	65.6	68.2	64.0
50 to 55	63.9	61.4	61.4	63.6
55 to 60	62.6	60.3	57.8	62.1
60 to 65	61.3	59.7	60.9	61.2
65 to 70	62.8	60.2	59.6	62.4
70 to 75	61.7	54.1	58.6	61.1
75 to 80	63.0	49.4	56.6	62.0
Total	62.9	61.9	61.9	62.8

Table A2 reports the number of eligible potential donors approached, and the consent rate for DBD and DCD potential donors by financial year. We see a large (32%) reduction in the number of eligible potential donors approached in 2020, coinciding with the start of the pandemic. The reduction was greater in percentage terms for DCD (-43%) than for DBD (-17%).

Table A2: Number of eligible potential donors approached, and the consent rate for DBD and DCD potential donors by financial year

Financial Year (April to March)	Number of eligible potential donors approached			Consent rate %		
	DCD	DBD	All	DCD	DBD	All
2010	1,281	914	2,195	52.0	65.3	57.5
2011	1,492	958	2,450	50.2	62.9	55.2
2012	1,679	987	2,666	52.5	68.4	58.4
2013	1,835	1,113	2,948	54.8	68.2	59.9
2014	1,848	1,136	2,984	52.8	67.1	58.2
2015	1,774	1,154	2,928	58.5	69.6	62.8
2016	1,702	1,207	2,909	59.6	69.0	63.5
2017	1,719	1,339	3,058	61.1	72.7	66.2
2018	1,640	1,364	3,004	63.0	72.5	67.3
2019	1,679	1,323	3,002	65.5	72.6	68.6
2020	952	1,094	2,046	64.6	74.1	69.7
2021	1,341	1,132	2,473	63.2	68.9	65.8
2022	1,988	1,382	3,370	57.6	69.0	62.2
Total	20,935	15,103	36,038	57.9	69.5	62.8

Table A3 reports the number of potential donors and consent rates by quarter, along with the percentage change relative to the corresponding quarters in 2019, i.e. before COVID-19. A large drop in April-June 2020 coincided with the first wave of the pandemic, with the drop particularly large for DCD (74.1%). By the final quarter for which data were available (April – June 2023), the percentage had recovered to be 4.7% above the corresponding quarter in 2019, while DBD remained 14.1% below its level in 2019. While there was a large drop in the number of potential donors, the consent rate tended to reduce less noticeably. Towards the end of 2022, consent rates remained 6.5 and 1.7 percentage points below their 2019 levels for DCD and DBD, respectively.

Table A3: Number of eligible potential donors approached, and the consent rate for DBD and DCD potential donors by quarter and change from the corresponding quarter in 2019

Quarter	Number of eligible potential donors approached			% change relative to corresponding quarter in 2019			Consent rate %			Absolute % point change relative to corresponding quarter in 2019		
	DCD	DBD	All	DCD	DBD	All	DCD	DBD	All	DCD	DBD	All
2019 q1	462	358	820				65.8	72.1	68.5			
2019 q2	402	319	721				64.2	72.1	67.7			
2019 q3	458	336	794				66.4	70.2	68.0			
2019 q4	439	366	805				64.7	73.8	68.8			
2020 q1	380	302	682	-17.7	-15.6	-16.8	66.6	74.5	70.1	0.8	2.4	1.6
2020 q2	104	208	312	-74.1	-34.8	-56.7	56.7	75.0	68.9	-7.5	2.9	1.2
2020 q3	334	340	674	-27.1	1.2	-15.1	65.3	74.7	70.0	-1.1	4.5	2.0
2020 q4	253	303	556	-42.4	-17.2	-30.9	66.4	71.6	69.2	1.7	-2.2	0.4
2021 q1	261	243	504	-43.5	-32.1	-38.5	65.1	75.7	70.2	-0.7	3.6	1.7
2021 q2	344	301	645	-14.4	-5.6	-10.5	62.7	68.8	65.5	-1.5	-3.3	-2.2
2021 q3	332	303	635	-27.5	-9.8	-20.0	58.4	65.0	61.6	-8.0	-5.2	-6.4
2021 q4	354	283	637	-19.4	-22.7	-20.9	63.8	76.0	69.2	-0.9	2.2	0.4
2022 q1	311	245	556	-32.7	-31.6	-32.2	68.2	65.7	67.1	2.4	-6.4	-1.4
2022 q2	358	297	655	-10.9	-6.9	-9.2	59.8	69.7	64.3	-4.4	-2.4	-3.4
2022 q3	379	275	654	-17.2	-18.2	-17.6	59.9	65.8	62.4	-6.5	-4.4	-5.6
2022 q4	380	286	666	-13.4	-21.9	-17.3	54.5	69.6	61.0	-10.2	-4.2	-7.8
2023 q1	430	249	679	-6.9	-30.5	-17.2	57.2	68.7	61.4	-8.6	-3.4	-7.1
2023 q2	421	274	695	4.7	-14.1	-3.6	57.7	70.4	62.7	-6.5	-1.7	-5.0

Figure A2 shows the number of consented donors from whom at least one organ was transplanted over time. This follows a broadly similar pattern to the number of consented donors, dropping sharply in the pandemic period in England and not yet having fully recovered, although this pattern is less evident in the other nations. This again suggests that a return to 2019 levels of activity has not yet occurred. Figure A3 shows the transplant rate and provided some evidence that a greater number of organs have been transplanted per consented donor in the COVID-19 era.

Figure A2: Number of consented donors that led to at least one organ being transplanted

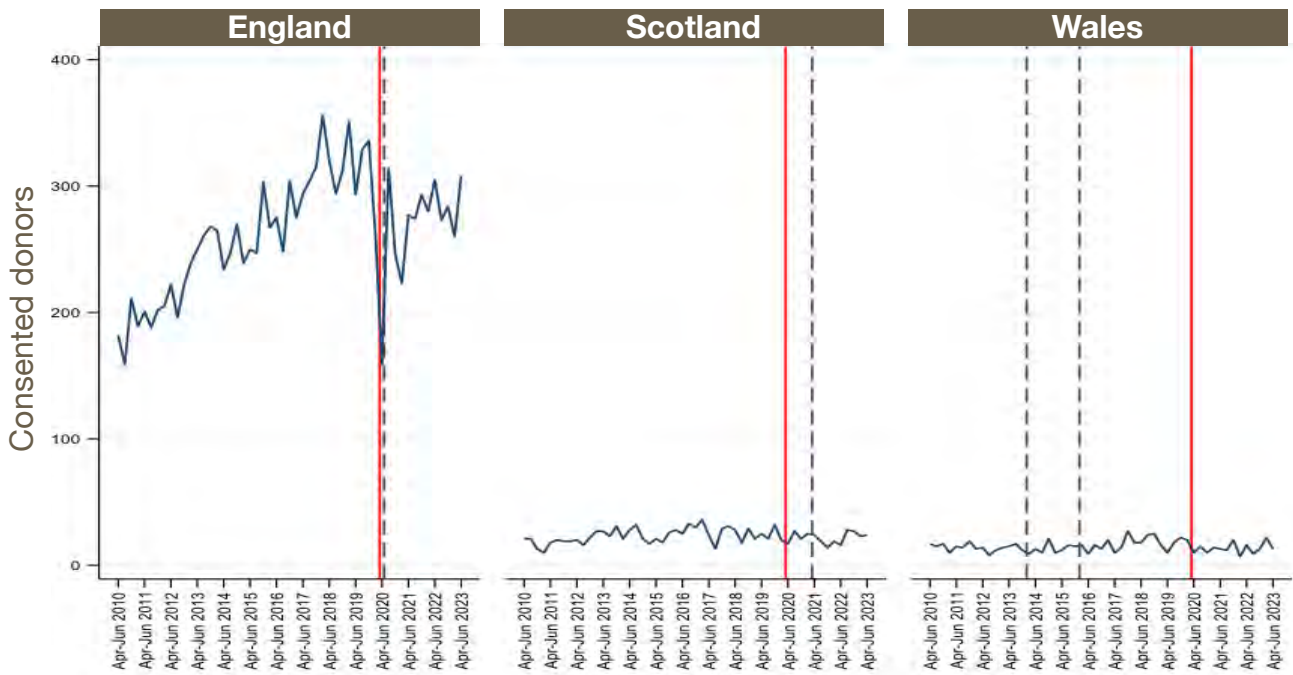
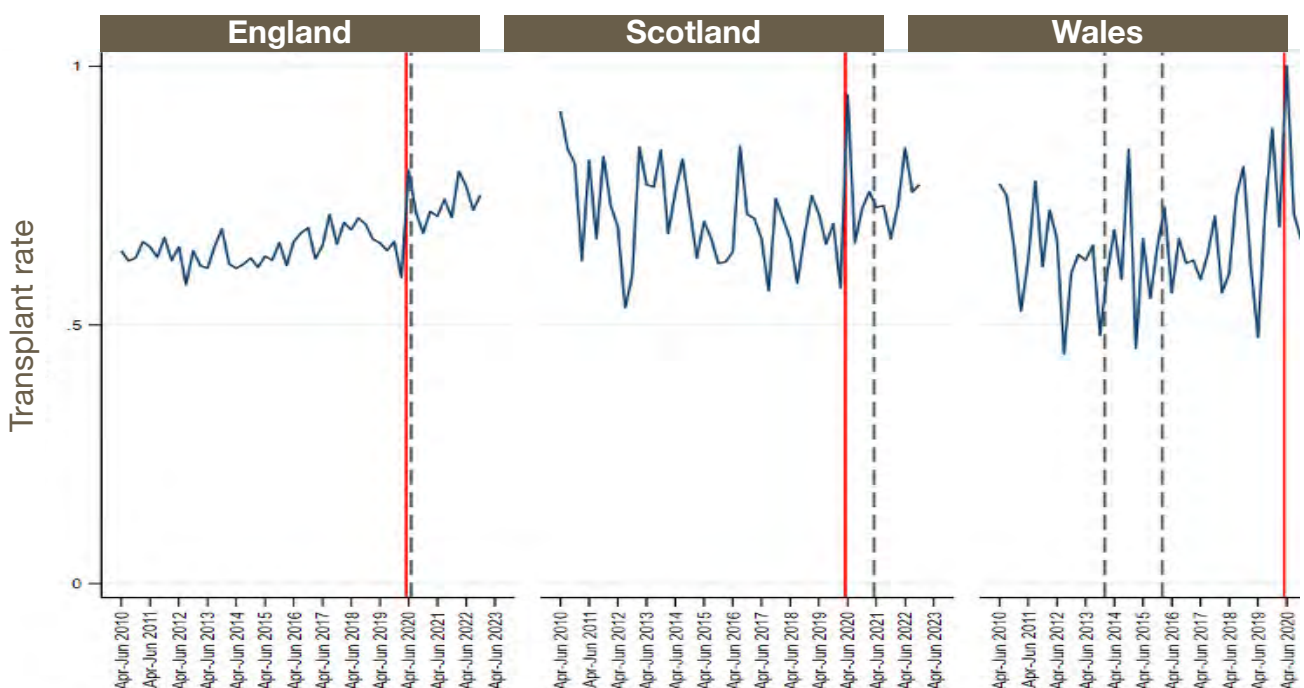
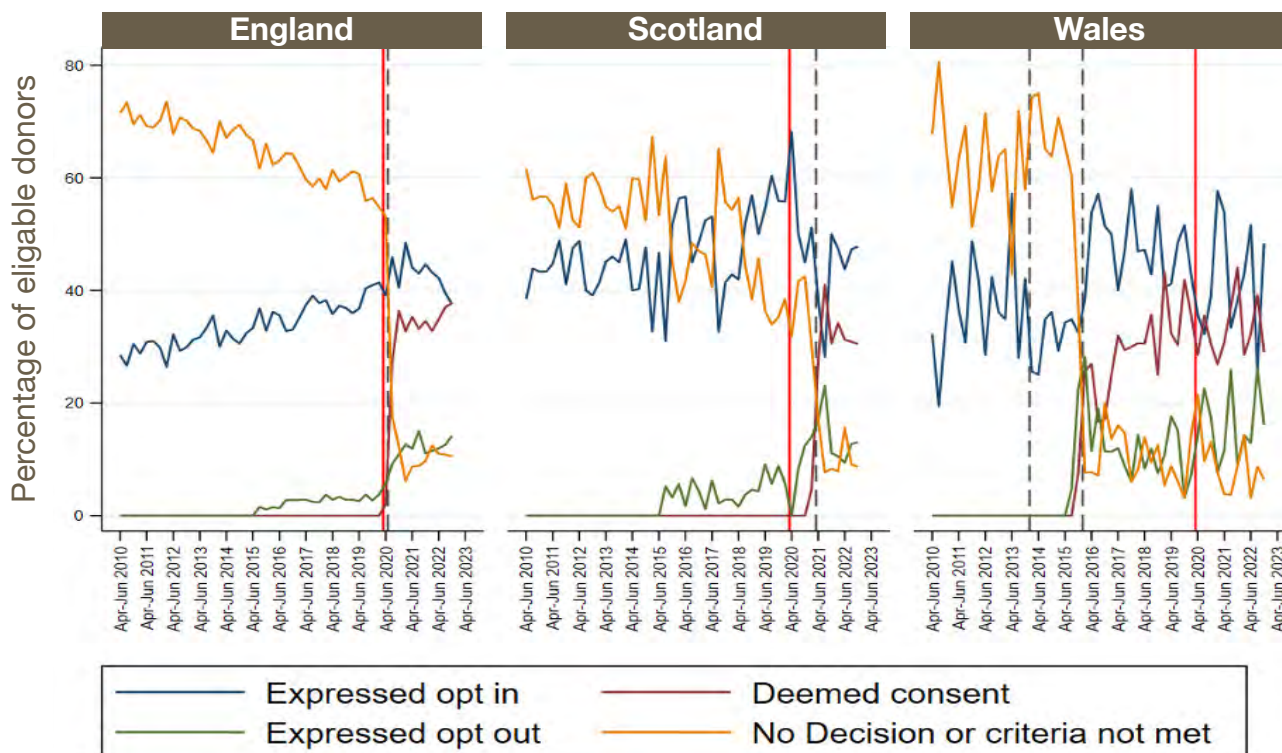


Figure A3: Transplant rate, defined as number of transplants divided by the number of consented donors by country



KEY: Red line: COVID-19 pandemic Dashed line: implementation of opt-out legislation

Figure A4: Consent grouping by country



To assess the change in patterns of consent associated with the law changes more directly, Figure A4 graphs the percentage of eligible donors in four consent groupings defined by whether the patient (a) had expressed an opt-in decision, (b) had expressed an opt-out decision, (c) met deemed criteria specific to each nation, or (d) had expressed no decision or the deemed criteria were not met. For each country, the proportion of donors in the last group dropped following the law change in that country. As one might expect, the proportion in the deemed consent group increased rapidly from zero after the law changes. However, in all three countries, this remained below 50% of the potential donors included in the analysis. In England, the proportion that had opted in was increasing before the law change but this has not continued after the law change which may be due to the law in theory providing a default of opt-in without the individual having to take any action.

Discussion

The findings of this study suggest that organ and tissue consent and donation rates have changed significantly over time, with an increase between 2014 and 2019 for the three countries combined, albeit this is dominated by changes in England. However, this trend was interrupted by major fluctuations during the COVID-19 pandemic. While the UK organ donation system shows signs of recovery from the pandemic, donation rates, the number of eligible potential donors and consent rates remain below their pre-pandemic levels. These findings are more likely to be attributable to the pandemic rather than the switch to deemed consent, given the trends observable in Wales which had moved to deemed consent long before the pandemic. The fact that consent rates in England had been increasing steadily before COVID-19 and the law change calls into question, to some degree, the assumed need for the change to deemed consent, especially since this was accompanied by warnings from experts that the change would be unlikely to be beneficial and could harm the organ donation system.[11-14]

During the pandemic, death rates were higher, while the number and proportion of deaths leading to organ and tissue donation and transplantation were lower. The number of eligible donors dropped sharply during the first wave of COVID-19, with a slow recovery in England. The number of consented donors from whom at least one organ is transplanted remains below pre-pandemic levels.

Although over the long term consent rates in deceased organ donation have been steadily increasing, year-on-year this figure remains highly volatile. Unexplained dips have on the whole been attributed to various national scandals within the NHS such as the Liverpool care pathway and the Alder Hey organs scandal, as well as more specific cases. While unrelated directly to deceased organ donation, most agree there is an inverse relationship between trust and a system which has been largely built upon the principle of altruism. Given the extraordinary context in which opt-out was implemented (a pandemic), and particular events which followed in England (Black Lives Matter, vaccine hesitancy, the death of the Queen, the Ukraine War, a cost of living crisis and an NHS consistently depicted in the media as at or beyond breaking point) it is perhaps unsurprising that the consent rates have not yet realised a sustained increase.

Overall, the findings suggest that a return to pre-pandemic levels in terms of number of eligible potential donors, consent rates and donation rates has not yet occurred, though the organ donation system shows signs of recovery from the COVID-19 pandemic. These results provide important insights into the lasting impact of the COVID-19 pandemic on organ and tissue donation rates and highlight the need for continued efforts to increase donation rates irrespective of whether the system is based on opt-out or opt-in principles.

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6

Subgroup differences in public attitudes, preferences and self-reported behaviour related to deceased organ donation before and after the introduction of the 'soft' opt-out consent system in England

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Summary

Background

In May 2020, England changed the law and introduced a 'soft' opt-out system of consent to organ donation with a view to increase consent rates. We aimed to learn more about the impact of the law change on attitudes and views likely to be relevant to consent to deceased organ donation between different population subgroups.

Methods

Mixed-methods design involving latent class analysis of data from twelve repeated cross-sectional surveys undertaken from 2015 to 2021 (n=19,011); analysis of the law change survey dataset collected quarterly from 2018 to 2022 (n=45,439); and interviews with purposively selected members of the public (n=30) with a focus on minority perspectives.

Results

Support for the principle of deceased organ donation remained high and stable in the general population (80%) but was 20% lower among ethnic minorities. From 2018-2022, an average of 58% of the general population was aware of the law change; this was lower among minority ethnic groups (31%). We identified four population subgroups: supportive donors (24% of the population); unengaged donors (22%); uncommitted donors (46%); and unsupportive donors (9%). Interview themes included the challenges of discussing organ donation decisions, balancing autonomy with family relations, targeted misinformation, frustrations at the lack of consensus between community leaders, limited understanding of what happens at the end-of-life care leading to organ donation and how this aligns with cultural values and preferences.

Conclusion

Implementation of the law change has not been associated to date with any change in public attitudes and preferences likely to influence consent overall or in minority ethnic groups in England. Uncommitted donors may benefit from encouragement to express their organ donation decision, and unengaged donors from attempts to address mis/information, confusion, and uncertainty. Interventions to raise the consent rate need to take account of the

(significant) role of the family as well as wider community influences on attitudes, preferences, and decision-making among certain minority (ethnic) groups.

The study

This chapter aimed to assess the public's knowledge, attitudes, reported behaviour and preferences towards deceased organ donation, and to learn more about the potential impact of the law change on public attitudes, preferences, and self-reported behaviour likely to be relevant to consent to deceased organ donation. We sought to answer the following research questions:

1. What is the level of awareness of organ donation publicity highlighting the change in the role of families in deceased organ donation decisions as a result of the law change?
2. Has the law change been associated with any changes in public support, reported behaviour, attitudes, and willingness to donate deceased organs since its implementation?
3. What are the barriers to deceased organ donation reported among the public in England?
4. Are there population subgroups with different preferences towards deceased organ donation in England, and may they benefit potentially from targeted policy interventions to encourage support for donation?

Theoretical framework

We applied the theory of rational choice to the analysis of the data. The theory assumes that individuals are rational and rely on information, reasoning and logic to make choices and decisions that give them the highest satisfaction.[1, 2] Thus, the choice that an individual makes when presented with options related to donating some or all their organs after they are dead will be rational depending on their positive or negative attitude towards organ donation. Rational choice theory suggests that individuals are in control of their decisions. Individuals do not make choices because of their unconscious drives, or because of environmental or cultural influences. The choice an individual makes to serve their best interest is dependent on their personal preferences and attitudes. For example, one person may decide that not smoking is the best choice for him/her for health reasons. Another person may choose to smoke to relieve his/her stress. Despite the choices being opposite, both individuals make these choices freely to get the best outcome for themselves.[3]

Although the law change was a manifestation of a strong value preference by legislators to move the default to everyone being opted-in unless they had specifically opted out, the media campaign was predicated on a value neutral assumption in relation to the decisions an individual could make. At the same time, there was nothing in the law per se that would necessarily make sharing a decision any easier. Accordingly, we modelled the willingness to donate organs subject to constraints set by the extent to which individuals were positively or negatively motivated towards organ donation. Rational choice theory was also used to analyse the qualitative interviews and integrate the quantitative and qualitative findings. This analytical and interpretative framework is presented in Appendix 4, Supplementary file 3.

Methods

Study design

We undertook a mixed-methods study involving analysis of both qualitative and quantitative data that were collected independently, analysed separately initially, and then brought together through mapping key findings onto the theoretical framework and developing an integrated narrative summary. The qualitative interview findings were also used to help explain some of the inter-ethnic group differences in findings from the latent class analysis of public survey data.

Data collection

Quantitative data

NHS Blood and Transplant's (NHSBT) national organ donation public survey data were shared with the research team. Data comprised (i) an Organ Donation Attitudinal Tracker Survey dataset of twelve repeated cross-sectional surveys collected, roughly eight months apart, from August 2015 to October 2022, and (ii) a Law Change Survey dataset of 32 waves of repeated cross-sectional data collected quarterly from 2018 to 2022 to gauge the level of public awareness of dedicated campaigns to inform the general public about the law change. Of note, the implementation of the media campaign was cancelled in March 2020 due to COVID-19 and a second post-implementation media campaign, entitled 'Leave Them Certain' was phased in from 2022.

The survey participants were recruited from Kantar's [4] online panel consisting of approximately 30,000 adults aged 16 years and over who have consented to take part in a range of surveys. Survey participants were recruited by quota sampling with random locational sample selection. Each quota was set based on national Census data on age, education, and geographical region. Different quotas were set for each survey to represent the changing population structure. Respondents were invited by email to answer the survey online. They were offered small financial rewards to complete the survey. The samples were weighted to be representative in terms of age, ethnicity, and social class of the adult population of England aged 16 years and above.

The questionnaire for the Organ Donation Attitudinal Tracker Survey included questions that elicited respondents' choices regarding their willingness to donate organs after death (Box 1).

Box 1: Questions for the analysis

Which of the following best describe your personal feel about organ donation after death?

Choice options:

1. I would definitely donate all of my organs if possible.
2. I would definitely donate some of my organs if possible.
3. I would consider donating all of my organs.
4. I would consider donating some of my organs.
5. I don't know if I would donate my organs.
6. I definitely wouldn't donate my organs.

Options 1,2,3,4 were associated with additional choices of motivations for why they would donate their organs(selecting from agree strongly to disagree strongly, and don't know) to these statements:

- Someone I love could one day need a transplant
- My organs will only go to waste when I die
- I would accept an organ transplant so I should be prepared to donate one.
- I feel a social responsibility to donate my organs
- It would be improving and saving the lives of others for those who need them
- It makes me feel good to know I could be helping someone when I die
- Donating would help my community
- I have personal experience of organ donation among my family and friends who have been donors or recipients

Continued on following page

Options 3, 4, 5, 6 were associated with additional choices of barriers for why they wouldn't donate their organs (selecting from agree strongly to disagree strongly, and don't know) to these statements:

- I worry my organs wouldn't be used for transplant
- I'm too old – my organs wouldn't be of any use
- I worry my family might be upset if I donate my organs
- I worry hospital staff might not do their best to save my life if they knew my organs were available for donation
- I want my body to be whole when it is buried or cremated
- I worry that organ donation will delay the burial or cremation time
- I think organ donation is against my cultural or religious/faith
- I don't want to donate to someone who doesn't deserve it
- I don't want to think about my death
- I don't know enough about it
- I am against organ donation in principle
- I do not agree with an opt-out system for organ donation

We excluded all respondents who did not provide their ages. The total sample for each of the Attitudinal Tracker Survey waves used in the analysis ranged from 997 to 2151 with an average sample of 1,710 over the survey period (Supplementary file 4). The total sample for each of the survey waves used in the analysis of the law change data ranged from 1,261 to 2,556 with an average sample of 1,420 over the survey period (Appendix 4, Supplementary file 5).

Qualitative data

We used the population profile of the NHSBT Organ Donor Register to guide construction of a purposive sample of potential participants to target for interviews. We also focused on groups less represented in previous research, and those groups our advisory group particularly wanted us to include, including people who had opted-out on the organ donor register, those not supportive of the change in law, and individuals from particular faith groups and non-white ethnicity. We developed a topic guide asking about their views on organ donation, the law change, NHSBT's publicity, specific ethnic and/or religious views on organ donation and the impact of COVID-19 (Appendix 4, Supplementary file 6).

Recruitment was a mix of convenience and snow balling via our patient and public network (discussed in the PPIE section below). Interviews were a mix of remote (due to COVID-19 telephone or Teams/Zoom) and face-to-face, one-to-one, with the exception of three small group interviews, ranged between 50-80 minutes and were undertaken by an experienced researcher (LMcL).

Data analysis

Statistical analysis

We used Stata Standard Edition version 18. Frequency distributions, weighted percentages, means, and standard deviations were used to describe the characteristics of respondents for the organ donation attitudinal tracker survey and the law change survey. Due to limitations in data, minority ethnic groups in this analysis refer to all respondents who self-described as having a non-white ethnic background.

Using a stated preference technique,[5] and assuming respondents had freely made choices from the options presented to them as shown in Box 1 regarding organ donation, we modelled individuals' preferences for deceased organ donation subject to their level of motivation or barriers (demotivating factors) to deceased organ donation using data from the attitudinal tracker survey. The motivating factors included altruism (e.g. saving lives, the good feeling that other lives could be helped after death, etc.), benefits (e.g. a loved one could benefit, avoidance of waste, seeing the need to donate based on being willing to receive a transplant, personal experience among family and friends), and social (social responsibility, donating will help the community). The demotivating factors included psychological (personal decisions-wanting the body to be whole when buried or cremated, emotional appeal-don't want to think about death; presumptions – I'm too old-my organs will not be of any use), lack of trust (worry that hospital staff might not do their best if they knew patients' organs were available for donation, worry that the donated organs would not be used for transplantation), and cultural (family support, worry the family might be upset by deceased organ donation, or that it is against their cultural and religious views) (see Box 1).

A key assumption of the choice options within a stated preferences approach is that the activities of interest (in this case consent to donating organs) can be described by their attributes and that an individual's evaluation of their options depends on the levels of these attributes. Individuals' responses to questions related to their motivations to donate their organs, and reasons why they would not donate their organs (see Box 1) were used to generate mean motivation scores and assign them to each of the six choice options in Box 1. We recoded the Likert-scale of the motivating factors such that those who selected 'strongly agree' to the statements were given a higher score (i.e. strongly agree = 5, agree slightly = 4, neither agree nor disagree = 3, disagree slightly = 2, and strongly disagree = 1). Reversed codes were used in the case of barriers/demotivating factors. Thus, the more an individual was willing to donate deceased organs, the higher their motivation score, and vice versa.

We used a latent class regression model to estimate and identify subgroups of the population that have a similar inclination towards deceased organ donation. The log-likelihood function maximized in the estimation is given as:

$$\log L = \sum_{n=1}^N \sum_{j \in B} y_{nj} \log \sum_{s=1}^S \left[\frac{\exp(\beta_s^{ASC_{js}} + \beta_s X_{njs})}{\sum_{h=1}^J \exp(\beta_s^{ASC_{hs}} + \beta_s X_{nhs})} \right]$$

Where:

J is the total number of alternative choices, $J=1, \dots, 6$; and \hat{J} denote particular choices among the alternatives.

y_{nj} is an indicator for whether individual n chooses j^{th} alternative within the choice set. This is equal to 1 (chosen) or 0 (not chosen), and we assume that an individual n will choose (\hat{J}) in preference to other alternatives (h) if and only if $U_{nj} > U_{nh}$, where U_{nj} is the level of motivation towards deceased organ donation.

s identifies a given subgroup among the S subgroups (latent classes);

$\beta_s^{ASC_j}$ is a vector of coefficients of the group-specific, alternative-specific constants for alternative \hat{J} .

X_{nj} is a vector of observed variables including the level of motivation for deceased organ donation, and socio-demographic characteristics; the estimates for their coefficients, β_s , are determined by maximizing the log-likelihood function.

To estimate the model, we first conducted statistical tests using the minimum of the Akaike Information Criterion (AIC), and the Bayesian Information Criterion (BIC) estimates to determine the number of subgroups, S , within the population to be included in the model (6-9). The tests were run on all twelve waves of survey data consecutively (see Table 1, and supplementary Table 4). The results showed a minimum of two subgroups and a maximum of four subgroups within the population with similar inclinations towards deceased organ donation. We therefore chose to present the results from the data set with most diverse population subgroup responses, wave 10, because these results may be especially useful for designing targeted interventions to support the new systems of consent to organ donation in the UK. The differences in association of the characteristics of individuals belonging to different subgroups of the population were determined using a t-test and Pearson's χ^2 test.

Qualitative analysis

Interviews were transcribed verbatim and uploaded into NVIVO version 12.[10] Thematic analysis was undertaken.[11] After familiarisation through reading field notes and re-reading transcripts, coding was undertaken to identify actions and behaviours following implementation of the law change, motivations to donate or not, media awareness (including 'nudges'), differences between ethnic minority perspectives, (barriers to) talking about and normalising organ donation as part of end-of-life care and suggestions to promote organ donation. The themes were then shared with a multi-disciplinary team of experts and a range of lay audiences to assist in developing a consensus set of findings. Findings were mapped against the theoretical framework.

Validity, reliability, and rigour

For the statistical analysis an additional layer of rigour was applied by comparing our analysis of the survey data to that of NHSBT. We used four quality criteria (credibility, dependability, confirmability, and transferability) to assess the qualitative analysis.[12] For example, interim findings were shared at several meetings with a multi-disciplinary advisory group which had opportunity to comment on the content and advise on ways to address gaps in the data and what might be further strengthened. The research team was also able to present the findings at events specifically focused on inequalities in organ donation to test their transferability.

Reflexivity

The research team comprised of professional and lay researchers with expertise in health and social care, qualitative and quantitative research methods, and experience of previous research into organ donation. Differences in interpretation were resolved through regular team meetings and discussion.

Patient and Public Involvement

We developed a wide network of patient and public involvement and engagement for this study including organisations and individuals representing ethnic minority general health and social issues, bereavement care services, and charities supporting donor families and transplant recipients, live donation, and blood donation. We also had a public member with experience of organ donation as a carer as a full member of the research team. This approach facilitated the recruitment of members of the public for interviews, and provided additional contextual information, as well as input into analysis, interpretation, and integration of findings.[13, 14]

Results

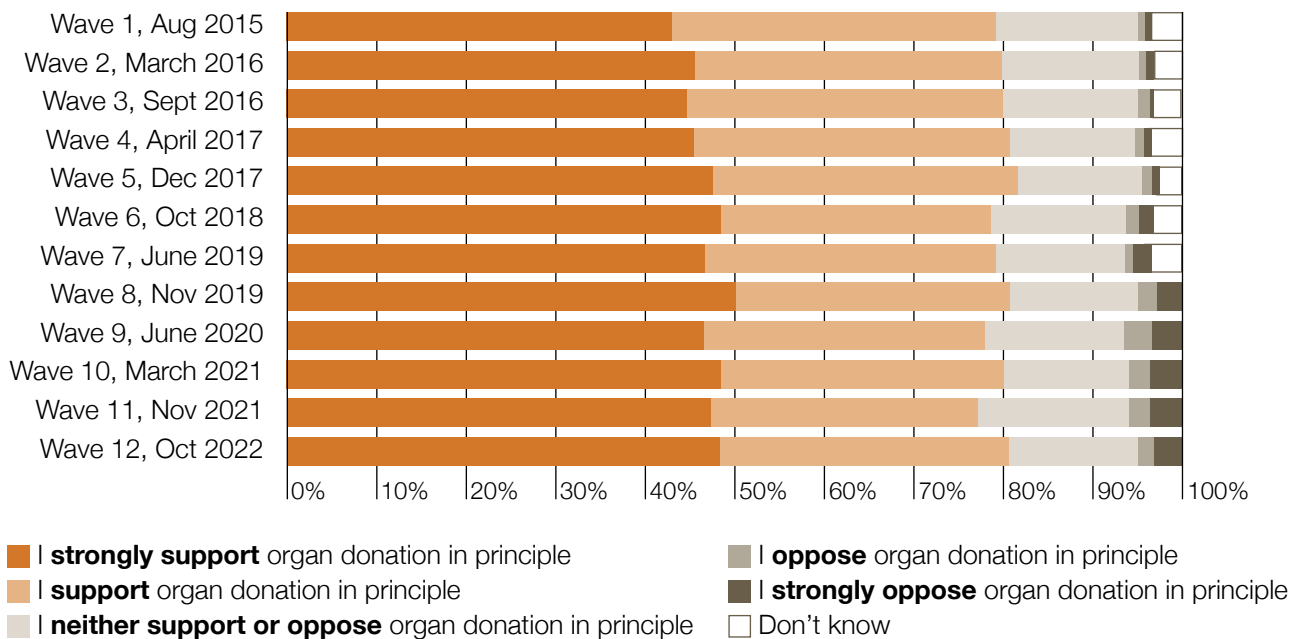
Quantitative results

Public attitudes and reported behaviour towards deceased organ donation

The results from the NHSBT Organ Donation Attitudinal Tracker Survey data showed that public support (those who reported being strongly supportive and/or supportive) for deceased organ donation in principle remained high and relatively stable over each wave,

with around 80% of the population in England in support (Figure 1). This was similar before and after the law change, except in wave 11 (November 2021) where the proportion in support of organ donation was about 2% lower.

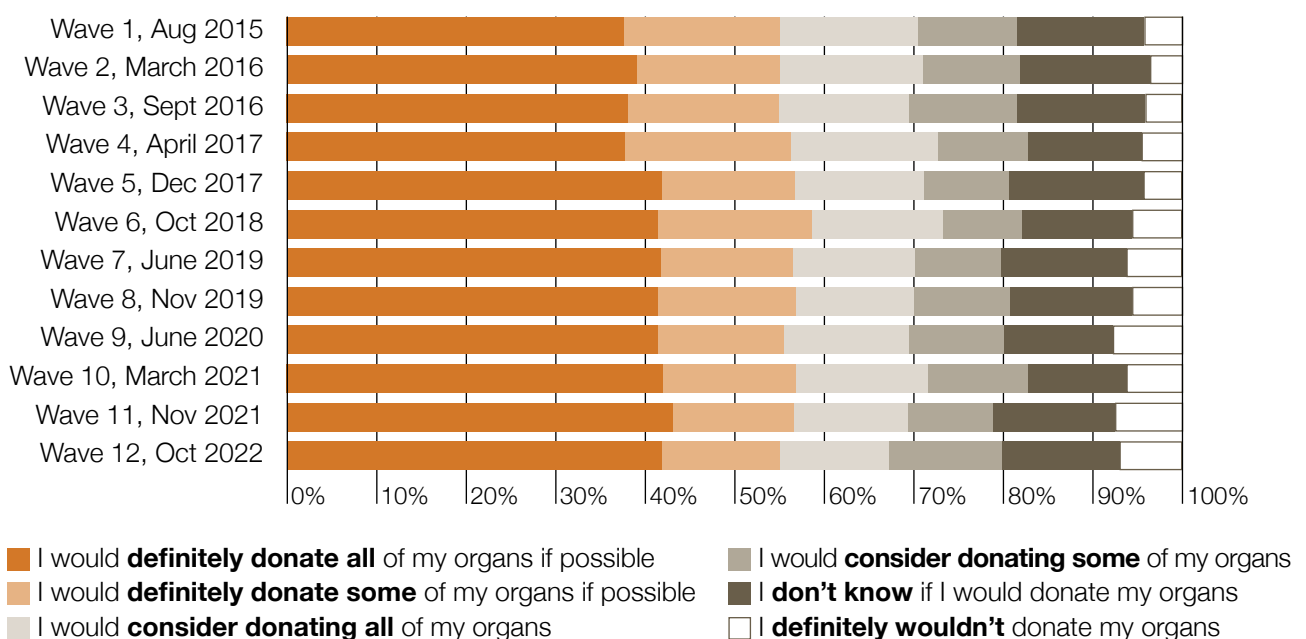
Figure 1: Public support for organ donation in principle



Source: NHSBT Organ Donation Attitudinal Tracker survey data (2015-2022).

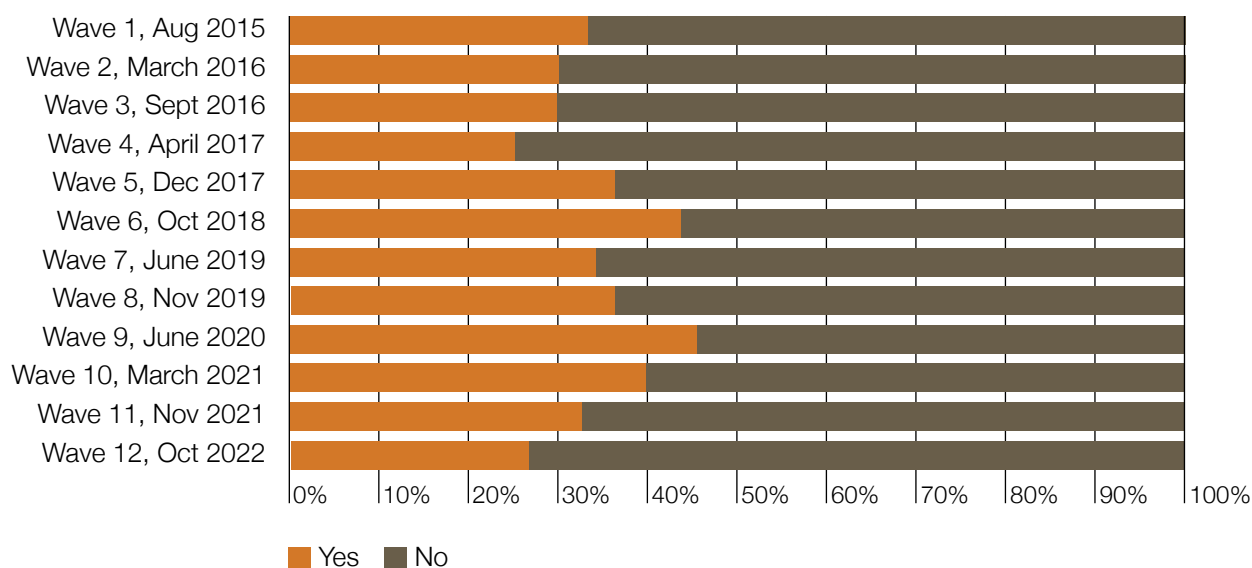
However, the proportion of the public that reported that they were willing to donate all or some of their organs after death was lower than those supporting organ donation as a general principle. On average, 56% of the population reported a willingness to donate all or some organs, 25% reported they would consider donating all or some organs, and the remaining proportions reported either that they were unsure or would not want to donate organs after death (19%) (Figure 2).

Figure 2: Willingness to donate deceased organs among the public



Source: NHSBT Organ Donation Attitudinal Tracker survey data (2015-2022).

Figure 3: Public awareness of general organ donation publicity (those who had ever seen, read or heard a news item, advert, publicity, or other type of information on organ donation)



Source: NHSBT Organ Donation Attitudinal Tracker survey data (2015-2022).

There was relatively low public awareness of the general organ donation publicity (i.e. proportion who had seen, read or heard the news item), with 36% of the population aware. The lowest proportion of public awareness of organ donation publicity was reported in wave 4 (April 2017) at 26%; while the highest level of awareness was reported in wave 9 (June 2020) at 45%. The results show a decreasing trend in public awareness of organ donation publicity after the law change. The proportion of awareness declined by about 6% on average from 45% in wave 9 (June 2020) to 27% in wave 12 (October 2022). Overall awareness of the general organ donation publicity was 10% higher among the minority ethnic groups compared to the ethnically white groups. The top five sources of information were television (21%), articles in newspaper or magazine (10%), Facebook, Twitter, Instagram, or other social media platforms (9%), hospital, GP surgery or clinic (8%) and the radio (7%) (See Appendix 4: Supplementary file 6).

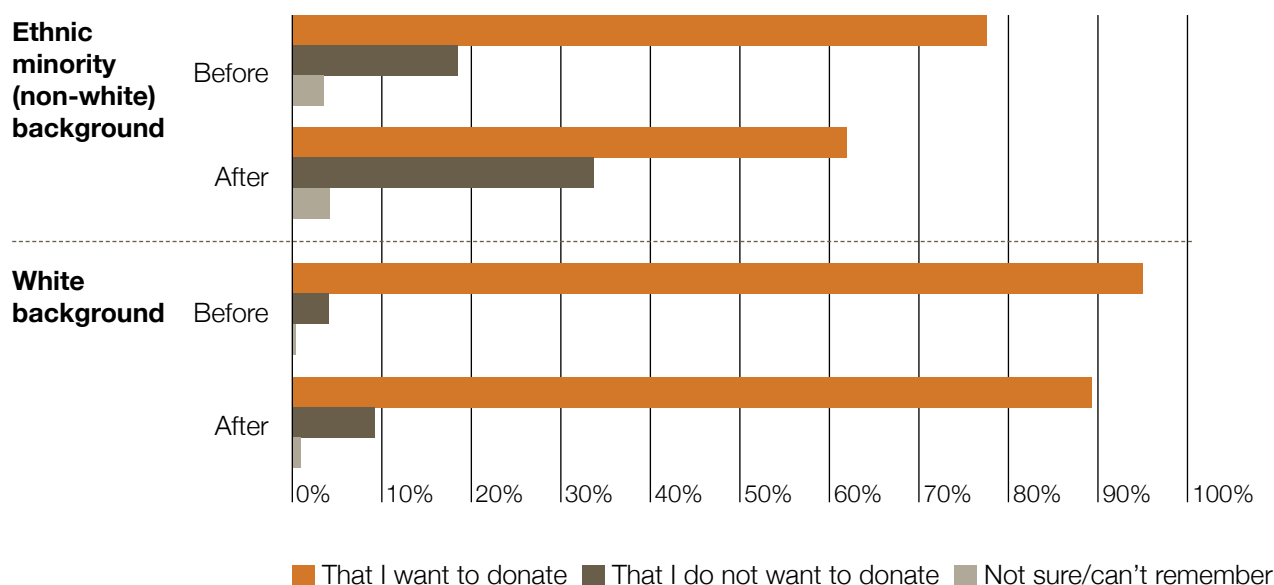
Awareness of the law change

Results from analysis of additional surveys conducted to assess awareness of the new law and the changes to the organ donation system in England show that 58% of the public was aware of the law change (31% among minority ethnic groups) (see Table 3 in supplementary file). The top five sources of information about the law change were Instagram (22%), online articles, news stories or adverts (16%), radio (16%), newspapers (15%) and television (14%) (see Supplementary file 7).

The Organ Donor Register

On average, 42% of the public had registered a decision on the organ donor register. Of those, 89% had registered a decision to donate and 10% had registered a decision not to donate. One percent did not disclose their registered decision. Figure 4 shows the reported decisions registered on the organ donor register comparing white and non-white ethnic groups before (November 2019) and after the law change (June 2020 to October 2022). The results show a similar trend for both groups, except that, in all instances, the proportion registering to donate among those who self-described as ethnically white was higher compared to those in the non-white group.

Figure 4: Reported decisions registered on organ donor register



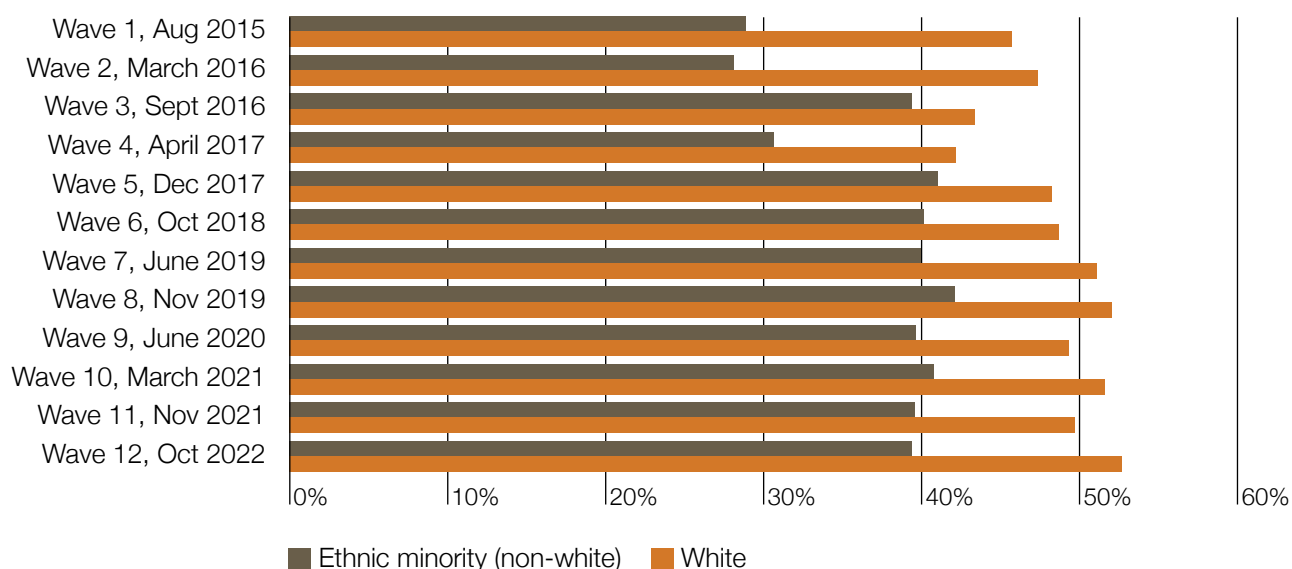
Note: results for before the law change were based on available data from wave 8 (November 2019), and that of after the law change (June 2020 to October 2022) was based on average responses for four waves (waves 9-12).
 Source: NHSBT Organ Donation Attitudinal Tracker survey data (2015-2022).

For both groups the proportion registering a decision to donate fell after the law change, by about 16% in the ethnic minority group, and 5% in the ethnically white group. Also, the proportion registering a decision not to donate increased among both ethnic groups after the law change, an increase of about 15%, among the non-white minority group, and 5% among the white group.

Talking about organ donation

The results in Figure 5 show a rising trend in the proportion of the public reporting that they have had conversations about organ donation, but this did not appear to have been sustained in the period following the law change.

Figure 5: Proportion of individuals who reported having had a conversation with a close relation or family member by survey wave



Source: NHSBT Organ Donation Attitudinal Tracker survey data (2015-2022).

Latent class (subgroup) results

To identify subgroups of the population in terms of their views and potential behaviours, and to help identify which groups might benefit from interventions designed to encourage them to consider deceased organ donation more positively, subgroup analysis was undertaken. Table 1 shows the results of the statistical tests used to identify the number of subgroups within the population with different inclinations towards deceased organ donation using survey wave 10, chosen for having the most diverse population subgroup responses (see Table 4 in supplementary file for statistical test results for other survey waves). The corresponding number of latent classes/subgroups where the minimum of both the Akaike Information Criterion (AIC) and the Bayesian Information Criterion (BIC) was achieved was four.

Table 1: Test results to identify optimal number of population segments/subgroups, wave 10, March 2021

Number of classes/subgroups	Log-likelihood function	Number of parameters	Akaike Information Criterion (AIC)	Bayesian Information Criterion (BIC)
2	-3677.5	3	7361.00	7378.06
3	-3654.24	5	7318.47	7346.91
4	-3644.62	7	7303.23	7343.04
5	-3644.61	9	7307.23	7358.41
6	-3644.62	11	7311.23	7373.79

We therefore estimated a four-subgroup latent class model. The regression results (Table 2) show latent class probabilities of 24%, 22%, 46% and 9%, respectively. These are the probabilities that a randomly chosen adult (16+) in England would belong to the first, second, third or fourth subgroup, respectively. The estimated latent class regression model has two main components. The first part of Table 2 presents the utility/motivation coefficients associated with deceased organ donation, and the second part shows the subgroup membership coefficients, capturing the impact of the characteristics on the probability of belonging to a particular subgroup. The membership coefficients for the fourth subgroups are normalized to zero to allow the remaining coefficients of the model to be identified in the estimation process.[8]

The utility coefficients of motivation were all statistically significant at the 1% level for all the four subgroups of the population with similar preferences towards deceased organ donation. However, the motivation coefficients for subgroup 1 and subgroup 3 were positive and those of subgroup 2 and subgroup 4 were negative. This indicates that individuals in subgroup 1 and subgroup 3 were more positively motivated to donate deceased organs, while those in subgroup 2 and subgroup 4 were less positively motivated to donate deceased organ(s). Comparing the magnitude of the coefficients for the motivated subgroups, subgroup 1 placed more value on deceased organ donation (6.99([3.845,0.111]) than subgroup 3 (0.56 ([0.383, 0.087])). Comparing the magnitude of the coefficients for the less motivated subgroups, individuals in subgroup 2 were less motivated to donate deceased organs (-1.03[-1.207, -0.930]) compared to those in subgroup 4 (-0.67[-0.858, -0.478]).

The regression results of the subgroup membership equation show that individuals in subgroup 1 were more likely to be older and female; less likely to be from North West England, North East England, Yorkshire and Humber, West Midlands, East Midlands and the South of England(excluding London); more likely to be white; less likely to be Christian or Muslim; much more aware of general organ donation publicity; more likely to support organ donation in principle; and more likely to be aware of the organ donor register, than those in subgroup 4 (Table 2).

Table 2: Four-subgroups latent class estimates for preferences towards deceased organ donation

	Subgroup 1: Cooperative donors	Subgroup 2: Sensitive donors	Subgroup 3: Ambivalent donors	Subgroup 4: Non-donors
	Coefficient [95% CI]	Coefficient [95% CI]	Coefficient [95% CI]	Coefficient [95% CI]
Share of population	23.8%	21.5%	45.6%	9.1%
Utility function – motivation towards deceased organ donation				
Motivation	6.99***[3.845,10.130]	-1.07***[-1.207,-0.930]	0.59***[0.383,0.799]	-0.67***[-0.858,-0.478]
Class/subgroup membership function				
Age	0.05[-0.011,0.111]	0.09**[0.007,0.170]	0.03[-0.035,0.087]	
Sex (Female)	4.92**[0.831,9.004]	***19.90[15.165,24.638]	5.22**[1.132,9.312]	
Region				
North West England	-9.42***[-14.656,-4.186]	-24.59[-29.631,-20.899]	-10.65***[-15.828,-5.468]	
North East England	-3.62[-9.655,2.419]	-21.02***[-26.871,-15.159]	-5.36**[-11.374,0.663]	
Yorkshire and the Humber	-8.72***[-14.234,-3.210]	-25.26***[-29.631,-20.899]	-10.25***[-15.719,-4.775]	
West Midlands	-8.94***[-15.151,-2.719]	-9.99***[-16.178,-3.806]	-10.01***[-16.247,-3.777]	
East Midlands	-11.38***[-16.722,-6.046]	-12.89***[-18.331,-7.454]	-12.29***[-17.561,-7.014]	
East Anglia	0.05[-7.695,7.795]	-0.47[-8.282,7.347]	-0.35[-8.030,7.328]	
East Midlands	-11.38***[-16.722,-6.046]	-12.89***[-18.331,-7.454]	-12.29***[-17.561,-7.014]	
South East England	-6.32**[-11.159,-1.485]	-7.13***[-12.202,-2.062]	-7.22***[-12.022,-2.426]	
South West England	6.24[-2.489,14.975]	5.51***[-3.144,14.164]	5.07[-3.659,13.807]	
Ethnic background				
White	10.51**[6.246,14.776]	9.59***[5.366,13.807]	9.97***[5.761,14.184]	
Religion				
Christianity	-3.82***[-6.654,0.984]	-4.28**[-7.317,-1.251]	-3.29**[-6.127,-0.447]	
Islam	-35.28[-29.631,-20.899]	6.68***[1.548,11.809]	3.37***[-0.746,7.490]	
Organ donation (OD)				
OD publicity awareness	7.40***[2.954,11.853]	6.98***[2.394,11.575]	7.17***[2.749,11.585]	
Support for OD	22.53[-155.309,200.362]	-11.67***[-19.219,-4.130]	7.25***[4.026,10.483]	
Awareness of ODR	7.29***[4.264,10.316]	5.32***[2.095,8.545]	6.60***[3.548,9.645]	
Constant	-26.23[-204.068,151.607]	-6.84***[-11.828,-1.845]	-7.66***[-12.263,-3.050]	
Log likelihood	-3192.23			
Observations	2180			

Note: coefficient significant at 5% ($p < 0.05$) (**); 1% ($p < 0.001$) (***). The membership function coefficients for subgroup four are missing because they are the comparison subgroup. Figures in parenthesis are the 95% confidence intervals. OD represents organ donation. ODR represents organ donor register.

In comparison to individuals in subgroup 4, those in subgroup 2 were more likely to be older, female, from all regions except South West England and London, and ethnically white. They were less likely to be Christians but more likely to be Muslims, more likely to be aware of organ donation publicity and the organ donor register, but less supportive of deceased organ donation (Table 2).

Comparing individuals in subgroup 3 to those in subgroup 4, those in subgroup 3 were more likely to be older, female, living in any regions other than South West England and London, ethnically white, less likely to be Christian but more likely to be Muslim, aware of organ donor publicity and the organ donor register, and supportive of organ donation in principle (Table 2).

Summary of characteristics of individuals belonging to the four deceased organ donor subgroups

Further analysis showed that most of the individuals in subgroup 1 were willing to donate all or some organs when deceased, totally supported organ donation in principle, were highly aware of organ donation publicity and the organ donor register, had registered a decision on the organ donor register and had held conversations with close relations about their decision and intentions regarding deceased organ donation. Also, most of them were ethnically white. Their average age was 52 years. Based on the positive coefficient of motivation towards organ donation, we labeled this subgroup of the population as “supportive donors”. This subgroup appears strongly to support deceased organ donation and is unlikely to be swayed in their views (Figure 6).

Figure 6: Summary characteristics of individuals belonging to the four deceased organ donor subgroups (See Table 5 in supplementary file for underlying statistics)

	Subgroup 1 Supportive donors (24%)	Subgroup 2 Unengaged donors (22%)	Subgroup 3 Uncommitted donors (46%)	Subgroup 4 Unsupportive (9%)
Willingness	Willing to donate	Don't know/Not willing to donate	Will consider donating	Don't know/Not willing to donate
Support	Total support for organ donation in principle	Indifferent about support for organ donation	Generally, have support for organ donation	Generally, oppose organ donation in principle
Awareness	Very much aware of organ donation publicity and organ donor register (ODR)	Not aware of organ donation publicity and organ donor register (ODR)	Aware of organ donation publicity and organ donor register (ODR)	Not aware of organ donation publicity and organ donor register (ODR)
Registration/discussions	Registered a decision on ODR/ held conversations	Not registered on ODR/no conversations	Not registered on ODR/no conversations	Not registered on ODR/no conversations
Ethnicity	Majority: ethnically white	Majority: ethnic minority	All ethnicity	Majority: ethnic minority
Age	Average: 52 years	Average: 42 years	Average: 40 years	Average: 39 years

Most of the individuals in subgroup 2 either do not know whether they will be willing to donate deceased organs or are not willing to donate; are indifferent about organ donation in terms of support in principle; and most were not aware of the organ donation publicity or the organ donor register. This subgroup was dominated by individuals from minority ethnic groups, with an average age of 42 years. We labeled this subgroup as “unengaged donors” based on these characteristics and the negative coefficient of motivation towards deceased organ donation.

Generally, individuals in subgroup 3 reported that they would consider donating their organs after death, supported organ donation in principle, were aware of the publicity about organ donation and the organ donor register but most of them had neither registered a decision on the organ donor register nor had a conversation regarding their preference with close relations. This subgroup was made up of individuals from all ethnic backgrounds with an average age of 40 years. This subgroup was labeled “uncommitted donors” based on their characteristics and the positive coefficient of motivation towards deceased organ donation.

The fourth subgroup was labeled “unsupportive donors” as individuals in this group generally do not know or are not willing to donate organs after death, as in the case of the sensitive donor group. However, individuals in this subgroup generally oppose organ donation in principle and are not aware of the organ donation publicity and the organ donor register. This subgroup was dominated by individuals from ethnic minority groups with an average age of 39 years.

Public perspectives from interviews

We undertook interviews with 30 participants some of whom had played voluntary roles to promote deceased organ donation from a public perspective. The majority were female (n=19), of Black or Asian ethnicity (n=24), Muslim (n=18) and were either uncertain of their organ donation registered decision or had opted out (n=24) (Further demographic details are reported in Table 6 in the supplementary file). We report eight key themes which relate to potential issues or concerns which may be contrary to the intentions of the law change.

1. Feeling it would be a (very) difficult conversation to have

For many individuals in ethnic minority groups, sharing their organ donation decision was perceived as a very difficult conversation to have with (some members of) their family. Even people who were strongly in favour of organ donation as a rational choice were still reluctant to have a conversation with their immediate family and it was very common to delay or put off registering or talking about organ donation with family member(s).

“It’s easier to go out into the world, but when you’re dealing with your own family, I’m acutely aware of how hard it is, I mean I was shocked by his [Son] response, he [son] was just dead against it, he [son] kept saying mum no, no, no, I want you to know I will be fighting it if anything happens to you. But what I couldn’t get was a definitive answer as to why, I couldn’t get past that initial anger and frustration. And I’ve not heard him talk so strongly really about anything pertaining to me. Now I’ve got this dilemma, I don’t want to hurt my family...but for the sake of not causing upset I’ve just kind of backed down. I may venture back to it, but I feel now is not the right time, he is expecting a child, so I’ve left it for now.” (Female, Black, Christian, 137)

2. Balancing what individuals want with what their family expects

The autonomy and personal choice in life assumed to be in place by the law change (i.e. giving decisions to individuals rather than their families) do not necessarily easily translate to families where decisions are often shared or hierarchically made. Individuals who were not necessarily seen as final decision makers in many situations (e.g. younger people, women, second or third siblings, etc.) frequently encountered barriers when trying to share their personal choice or make their organ donation decision known. For some people, the rational choice was not theirs to make, and the choice belonged to their family or wider community.

“I registered, I was so happy and then I got a message – “now it’s time to tell your family” – I thought really!? Why, why are you making me do this – is this not enough? Especially for us in an African setting, women are a bit submissive to their husbands and so for every decision that you take it’s got to be like both of making this decision.” (Female, Black, Christian, 138)

“It doesn’t matter what I do, I can register or not, but I know if the time came my husband wouldn’t allow it – it is him that needs convincing not me.” (Female, White, Muslim, 242)

“It is probably something we need to talk about, it has to be a family environment because I’ve got 4 siblings there are 5 of us and from the South Asian Tradition it is the eldest sibling that will carry the burden and make decisions. So, if my other brother knows exactly what mum and dad want, their wishes will be carried through, but it is a very intimate conversation.” (Male, Asian, Sikh, 156)

3. Feeling unsure and ill-informed about organ donation

People involved in paid or unpaid roles to help promote organ donation highlighted the importance of individuals sharing their choices by making them known through the Organ Donor Register and/or encouraging them to talk about their organ donation decision with relatives, but many felt ill-equipped to answer more detailed questions about organ donation such as how, when, and where deceased organ donation comes about. This additional information is often needed by people in order to make a rational choice concerning organ donation. People who were much more reluctant to donate their organs remained so and many people tasked with promoting organ donation after the law change still felt they had insufficient knowledge, access, and communication skills to reach those harder to engage groups and individuals.

“The other thing is the question of how this is done, I had a guy ask me, “now if I want to donate my heart won’t they kill me faster because they want to have my heart ticking” So what is it I’m donating, at what point in time, when would it happen, we need to do so much more work to sensitise the whole process – people don’t understand just how much we don’t know, we are just getting our heads around blood for god’s sake and now you want us to do this!” (Female, Black, Christian, 138)

There were frequently deep-seated cultural attitudes which influenced views and perceptions of deceased organ donation, often related to associations with trafficking organs and dismembering of bodies. These lay perceptions and views (particularly from people from a black ethnic group) were perceived as rational by individuals, and they negatively influenced their choice and decision to donate their organs.

“It’s, dark, for us it is to do with witchcraft, with sacrifice, people go out get money so they can donate to their witchdoctors. I even remember growing up my mother would say if I don’t come home immediately somebody’s gonna cut your ear off, somebody will take your eyes. So, in Africa this is what it is witchdoctors who need eyes and breasts!” (Female, Black, Christian, 138)

4. Wanting to refocus on the high need for transplants amongst minority ethnic groups

Most people from ethnic minorities felt that messaging related to deceased organ donation needed to increase the focus on the unmet need for transplants, especially in relation to people from Asian ethnic backgrounds. People wanted the messages to include the high costs of dialysis compared with transplants, the waiting list for organs and the consequences when people are unable to get an organ. Many people from these minority ethnic groups felt that people would be able to more easily make a choice to donate their organs if they knew that more people within their community needed transplants and that they would benefit and have a better quality of life if they received a transplant.

“I mean it is our people that our dying, I didn’t know that, and that is the message that needs to be out there.” (Female, Christian, Black, 137)

“A friend of mine is on dialysis, refusing an organ, I said to him do you know how much you are costing me!? I think if more people knew the real scale of the problem, they would help, there are few people in the world who don’t want to help, very few.” (Male, Asian, Hindu, 149)

“I’ve asked so many questions to people and they’ve all said, “It’s not affecting us, so why should we bother?”” (Female, Asian Muslim, 242)

5. Lacking in trust and the need to build it

Misunderstandings, misinformation, and fake news (that all seemed rational to individuals, but which negatively influenced their organ donation choice) were very commonly discussed, often fuelled by historical mistrust of state agencies (including the NHS) among people from minority ethnic groups and certain faith groups especially Muslim or Jewish people. Some people thought wrongly that the law had been modified to include families in decisions, following protests from organisations representing faith groups. The COVID-19 pandemic, including controversies about vaccines, and the Black Lives Matter movement were frequently cited by interviewees from a minority ethnic background as potential barriers and explanations as to why people might have opted out in masse in certain communities. Many people, particularly from a Black or Asian ethnic background or a Muslim faith, who had opted out had done it in response to a text message or word of mouth which contained inaccurate information relating to a deadline to opt-out, after which, it was claimed, their organs would be the property of the UK Government.

“In our minds the NHS is government, too much has happened historically where the NHS has taken bodies, they’ve done so much that everybody is so nervous, so you come out and say, ‘we’re going to take your organs we are like no you are f\$king not – everyone gets your name off’ and that’s essentially what happened.” (Female, Black, Christian (139))*

The majority of those from minority ethnic groups felt that a trusted community leader was a key voice in helping to bring a rational and reasoned debate about organ donation into their communities. NHS Blood and Transplant had recently set up several schemes to support this grass roots work – but many were struggling to identify the impact of these schemes and felt that the performance measures used by NHSBT (e.g. number of people registering on the organ donor register, number of people at events, etc.) were too blunt and missed the fact that most people had never before heard of organ donation and would need multiple engagements to enable them to make a rational and informed choice based on correct information.

6. Bringing organ donation, and end of life care, rituals and beliefs closer together

Although most people (irrespective of ethnicity or faith) felt the law change was a good idea in principle, many were not confident that their cultural preferences and rituals related to death, repatriation of the body and burial were consistent with the legislation. There was also misinformation regarding the care taken to retrieve organs and the physical appearance of the body afterwards. For these people, this had a major impact on their likelihood of deciding in favour of deceased organ donation. This was another example whereby support for the law was counteracted by public knowledge and understanding (sometimes incorrect) that swayed the choice towards not donating organs.

“The law is right, but I’ll tell you, imagine my body arriving home, you know it has a scar or whatever. People check your body left, right and centre, it is not like here where you are all wrapped up, they will wash you, smear you in Vaseline – I mean the whole village. So, imagine my illiterate mother seeing her daughter’s body in bits and pieces. She will scream

– she will not allow me to be buried before she has the answers. You get the point? I was talking with a Nigerian man on Sunday he said, ‘If I arrived home and I do not have some body parts they are not going to put me in the main cemetery, because I’m not full.’ (Female, Black, Christian)

Others, particularly people from the Jewish faith, were concerned over the definition of death (irrespective of the law change) and had opted out in protest that the law did not go far enough to provide clarity and reassurance that individual faith perspectives would be protected, including their views on brain death.

“I’ve opted out, the nebular statement saying religious concerns will be noted is not good enough given the weight and seriousness with which Judaism views end of life issues. This is nothing to do with organ donation – Judaism supports that – it is brain death. Now medicine is moving at the speed of light, this might not be an issue in 5-6 years. But there is no black and white, every case is on its merits, that is why the nurses need better training, but the numbers are so small [of people eligible and go onto become organ donors], the guilt I felt for opting out was relatively low [because I’m so unlikely to become a deceased organ donor].” (Male, White, Jewish, 192)

7. Lack of consensus among faith and community leaders on organ donation

Most people from a Muslim faith felt frustrated by the lack of clear and consistent messages from their religious and/or community leaders. They reported that such people either could not agree or were reluctant to engage with organ donation. Many people felt that the reluctance to discuss and come to a consensus on organ donation was a matter of power and control rather than anything directly related to whether organ donation is deemed permissible or not in Islam. The resultant uncertainty seemed to sway people towards a choice not to donate.

*“Where I live, we got a lot of mosques, a lot of mosques, and it is like if I am running an event supporting this or that, then guaranteed the guy across the road is running an anti-event, I mean why can’t they just get on and get on with it. I’ve been campaigning for a long time and honestly it is so tired now, f\$*k em, this is about nothing more than power and control – and it’s so frustrating to listen over and over to the endless bickering and same old rants about what is in the book or not, permissible, or not. I mean it wasn’t written for this [organ donation] end of story!”* (Male, Asian, Muslim, 165)

“There is her [Imam], but no he [Imam] is against it. But I mean we all do things that are not in the book, we all eat Nandos and this and that...we just don’t know. But I do know Islam is a very very giving religion, it really is. I guarantee if they just came out and said it was permissible, we would all do it.” (Female, Asian, Muslim, 242)

“Yes, they just say no its not allowed...But the thing is you can give a kidney whilst you are alive, so how does that work, because you are not going back in your grave complete, do you understand what I am saying?” (Female, Asian, Muslim, 242)

8. Doing nothing to share an organ donation decision causes (more) problems

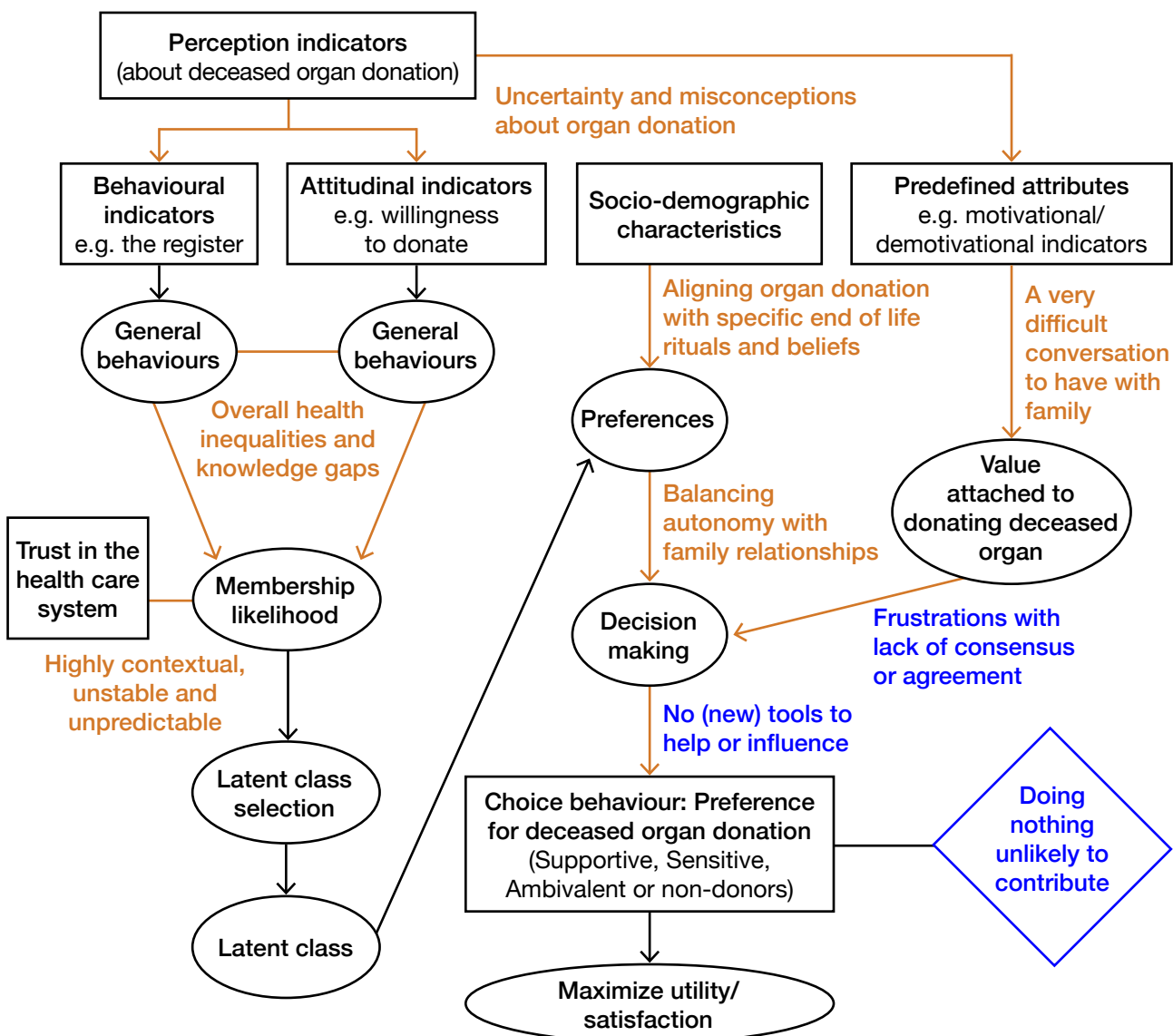
The legislation provides several options for people to make a choice. Some people were very happy with the idea of deemed consent (i.e. the choice to do nothing in life and thus be presumed to have no objection to being an organ donor) as it gave them one less thing to do in an otherwise very busy life. Others felt that organ donation was very important and felt guilty that they had not thought about it or done more to convey their decision by registering or talking about it to their families. People who did not know about the law change (and who supported organ donation) sometimes felt embarrassed or naive that they did not know and subsequently worried about what they should or needed to do next to convey their decision.

Most people still felt that if somebody did not register or discuss organ donation in life, and so came under deemed consent, the family would not feel sufficiently reassured that this was a legitimate and rational choice. The law would not provide any (new) ways to alleviate any of the concerns (discussed above) from minority ethnic perspectives.

Discussion

Figure 7 presents a visualization of the quantitative and qualitative findings mapped against the analytical framework (rational choice theory). What follows below is an integrated summary of these principal findings.

Figure 7: Integration of findings using the analytical and interpretive framework



Orange = qualitative interview data highlighting where additional ethnic minority perspectives overlap and potentially conflict with the intentions of the Act and where additional consideration may be needed.

Blue = PPIE and interview data highlighting where additional ethnic minority perspectives overlap and potentially conflict with the intentions of the Act and where additional consideration may be needed.

Black = quantitative data summary key results and/or signposted to in the manuscript and/or supplemental material. Factors in rectangles represent the variables that inform individual's decision-making process about donating deceased organs that are observed by researchers, and those in ellipses are latent/unobservable by researchers.

Changing the law has had little impact on the general public's overall, in principle, support for organ donation which has remained high and stable (80+%). Further, it does not appear to have influenced people's willingness to become deceased organ donors which is lower at 56% with considerable variation in what people wish to donate.

Ethnic minority support and willingness to donate remains lower (20+%) than in the white population. At the same time, we also found that individuals from minority ethnic groups could potentially be supportive of organ donation, but family, and cultural factors sometimes tended to prevent them from doing so. Thus, it was not always the individual's decision to make, contrary to the assumptions of rational choice theory. There were also (very) low levels of understanding of deceased organ donation and how it comes about in ethnic minorities as well as concerns about whether the processes of organ retrieval aligned with their cultural beliefs and preferences. This knowledge and experience can contribute to a decision that is perceived to be perfectly rational from the individual's perspective. Their choice is, however, often perceived as irrational and misinformed by professionals and at odds with the principle underlying the law, which assumes that people will make a personal rational choice based on public information campaigns and official sources of information.[15]

The level of awareness of general organ donation publicity was relatively low (36%) and unstable over the surveys but awareness of the law change was perhaps surprisingly, at 58% in the white population but lower in ethnic minority populations (31%). Additionally, minority ethnic groups were often unaware and shocked by the long waiting time for organs, and frequently wanted awareness of the impacts of organ donation on their communities to be increased. This information was needed to inform their rational choice to donate their organs. The lack of information and level of misinformation were exacerbated by frustrations with inconsistencies and lack of consensus on organ donation on the part of people in positions of leadership, whom many felt should take a more positive role in addressing these inequalities. People in leadership positions can control the narrative and knowledge which community members use to make their decisions about organ donation.

The number of people registering on the organ donor register has stagnated. Of those registered, 89% have opted-in and are predominately white; about 10% have opted out and are predominately non-white. However, these findings relate to the early period of the implementation of the new law which was marked by a series of extraordinary events including COVID-19, the murder of George Floyd in the US, and vaccine hesitancy which contributed to a narrative of government conspiracies directed at harming members of ethnic minority groups, including, by implication, the NHS and resultant mistrust. We also observed the consequences of misleading targeted campaigns against organ donation which rapidly and easily spread due to social media. Minority ethnic families frequently used WhatsApp to talk to their relatives overseas as well as to access community information. This tended to encourage people to opt-out of organ donation, which was a rational choice faced with misinformation in an atmosphere of mistrust.

There was an overall increase in the proportion of the public that had conversations about organ donation. However, the intentions of the law change (to give decisions to individuals) were frequently misunderstood, and arguably difficult to be easily translated into families where decisions of any kinds are arrived at collectively, not just those related to organ donation.

Of the four identified population subgroups, supportive and unsupportive donors are unlikely to respond (positively or negatively) to interventions designed to raise the consent rate. Unengaged donors displayed the most uncertainty about organ donation and may respond to targeted interventions to promote and raise awareness of organ donation. Apart from the supportive donors, most in the other three groups had not discussed their organ donation

views or preferences and may benefit from more opportunities to talk or register on the organ donor register (especially uncommitted donors). This is important as, although most people supported the changes, the presumption of consent left gaps in people's knowledge, they wondered what they needed to do while alive, what would happen if they or their relative who died was eligible for organ donation and critically what they would do if they did not know what their relative who died had wanted. Thus, the assumption underpinning the 2019 Act of individuals acting freely and making rational choices autonomously in life is far from an accurate description of the situation of many people, especially in some ethnic minority families. In general, more opportunities to indicate a choice/decision on the organ donor register via 'nudges' embedded in day-to-day life are needed alongside more opportunities to update choices/decisions regularly and in ways that align with how people live and access services today (digitally).

Strengths and limitations

A strength of this research is the theory-informed mixed-methods design (population surveys, latent class analysis and semi-structured, in-depth interviews) with a particular emphasis on groups traditionally underrepresented in research in general and specifically in organ donation. This enabled not just a description of trends but also integration of additional causal explanations and contextual features to help identify the policy implications. Our theoretical framework helped in exploring highly complex decision making and the strengths of the mixed-method design were shown in the additional issues uncovered from interviews with ethnic minorities in the context of analysis of representative population survey data on attitudes and behaviours towards deceased organ donation.

The findings also reveal some of the limitations of rational choice theory, namely, its focus on individual decision-making whereas for many respondents, organ donation decisions involve more than one person in a family context. In organ donation, the potential donor needs to make a choice during life and then when they die their family members are supposed to honour their relative's rational choice. In practice, in some families, other family members make these organ donation decisions on their behalf. Rational choice theory also does not explicitly take into account that the potential organ donor likely died in tragic circumstances and that the choice to be made by family members will be emotionally (not purely rationally) based, and in the highly emotional crisis context the decision will be influenced by personal biases, intuitive reasoning and a fight or flight survival instinct. For choice and decisions that must be weighted up and made quickly in tragic circumstances (such as in organ donation), rational choice theory may only partly explain the decision reached by family members. On the other hand, this study was able to contribute to understanding the role of public knowledge and related logic, especially among some ethnic minority groups in making what was from their perspective a rational choice. Some people had to go along with the choices of the community or family no matter how ill-informed it was or whether it matched their own preferences.

Our study is novel in that studies in this field have tended to look at overall trends without addressing sub-population nuances and therefore have been unable to highlight new or more targeted interventions to address (increasing) inequalities in organ donation.

The main limitation of this study is that the authors were not involved in the survey questionnaire design or data collection and so were limited in the latent class modelling by the available variables. Overall, the model predicted 84% of the factors associated with belonging to a given organ donor subgroup. Future studies should help to account for the remaining 16% of the factors not accounted for in this study. Also, with more variables available, it might have been possible to categorise individuals in the sample more completely rather than being limited to a blunt 'white' or 'non-white/ethnic minority' category. The

surveys were repeated cross-sections, not longitudinal, so we were unable to explain changes over time, including the sequence of events which may have influenced public attitudes to deceased organ donation as well as the possibility that individuals might transition from one subgroup to another over time.

Implications of the study for policy, practice and research

To date, the law change in England from opt-in to 'soft' opt-out appears to have had little impact on factors known to influence consent rates or in addressing inequalities in organ donation. Unsupportive donors and especially those from minority ethnic communities are unlikely to be swayed by generic mass media campaigns. Agencies tasked with promoting organ donation may benefit from targeting unengaged donors to encourage them to express their organ donation decision, and uncommitted donors to address their exposure to likely mis/information, as well as community confusion and uncertainty. Interventions need to take account of public knowledge and perceptions that are very difficult to challenge or change and the (significant) role of the family as well as wider community influencers on attitudes, preferences and decisions. More and new opportunities need to be created for people to register and/or update their organ donation decisions over time. Future surveys to monitor public attitude towards organ donation could be longitudinal in nature to enable the analysis of both time-invariant factors, and those factors and incidences that change over time to fully unpack the issues that affect public decisions towards deceased organ donation.

Conclusion

Despite a high apparent level of support for the principle of organ donation, individuals are far from unanimous when it comes to their personal willingness to donate their organs after death. If consent rates to deceased organ donation are to be raised in England in the future, attention needs to be given to engaging with subgroups who are sceptical, undecided or who have thought little about donation, especially those from ethnic minority groups.

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7

Perceptions and experiences of healthcare professionals of implementing the Organ Donation (Deemed Consent) Act in England during the COVID-19 pandemic

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Summary

Context

In May 2020 during the COVID-19 pandemic, England implemented a 'soft' opt-out system of consent to deceased organ donation. As part of a wider evaluation, this analysis focused on the perceptions of health care professionals, specifically their experiences of implementation.

Methods

Mixed-methods study informed by Normalisation Process Theory, based on two national surveys of health care professionals and interviews, observations and document analysis, across two case study sites. Routine NHS Blood and Transplant's audit data provided context.

Findings

67 interviews with 59 staff and 244 first and 738 second surveys. COVID-19 affected every aspect of implementation. Although supportive in principle, many staff were unconvinced that legislative changes alone would increase consent rates. Many staff were redeployed or left their jobs. As a result, staff were not able to work collectively as intended for implementation. Staff received routine donor audit data suggesting the law was yet to make a difference to consent rates, reducing their enthusiasm and commitment.

Conclusions

Implementation could have been more impactful if delayed. The National Health Service needs to reprioritise organ donation and relaunch the implementation plan in the post-pandemic period, though it is unlikely the changes will bring about a significant increase in consent rates.

Introduction

In this chapter we focus on the experiences of health care professionals (including their systems of support) who are directly (NHSBT) and indirectly (e.g. Intensive care, accident and emergency) tasked with delivering organ donation services in England, in order to learn more about the impact of the changes on their perceptions and experiences.

The objectives were to examine the impact of the law change on NHSBT and other key NHS staff in terms of:

- whether staff perceptions and experiences on organ donation legislation and the new system had changed over time;
- staff understanding and awareness of the law change and new system, particularly related to the role of the family, what was included and excluded under the new system, and the new operating procedures;
- staff confidence in explaining the new system to families or next of kin or directing them to information and, if not, what would assist them;
- staff support for the new system and, if unsupportive, why this was;
- whether the work of staff, including their conversations with families, had been impacted negatively or positively by the law change and the new system;
- whether staff felt they had sufficient support from NHSBT and other agencies (e.g. the Human Tissue Authority, Department of Health and Social Care, NHS England), including sufficient training to implement the law change as intended; and
- whether staff felt able to undertake what was expected of them under the law change.

We were also interested in exploring the changes in the NHS and organ donation system brought about by the COVID-19 pandemic response and during the post COVID-19 recovery which coincided with implementation of the ‘soft’ opt-out legislation.

Methods

Design

We used a mixed-methods convergent analysis design.[7] We sought to capture the views and experiences of an extensive range of respondents (including NHSBT staff, Clinical Leads in Organ Donation [CLODs]), emergency care unit staff, operating theatre staff and adult intensive care unit staff) with a widely distributed survey, and an in-depth understanding of health care professionals tasked with the implementation of the law change using semi-structured interviews with purposively sampled staff in two purposively selected NHSBT regions, based on organ donation activity, geographic coverage, consent rates and higher than average ethnic minority populations.

The theoretical framework underpinning our exploration of implementation processes and staff perceptions and experiences was Normalisation Process Theory (NPT).[8] This is a widely used framework for understanding the factors influencing the implementation of policy or service change in the health care sector in terms of the degree to which the change becomes “normalised” by staff. NPT investigates the levels of coherence (sense making); cognitive participation (relational work); collective action (operational work); and reflexive work (appraisal work) involved in the implementation process. NPT guided the survey questions and topic guides for interview, analysis and data integration.

Data collection tools

The two surveys were designed to collect information about staff awareness and understanding of the law change; degree of support for the change in the law; reasons for supporting/not supporting it; and the impact of COVID-19. The second survey additionally collected information about the implementation of the changes; their perceived impact in general and on organ donation rates in minority ethnic groups and faith groups; ways of addressing concerns of families whose involvement did not lead to organ donation; and views on NHSBT's key performance indicators. Similarly, the topic guides for the interviews were devised to explore perceptions and experiences, perceived impact, changes over time and COVID-19 considerations. The two surveys and topic guides were shared with key stakeholders (including the study's advisory group) and the study's Patient and Public Involvement and Engagement (PPIE) representative (JB) to ensure they captured relevant information.

Sampling

Surveys

Two surveys were conducted with NHS/BT staff in England (08/2021-01/2022 and 11/2022-01/2023). This enabled us to observe changes in views over time. The surveys were disseminated using the online survey platform Qualtrics XM. Invitations to the survey were disseminated using a combination of direct invitations sent by the Legislation Project Lead at NHSBT to NHSBT staff (nurses and managers) and CLODs, alongside cascading invitations through various professional networks and encouraging completion through the British Association of Critical Care Nurses (BACCN) newsletter which has the widest reach of critical care nurses in the UK. Respondents to the first survey were asked to provide an e-mail address for the second one; those who did so, received a direct invitation to complete the second survey. To incentivise the completion of the second survey, we offered a £5 Amazon voucher to the first 500 respondents who completed the second survey.

Interviews

Two NHSBT regions were purposively selected as sites for the staff interviews. Box 1 describes the rationale for their selection and interview processes.

Box 1: Rationale for the selection of two NHSBT regions as case study sites, and interview process

London was selected for its high(er) numbers of potential organ donors, ethnically diverse population, and concentration of large acute hospitals. The North West England site was selected as it covers north England, has higher than average numbers of ethnic minority and under-represented groups, and covers a wide geographic area. Within each region two NHS Trusts were selected based on factors such as high and low performance regarding organ donation consent rates, NHSBT classification of level 1 and level 2 centres for a high enough level of organ donation activity to examine in more depth the interactions, processes, and activities between NHS and NHSBT staff.

We aimed to undertake two rounds of interviews with a minimum of 20 interviews across each site and follow-up 12-18 months into implementation. Interviews were undertaken by two experienced female researchers (LM & LW), mostly virtual (Teams, Zoom) with a small number face-to-face interviews. LM undertook interviews across both sites and had previously worked with some participants on a similar evaluation in Wales. In each NHS Trust, we identified participants through purposive and snowball sampling. This included healthcare professionals working directly in organ donation, such as SNODs, SRs and CLODs, and indirectly, e.g. those working in Intensive Care

Units (ICU) and Emergency Departments (ED). Key NHSBT personnel, including regional and team managers were contacted directly to identify potential participants to recruit. Each Trust's CLOD acted as a lead Principal Investigator (PI) to help identify and recruit NHS personnel working within the targeted specialities, namely intensive care units and emergency departments, as well as from other linked clinical areas, e.g. Stroke units. We sent an 'invitation to participate email' to the identified individual, along with a participant information sheet.

Analysis

Surveys

Survey responses were mainly analysed and presented as the number of responses (and percentages) by professional group. The small number of responses from some professional groups (especially in the first survey) prevented us from testing the statistical significance of differences in responses. Open-ended narrative responses were analysed alongside qualitative interview data.

Interviews

Interviews were transcribed verbatim, coded against NPT [8] and analysed in NVivo 12 using the Framework approach.[9, 10] Familiarisation with the data was achieved by researchers reading and re-reading transcripts and accompanying audio recordings, and by annotating and making notes and memos on initial thoughts. Visual maps of the NPT constructs aided the analysis. Summary findings were also coded as broadly "positive", "negative" or "no difference" against NPT in terms of respondent responses to the changes in organ donation system processes, practices and perceived impacts.

Data integration

The research team met to discuss, refine and agree the analytical coding framework (see Table 1 on the following pages) where NPT constructs were interpreted and mapped for both interview and survey data. We analysed the quantitative and qualitative data separately, and then brought the initial findings together into a narrative using NPT as the organising framework to present the findings.

Table 1 NPT analytical framework

Construct/subconstruct Name	Description	Example of evidence in Organ Donation evaluation
<p>Coherence <i>Coherence is the sense-making work that people do individually and collectively when they are faced with the problem of operationalising some set of practices.</i></p>	<p>Making sense of it The extent to which study participants had clear knowledge and understanding of the change in the law (the intervention). Sense making of new practices – the meaningful qualities of a practice.</p>	
<p>Differentiation <i>An important element of sense-making work is to understand how a set of practices and their objects are different from each other.</i></p>	<p>Do people across the area see a coherent model and distinguish it from current ways of working? Do they see this as a new way of working? Or is this business as usual? How is what is being implemented different from what already happens? Are people able to see a difference between the old and new practices – can they differentiate between what happened before and now.</p>	<p>What's changed/different? <i>Capture all experiences, descriptions actions, activities that have changed/are different (or not) as a result of opt-out from the multiple perspectives.</i></p>
<p>Communal specification <i>Sense-making relies on people working together to build a shared understanding of the aims, objectives, and expected benefits of a set of practices.</i></p>	<p>Do people collectively agree about the purpose of the intervention? What does the intervention mean for team working? How will the new system change the current work of the team? Is there a collective or shared idea of the change in the law and the practice around that – e.g. between NHSBT and NHS Staff in different departments and areas of work – good integration of practice (are SRs and CLODS working with other clinicians to integrate this into practice).</p>	<p>Awareness/understanding/support (team, wider service, systems) <i>Capture experiences, thoughts, descriptions, of the ways opt-out is working (or not) from a team wider/service perspective.</i></p>
<p>Individual specification Sense-making has an individual component too. Here participants in coherence work need to do things that will help them understand their specific tasks and responsibilities around a set of practices.</p>	<p>Do individuals understand what tasks the intervention requires of them? What does the change in the law mean for specific people (how do individuals understand how the OD affects their work). Do people on the whole understand the new consent law and how it is intended to operate.</p>	<p>Awareness/understanding/support (personal, individual job role) <i>Capture experiences, thoughts, descriptions, of the ways opt-out is working (or not) for individuals.</i></p>
<p>Internalisation <i>Finally, sense-making involves people in work that is about understanding the value, benefits and importance of a set of practices.</i></p>	<p>Do all the stakeholders grasp the potential benefits and value of the intervention for their work? Do they support it? Are people attributing work to the change in the law and taking ownership – are they internalising the new practice – what processes are in place to stimulate this internalisation? e.g. communicating evidence of progress – data on consent rates) or informal discussions on progress and impact of the law change.</p>	<p>What difference will it make? <i>Experiences, opinions, thoughts on what difference opt-out will make, on whom and why.</i></p>

Construct/subconstruct Name	Description	Example of evidence in Organ Donation evaluation
<p>Cognitive participation</p>	<p>Working out participation – ‘buy in’ The extent to which participants bought in to the law change, engaged with it, and committed to it (training modules). Establishing relationships and divisions of labour to support the intervention (enrolment and engagement of individuals and groups) – “What does good look like”.</p>	
<p>Initiation <i>When a set of practices is new or modified, a core problem is whether or not key participants are working to drive them forward.</i></p>	<p>Who is driving this? Are they willing and able to engage others in the implementation? Who are the key people and what are they doing? How is the new practice initiated? Is there high-level formal agreements to implement and make resources available among leaders – clear arrangements (formal) steering groups, implementation plans and governance.</p>	<p>Normalising organ donation <i>Experiences views and actions of making organ donation a normal/routine part of end of life care.</i></p>
<p>Enrolment <i>Participants may need to organize or reorganize themselves and others in order to collectively contribute to the work involved in new practices. This is complex work that may involve rethinking individual and group relationships between people and things.</i></p>	<p>Do people agree this should be part of their work? How are people enrolled forming and organising how participants join new practices – any new roles – any boundaries hindering enrolment. Do the stakeholders believe they are the correct people to drive forward the implementation? How do participants become involved in the intervention (how are staff made aware – trained).</p>	<p>Concerns/problems <i>What’s stopping organ donation becoming normal from multiple perspectives.</i></p>
<p>Legitimation <i>An important component of relational work around participation is the work of ensuring that other participants believe it is right for them to be involved, and that they can make a valid contribution to it.</i></p>	<p>Do people buy in to it? Do they believe it is appropriate for them to be involved in the intervention? Why should a participant participate? How is legitimacy established? How staff work to shape their role and establish legitimacy.</p>	<p>Influences/Influencers <i>Experiences, activities and descriptions of influences on opt-out and associated processes e.g. training, transplant, live donation).</i></p>
<p>Activation <i>Once it is underway, participants need to collectively define the actions and procedures needed to sustain a practice and to stay involved.</i></p>	<p>Do people continue to support the intervention? Can stakeholders identify what tasks and activities are required to sustain the intervention? What processes will support people staying on task – making it work well.</p>	<p>Motivation to stay involved <i>Experiences, views and activities of people’s motivations to change/adapt.</i></p>

Construct/subconstruct Name	Description	Example of evidence in Organ Donation evaluation
<p>Collective action <i>Collective Action is the operational work that people do to enact a set of practices, whether these represent a new technology or complex healthcare intervention.</i></p>	<p>Doing it The work done by individuals and organisations to enact the new practice. The allocation of organisational and personal resources to support the change in the law and how this has been operationalised – how roles and responsibilities are defined. The operational work of implementation (interaction with already existing practices).</p>	<p>Implementation</p>
<p>Interactional workability <i>This refers to the interactional work that people do with each other, with artefacts, and with other elements of a set of practices, when they seek to operationalise them in everyday settings.</i></p>	<p>Do all people involved clearly perform the tasks required for the intervention? Does the intervention make it easier or harder to complete tasks? How does the intervention affect existing working practices and relationships? (Is it disruptive?)</p>	<p>Experiences of implementing opt-out <i>Capture actual experiences of implementing opt-out, associated policies, procedures, practices.</i></p>
<p>Relational integration <i>This refers to the knowledge work that people do to build accountability and maintain confidence in a set of practices and in each other as they use them.</i></p>	<p>Do people trust each others work and expertise in the intervention? Do those involved in the implementation have confidence in the new way of working? How are confidence in, and accountability for the intervention built?</p>	<p>How are people adapting <i>Capture experiences, views and activities of the ways people are adapting to opt-out.</i></p>
<p>Skills set workability <i>This refers to the allocation work that underpins the division of labour that is built up around a set of practices as they are operationalised in the real world.</i></p>	<p>Is there appropriate allocation of work? Do those implementing the intervention have the correct skills and training for the job? Who does what?</p>	<p>Who’s doing what, and why? <i>Capture differences in people’s experiences of implementation, what’s important for them etc.</i></p>
<p>Contextual integration <i>This refers to the resource work – managing a set of practices through the allocation of different kinds of resources and the execution of protocols, policies and procedures.</i></p>	<p>Is implementing the law change adequately supported by participating organisations? Do local and national resources and policies support the implementation? Who gets what, and how? (Resource allocation – any additional resources?)</p>	<p>What do people have or need? <i>Capture experiences and views on what people need in order to deliver opt-out as intended.</i></p>

Construct/subconstruct Name	Description	Example of evidence in Organ Donation evaluation
<p>Reflexive monitoring</p> <p><i>Reflexive Monitoring is the appraisal work that people do to assess and understand the ways that a new set of practices affect them and others around them.</i></p>	<p>How is it working?</p> <p>Appraisal and evaluation – assessment of impact, process of reflection, learning and refinement. Evaluating implementation to promote embedding (how a practice is understood and assessed by actors implicated in it).</p>	<p>What's worked/working?</p>
<p>Systemization</p> <p><i>Participants in any set of practices may seek to determine how effective and useful it is for them and for others, and this involves the work of collecting information in a variety of ways.</i></p>	<p>Do people get and use information about the effects of the implementation of the law change?</p> <p>Will stakeholders be able to judge the effectiveness of the intervention? How is information obtained to inform appraisal? Outcome and process data.</p>	<p>What's worked/working well or not across the system</p> <p><i>Capture views, thoughts, experiences.</i></p>
<p>Communal appraisal</p> <p><i>Participants work together – sometimes in formal collaboratives, sometimes in informal groups to evaluate the worth of a set of practices. They may use many different means to do this drawing on a variety of experiential and systematized information.</i></p>	<p>Do people collectively assess the law change as worthwhile?</p> <p>How will stakeholders collectively judge the effectiveness of the intervention? How do participants work together to appraise the intervention? Formal and informal meetings – other.</p>	<p>What's worked/working well or not across the system</p> <p><i>Capture views, thoughts, experiences.</i></p>
<p>Individual appraisal</p> <p><i>Participants in a new set of practices also work experientially as individuals to appraise its effects on them and the contexts in which they are set. From this work stem actions through which individuals express their personal relationships to new technologies or complex interventions.</i></p>	<p>Do people individually assess the law change as worthwhile?</p> <p>How will individuals judge the effectiveness of the intervention? How do participants evaluate the impact of the intervention individually? Process and context.</p>	<p>What's worked/working well or not across the system</p> <p><i>Capture views, thoughts, experiences.</i></p>
<p>Reconfiguration</p> <p><i>Appraisal work by individuals or groups may lead to attempts to redefine procedures or modify practices – and even to change the shape of a new technology itself.</i></p>	<p>Do people modify their work in response to appraisals of the implementation of the law change?</p> <p>Will stakeholders be able to modify the intervention based on evaluation and experience? Can participants modify aspects of the intervention? If so how?</p>	<p>Recommendations: What people recommend for the future.</p>

Ethics

This study was part of a broader national evaluation of the evolving organ donation system in England following the introduction of a ‘soft’ opt-out policy in May 2020.[6] Ethical approval for the study was obtained (LSHTM ethics committee (Ref: 26427) and HRA (Ref: 21/NW/0151). Informed consent was obtained before each interview and survey.

Validity, reliability and rigour

We took a number of steps to maximise the validity, reliability and rigour of the data we were collecting, and the subsequent analyses. To minimise the risk of social desirability bias of responses to our surveys, we emphasised in our information sheet that responses would be anonymised in reports. We also piloted the survey questions with a number of individuals with similar characteristics to those completing the survey to ensure that the question wording was unambiguous, neutral, and in the case of closed-ended questions, that we had categorical options to select from. We randomised response options where appropriate to minimise primacy bias. We agreed beforehand the analysis plan for the two surveys and the qualitative research. We used the four-dimension criteria (credibility, dependability, confirmability and transferability) as qualitative markers of rigour throughout.[11] Detailed fieldnotes were often read out to the team who were then able to share their expertise and perspectives to help further contextualize data. We also presented emerging findings at meetings attended by our advisory group and wider stakeholders to check whether they found our interpretation of the data credible.

Reflexivity

The research team consisted of academics and lay representatives with various experience in health, social and policy research and organ donation. Two members of the team (LM and JN) were involved in a similar evaluation of the changes to the Welsh law on organ donation.[12] The Welsh evaluation reported that the changes had only marginal impact on donation rates in Wales and that any changes could not be attributed to the law change. We sought to minimise the risk of the views of the researchers influencing the qualitative data collection and interpretation by agreeing the topic guide for the interviews beforehand and conducting joint analysis meetings. The inclusion of a lay member on the team aided objectivity and was used as a ‘bias check’ throughout.

Stakeholder engagement and Patient and Public Involvement and Engagement (PPIE)

Researchers attended meetings and training events, organ donation committee meetings, NSHBT team meetings including those allocated to Specialist Requesters, SNODs and management and reviews of documents and processes. We recruited a lay member as a core member of the research team, who has experience of organ donation as a carer. Our advisory group was made up of expert and lay members including donor families who had input into the data collection, interpretation and validation of results.

Findings

We recruited 244 NHS and NHSBT staff to the first survey and 738 to the second (see Table 2 for breakdown of survey responses by professional group). It was not possible to calculate the response rate to the surveys, since invitations were disseminated using newsletters to professional groups whose size cannot be measured accurately to provide a denominator for the response rate estimates. A total of 67 interviews representing 59 staff were completed across the two sites (see Table 3 for details). Key performance indicators in relation to organ donation across both sites mirrored the national picture; all indicators either stayed the same or worsened (see Box 3) .

We report findings using the four NPT constructs (coherence; cognitive participation; collective action and reflexive monitoring). For each construct, an overview is presented from the survey data and then more detailed perspectives from the qualitative data are presented by professional group: NHS, NHSBT or both.

Table 2: Survey responses, by professional group

Professional Group	First survey		Second survey	
	Number of responses	% contribution to overall sample	Number of responses	% contribution to overall sample
NHSBT staff	105	43%	156	21%
Adult intensive care unit staff	51	21%	413	56%
Clinical Lead in organ donation	44	18%	70	9%
Operating theatre staff	14	6%	24	3%
Emergency care unit staff	6	2%	42	6%
Other	22	9%	33	4%
Total	242	100%	738	100%

Table 3: Characteristics of interview participants from the two sites

Site		Site	
London	Number	North-West	Number
NHS staff including, CLODs, R-CLODs, Specialist consultants, ITU management & nurses, ED and A&E nurses.	N=13* <i>N=2 second round</i>	NHS staff including, CLODs, R-CLODs, specialist consultants, TRODs, Bereavement care support staff, ITU management and nurses, ED and A&E management and nurses, Link nurses	N=16* <i>N=5 second round</i>
NHSBT staff including, SNODs, SRs, PDS, and ODC committee members and chairs	N=11* <i>N=1 second round</i>	NHSBT staff including, SNODs, SRs, Managers, PDS, Tissue services and ODC committee members and chairs	N=14* <i>N=8 second round</i>
Total	27 interviews with 24 staff	Total	43 interviews with 35 staff

Key

Clinical Leads Organ Donation (CLOD)
 Regional Clinical Leads Organ Donation (R-CLODs)
 Trainee Representative Organ Donation (TROD)
 Intensive Treatment Unit (ITU)
 Specialist Nurse Organ Donation (SNOD)

Specialist Requester (SR)
 Organ Donation Committee (ODC)
 Practice Development Specialists (PDS)
 Emergency Department (ED)
 Accident and Emergency (A&E)

Box 3: Comparisons between the sites

North-West region and NHS sites	London region and NHS sites
Description	
<p>The North-West region was made up of a typical NHSBT region with the addition of an Educational and Paediatric lead, 27.2 Whole Time Equivalent (WTE) SNODs and SRs.[13] The Level one trust included 9 hospitals with the majority of adult potential donation coming from 3 sites, the trust also had a Paediatric, Cardiothoracic and Transplant specialist centres. Two CLODs and three SNODs had embedded time. The Level 2 trust included three hospital sites, the majority of adult donation came from one site, one CLOD and one SNOD had embedded time.</p>	<p>The London region was made up of a typical NHSBT region, 31 SNODs and SRs.[14] The Level 1 organ donation trust included: 7 hospital sites with the majority of adult donation coming from 3 sites, the trust also had an Adult Neurology, a Major Trauma Centre, a Paediatric, Cardiothoracic and Transplant centres. Three CLODs and three SNODs with embedded time. The Level 2 trust included 4 hospital sites with the majority of donation coming from two hospitals, one CLOD and one SNOD with embedded time.</p>
Organ donation committee(s)	
<p>The North-West had active and fully functioning local and regional committee(s) supporting implementation and monitoring impact. They regularly reported on KPIs drilling down into individual cases, what happened and why, and what they needed to do to address any perceived barriers or problems to progressing the organ donation agenda.</p>	<p>The London site were not as routinely active, some had not met for some time. One had a change in chair and there was currently no chair. The overall focus was generally on resourcing and staffing.</p>
Specific characteristics	
<p>The North-West site had long established leadership teams including NHSBT nurse management, clinical leadership and regional and local chairs. The leadership team had recently developed a localised version of the national NHSBT strategy,[15] set out as a regional strategic action plan, which the rest of the regions were adapting.</p> <p>NHSBT staff in this region had been exposed to the Act over a longer time due to cross covering Wales (who switched in 2015). Most SNODs/SRs in the Northwest had experience of applying the legislation, were very aware of when, where and how it should be applied as well as any specific nuances.</p>	<p>The London sites were hit more by COVID-19. Most sites were reconfigured to COVID-19 specialist centres. When organ donation services did resume some CLODs did not currently have or even know who their link nurses were. Priorities included recruiting and training SRs/SNODs, ensuring rota and geography coverage.</p>

North-West region and NHS sites	London region and NHS sites
Specific concerns in relation to the law change	
<p>The NHSBT management responsibility for the geographic area was reconfigured, now responsible for the North-West (including parts of Wales), Isle of Man and Northern Ireland – covering 4 different opt-out legislations, each with different nuances.</p> <p>Over time staff and management continued to reflect that they were seeing and hearing the same issues and the law had done nothing to resolve these issues. It was the local NHS Trust activity that was central to resolving any local issues which had nothing to do with the legislation.</p>	<p>The highly diverse population not just in terms of ethnicity, but in terms of language and culture i.e. not plugged into the mainstream media were central in the site’s priorities. Local implementation was potentially causing more harm than good, <i>“It’s not just different nations, but we need to try to understand if somebody is approaching end of life because they’re on holiday or because they live and work here, do they live and work here permanently or do they live and work here for a period of time.”</i> (Clinician, Interview)</p> <p>It was the local NHS Trust activity that was perceived to have more benefit addressing local issues for example working with local councils, giving talks within communities, working with community leaders and identifying innovators – such as a Hindu family who lost a son – to act as patrons to the cause, and was cited as a key mechanism in why the Hindu population largely now support organ donation.</p>
Priority agenda items	
<p>Requests for CLOD PA time for what was currently unpaid consultant input into the organ donation agenda, the switch from paper-based to an entirely virtual system, merging of trusts, recruiting and encouraging wider proactive committee membership, maintaining and expanding organ donation visibility, progressing organ donation memorials, overall organ donation performance mapped against KPIs (in particular what was and was not missed potential for organ donation), highlighting excellent cases and good news stories and ways to maintain and update policies across the hospital. These items often aligned with annual events such as organ donation week, the order of St. Johns awards and the collaborative meetings. Overall there was a very high focus on limited resource allocation, which often included the very high burden of finances and moving funding in and between services and systems, payments and claims, discussions on equity and parity (e.g. paying for taxis for a family of potential organ donor and not paying for taxis for a family where the deceased was not an organ donor), rewarding staff in ways that were inclusive, division of funds across hospitals, ensuring organ donation funding was protected especially over financial years to develop research and wider partnerships. Staffing (recruitment, retention, turnover, sickness) and what they were able to achieve to support the organ donation agenda in addition to their fulltime roles were prominent.</p>	<p>The competing priorities of the NHS were again highly cited as well as a whole new set of resource issues in the wake of COVID-19.</p> <p><i>“NHS has a lot of big fish to fry right now. We’re not getting through surgery, our hospitals are full, our nurse retention staff is awful, all the workforce that were here two years ago, 90 percent of them in the intensive care have changed because the old guard have tired and left. The ones that’ve come don’t stay very long because they don’t like it, they want to go. So we are dealing with very, very different problems, and I suspect that now, organ donation has fallen down to the back of the queue, I have to say, in the grand scheme of things. Even though it’s a false economy, I think the only way that you’d bring it to the top of the queue will be to show how cost effective it is in terms of the government’s eyes.”</i> (Clinician Interview)</p> <p><i>“Funding and spending were again highly cited, and the region was exploring ways to make money go further, and work more smartly, “we have a large pot of money for organ donation but we’re not finding clever ways to use it. It’s not big enough to do anything huge, but it’s too big to ignore, so the trust says, “Well, if you don’t use it, we’ll have it,” so we’re wasting a lot of time talking about what to do with money.”</i> (Clinician Interview)</p>

Key performance indicators comparison (2018-19: pre-COVID-19 and pre law change and 3 years post implementation)
Red = observably worse **Black = no clear difference** **Green = observably better** [16]

United Kingdom including Channel Islands and Isle of Man		2018-19 pre-COVID-19 and law change	2022-23 3 years post law change		
Referrals		94% (7297)	94% (6502)		
Neurological death testing		86% (1719)	78% (1560)		
SNOD presence		91% (2959)	92% (2725)		
Consent		67% (2186)	61% (1806)		
Number of donors		N=1600	N=1429		
Number of transplants		N=3951	N=3558		
England		2018-19	2022-23		
Referrals		94% (6329)	93% (5674)		
Neurological death testing		85% (1467)	78% (1331)		
SNOD presence		92% (2551)	93% (2347)		
Consent		67% (1865)	61% (1536)		
Number of donors		N=232	N=228		
Number of transplants		N=577	N=560		
Key performance indicators			Key performance indicators		
North-West	2018-19	2022-23	London	2018-19	2022-23
Referrals	93% (1085)	92% (924)	Referrals	94% (775)	90% (640)
Neurological death testing	83% (228)	77% (191)	Neurological death testing	87% (266)	78% (240)
SNOD presence	98% (390)	96% (297)	SNOD presence	93% (399)	95% (306)
Consent	65% (259)	64% (199)	Consent	62% (264)	52% (166)
Number of donors	N=192	N=155	Number of donors	N=198	N=136
Number of transplants	N=458	N=414	Number of transplants	N=524	N=353

Key performance indicators comparison (2018-19: pre-COVID-19 and pre law change and 3 years post implementation)
Red = observably worse **Black = no clear difference** **Green = observably better** [16]

Key performance indicators			Key performance indicators		
North West			London		
Level 1	2018-19	2022-23	Level 1	2018-19	2022-23
Referrals	93% (127)	86% (153)	Referrals	95% (107)	93% (97)
Neurological death testing	80% (24)	74% (26)	Neurological death testing	80% (43)	80% (40)
SNOD presence	100% (45)	100% (22)	SNOD presence	97% (59)	97% (59)
Consent	58% (26)	68% (7)* Number dropped significantly	Consent	56% (34)	54% (33)
Number of donors	N=19	N=12	Number of donors	N=24	N=25
Number of transplant	N=45	N=41	Number of transplants	N=70	N=60
Level 2 to 3	2018-19	2022-23	Level 2 to 3	2018-19	2022-23
Referrals	100% (53)	97% (32)	Referrals	97% (31)	100% (27)
Neurological death testing	100% (11)	88% (7)	Neurological death testing	88%(7)	62% (13)
SNOD presence	89% (17)	100% (4)* All other years this was 95/100%	SNOD presence	100% (15)	100% (17)
Consent	63% (12)	75% (3)* Number dropped significantly	Consent	73% (11)	59% (10)
Number of donors	N=10	N=2	Number of donors	N=9	N=9
Number of transplants	N=22	N=5	Number of transplants	N=25	N=24

Coherence: making sense of the law in relation to practice

Support for the law change in general was high in the first survey (see Figure 1). The workforce seemed to become more aware of the changes over time (see Figure 2). In general, the more remote from direct involvement in deceased organ donation, the less staff felt that the law change had any relevance for them or impact on their practice. There were more nuanced reflections when we probed deeper in our qualitative research and analysed survey questions with free-text responses, below.

Figure 1: Support for the organ donation law change (first survey)

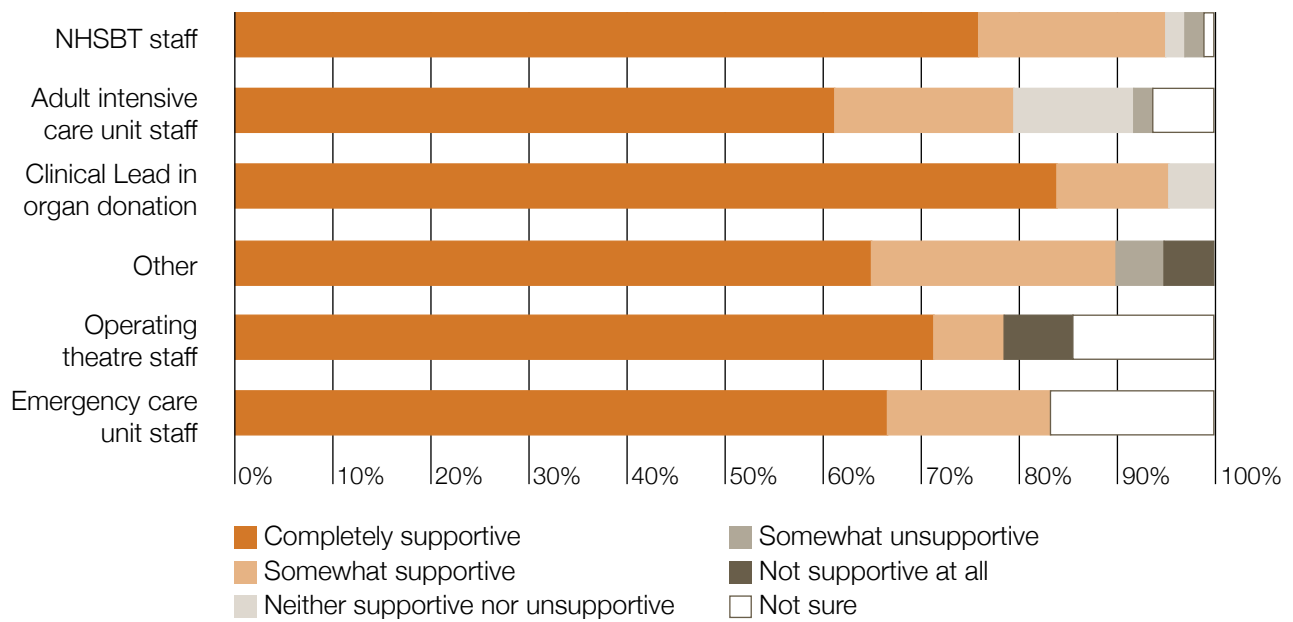
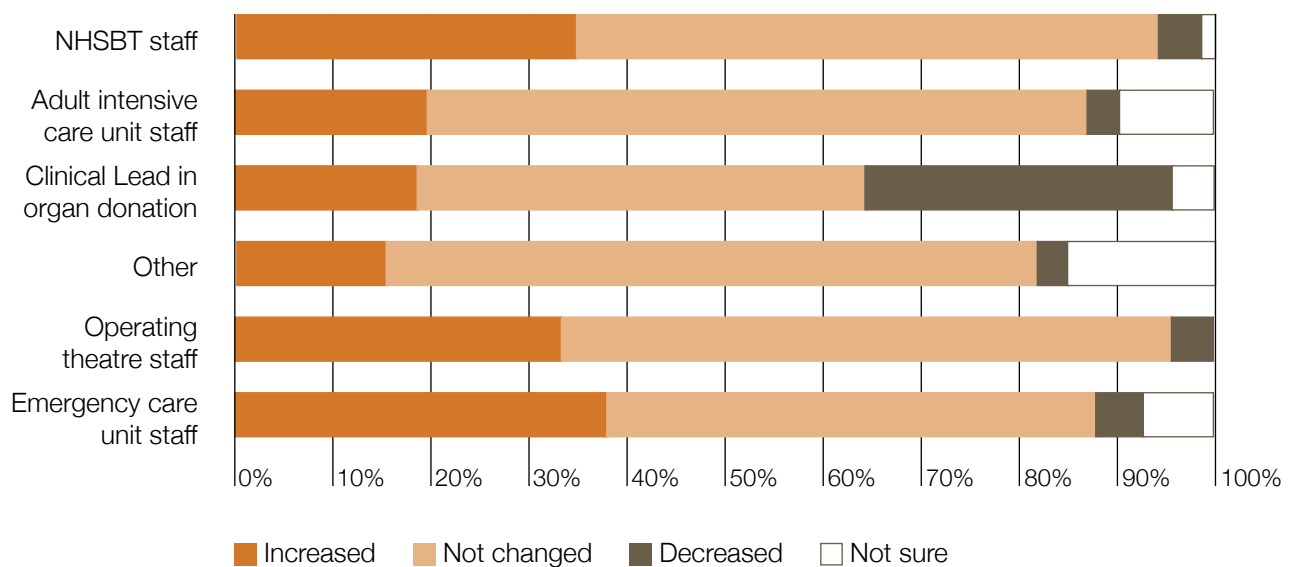


Figure 2: Changes in support for deemed consent since the introduction of the change to the law on organ donation in England in May 2020 (Second survey)



NHS staff

Most intensivists took the position that the changes were “ethically morally, culturally the right thing to do” (Clinician, interview) but could see no obvious changes to their day-to-day activities. Some were optimistic that the changes might give greater priority to organ donation within intensive care – as something that is delivered as an integrated part of the service – but were cautious about whether the law change would assist with any specific local issues such as bed capacity, staff turnover and burnout. Most preferred to focus and build on what individuals were already doing irrespective of the law change, such as promoting the stories of donors who went on to save multiple (young) lives, excellent examples of multi-disciplinary team working, community engagement and general organ donation promotion.

Many clinicians felt a law change overlaid on the complexity of death and dying conversations, which are ultimately emotional (not rational), would make almost no difference to their practice or consent rates. The ‘softness’ of the legislation was both regarded as ‘good enough’ i.e. at the limit of what is currently likely to be acceptable in the UK, but a cause of frustration especially when trying to explain to colleagues what in fact had changed or what they might need to consider doing differently, if anything. Others commented that the organ donation service might now potentially have put itself in a weaker position by relying on the fact that people have not opted out instead of people having to opt-in. They judged that opt-in still remains easier to talk about and to promote to families and colleagues especially when organ donation is infrequent. Overall NHS staff in London were more concerned with staffing issues (than the law change), some not currently having a link nurse or even seen a SNOD since before the pandemic.

NHSBT staff

Some SNODs/SRs were initially concerned that the law change would take away the family’s capacity to ‘gift’ (as decisions are given to individuals to make while they are alive) and the greater emphasis in performance assessment being given to consent rates. Many explained how the nature of their conversation with families had changed, but that this had evolved over time (especially in the Northwest as many SNODs/SRs had been in post for longer) and most still found talking about the benefits of organ donation easier and preferable than discussing the law. Some were interested to see what the law change would do to their individual consent rates, and a few suggested that the changes in the ways data are collected and presented now would give a more accurate picture of the complexities SNODs/SRs encounter on a daily basis.

NHS and NHSBT staff

Within NHSBT and NHS staff involved in organ donation there was overall disappointment that the changes did nothing to stop families overriding the decisions of people who had opted in and many wondered what proportion of “new deemed cases” would have said “yes” anyway under the old system, making measuring change very challenging:

“How many true deemed, I don’t know. Our conversations have changed, but you’re kind of largely just reinforcing with the family what they were already going to do...” (SR/SNOD interview)

Survey and interview data reflected similar tensions, especially how, when and where the law would be used to influence families’ behaviours, and this was often couched in terms of concerns about the public’s awareness and understanding:

“It seems a bit unethical because a line could be crossed and a non-consenting donor who hadn’t opted out would be assumed as a donor.” (Second staff survey, Adult intensive care unit staff)

“Being required to mention the law and that consent is deemed even though relatives completely support donation makes them feel like something is being taken away from them. We have to deem consent when in fact it is being given.” (First staff survey, NHSBT staff)

“SNODs are also discouraged from using the word ‘law’ in family conversations. However, all of the media campaigns use the word ‘law’, and by using the phrase ‘the legislation has changed’ we are making the assumption that everyone understands what we are referring to.” (First staff survey, NSHBT staff)

“Although some families are aware of the law change, many still aren’t and so it can become quite difficult when you bring in the notion of a ‘change in law’ when families themselves aren’t even aware and so feel their loved one may not have been either, so have been unable to opt-out.” (First staff survey, NSHBT staff)

Cognitive participation; relational work to building, sustaining, reproducing and transforming practice to implement the new system

NHSBT staff who responded to the first survey felt that they had received sufficient training, personal development and support in carrying out tasks in relation to the law. For wider NHS staff, there was variation between professional groups in terms of training received (see Tables 4, 5 and 6 for details).

Table 4: Percentage received/ haven’t received in-house training/ professional development on donation law (First survey)

Professional group	Received training	Haven’t received training	Can’t remember	Total number
NHSBT staff	100%	0%	0%	104
Adult intensive care unit staff	44%	44%	13%	48
Clinical Lead in organ donation	33%	64%	3%	36
Operating theatre staff	38%	54%	8%	13
Emergency care unit staff	17%	83%	0%	6
Other	41%	53%	6%	17
Total	150	65	9	224

Table 5: Whether received training/professional development on donation law from professional body/association (First survey)

Professional group	Percentage within professional group			Total number
	Received training	Total number	Can’t remember	
NHSBT staff	31%	63%	7%	88
Adult intensive care unit staff	42%	53%	5%	43
Clinical Lead in organ donation	43%	49%	8%	37
Operating theatre staff	31%	62%	8%	13
Emergency care unit staff	0%	100%	0%	6
Other	38%	63%	0%	16
Total	71	120	12	203

Table 6: Whether received training/professional development on donation law from NHSBT (First survey)

Professional group	Percentage within professional group			Total number
	Received training	Total number	Can't remember	
Adult intensive care unit staff	53%	35%	12%	43
Clinical Lead in organ donation	93%	2%	5%	43
Operating theatre staff	23%	62%	15%	13
Emergency care unit staff	17%	83%	0%	6
Other	63%	32%	5%	19
Total	79	35	10	124

Nonetheless, nearly two thirds (69%) of non-NHSBT staff felt that they were adequately prepared for the law change (see table 7) and so was their organisation (63%) (see Table 8). Interviews and free-text responses however, revealed challenges from the NHS's and NHSBT's perspectives.

Table 7: Extent to which non-NHST staff agree with the statement "I feel that I was adequately prepared for the change in the law on organ donation", by professional group (First survey)

Professional group	Percentage of respondents					Total number
	Strongly agree	Agree	Disagree	Strongly disagree	Not sure	
Adult intensive care unit staff	10%	43%	27%	8%	12%	49
Clinical Lead in organ donation	41%	55%	5%	0%	0%	44
Operating theatre staff	7%	36%	14%	14%	29%	14
Emergency care unit staff	0%	17%	33%	33%	17%	6
Other	25%	60%	0%	5%	10%	20
Total	29	63	19	9	13	133

Table 8: Extent to which non-NHST staff agree with the statement "I feel that my organisation was adequately prepared for the change in the law on organ donation", by professional group (First survey)

Professional group	Percentage of respondents					Total number
	Strongly agree	Agree	Disagree	Strongly disagree	Not sure	
Adult intensive care unit staff	8%	45%	27%	4%	16%	49
Clinical Lead in organ donation	23%	66%	9%	0%	2%	44
Operating theatre staff	0%	36%	7%	7%	50%	14
Emergency care unit staff	0%	0%	0%	33%	67%	6
Other	15%	55%	5%	10%	15%	20
Total	17	67	19	7	23	133

NHS staff

There were concerns about variation in practice across the NHS and in specific areas (e.g. paediatrics and neonatal intensive care) and even discussing organ donation with some colleagues remained a challenge in these settings. The law had not helped and in some ways potentially created another hurdle as the law did not apply to under 18s.

For many, the law change and its implementation were perceived as too abstract and subtle to figure highly on the NHS Trust agenda. The preference and focus for CLODs was to highlight more visible performance indicators especially related to organ retrieval and transplant. At a hospital level, this is what is used to try to increase the profile and priority given to organ donation but changing the law did nothing to help.

Intensivists confirmed that their main role(s) (and problems) were the steps before consent e.g. admitting and neurological death testing and that once this was working well on the intensive care unit, the pathway to organ donation is self-declared, which is unrelated to the law change and consent for organ donation, with consent remaining the SNODs/SRs job.

Some testimonies from intensivists cited poor previous experiences (e.g. a perception of withdrawal of treatment happening too soon or too late) as reasons why some colleagues did not (fully) engage with organ donation. Another factor for some intensivists was suddenly feeling left out of decision making, when there was a direct link created between NHSBT and the family at end of life, and observing the high(er) burden on families. The law in practice did nothing to reduce these issues and CLODs in particular reflected a tension between their role in promoting organ donation and maintaining or re-enforcing NSHBT standard operating procedures (SOPs) which are designed to keep organ donation separate from end-of-life care.

“The thing that annoys me most is the doctor or nurse who accidentally mentions ‘organ donation’ to the family. We know it’s not best practice and I can see the arguments, but I remember a time when no one was interested in organ donation, I used to pat everyone on the back in the group who mentioned it, but now you can’t do that. I do feel sorry for colleagues who feel that or accidentally bring it up to the family, and then of course you have a big red flag over our unit, then I have to go and talk to them, and its like “I know you were working with the best intentions and I’m really grateful you’re thinking of organ donation but we think we get better consent rates if we do it this way and also these guys are the experts on organ donation. You only deal with them once a year, once every six months if you’re lucky”. Or I’d say unlucky because there is a lot of hassle involved in organ donation.” (Clinician, interview)

Other ITU staff were explicitly told that nothing had changed for them, not to worry and just keep doing what they had done before, as non-NHSBT staff did not have the same level of training to have these specialised conversations with families:

“We actually have been told that we shouldn’t broach the conversation of organ donation to the family, it has to be through the SNOD. It probably is because we are not trained with the correct terms and how the conversation should go on.” (ICU Nurse, interview)

Some felt the law posed a real threat to the work achieved (over 20 years) to clearly separate organ donation and end of life conversations, and it was this tension that many NHS staff reflected back, i.e. that the law was highly unlikely to have any positive impact on their day-to-day practice as they were not even able to discuss the prospect of organ donation before the law change, and so would not be discussing any change in consent policies after the law changed:

“Referring [for potential organ donation] is straightforward but in the past I have found the organ donation nurses do not like it if we have spoken with the family regarding organ donation and several times have made me feel that I have overstepped the mark even after explaining that the subject was raised by the family.” (Second staff survey, Adult intensive care unit staff)

In day-to-day practice, the lack of immediate access to a SNOD/SR and delays to their arrival on site amplified these tensions in terms of who does what and when since such delays were not always seen as in the best interests of the bereaved family:

“In suitable cases [for potential organ donation] we sometimes have to wait a considerable time for the SNOD/[SR] (several hours) to arrive which can be very frustrating.” (Second staff survey, Adult intensive care unit staff)

NHSBT staff

SNODs/SRs self-identified as the key people for sustaining a culture of organ donation in the hospital. However, SNODs/SRs were also concerned about adding pressure or upsetting an overworked and burnt-out intensive care workforce. They particularly did not want to risk damaging relationships (built over time) by highlighting missed organ donation opportunities when cases were overlooked or not referred. A visible presence of SNODs was regarded as key (by everyone) in sustaining key performance indicators but this was frequently cited as a challenge due to staffing:

“[We need] more staff. Sadly, with the new 7 day working pattern there is a reduction in embedded hours. The embedded role is fundamental to relationship building with our stakeholders, increasing our presence and identifying potential donors. This is crucial to successful donation outcomes.” (Second staff survey, NHSBT staff)

Collective action: operational working together to achieve the common objective of implementing the new system

A large majority of respondents to the first staff survey (92%) agreed with the statement that they knew where to go to seek additional information and support material such as standard operating procedures and codes of practice on organ donation in their organisation. The first survey also revealed that over half (60%) of staff (not based in NHSBT) felt that NHSBT supported them in carrying out their tasks in relation to implementing the law change. This was highest among CLODs, where 98% of respondents responded that this was the case. Almost three-quarters of respondents to the first survey (73%) reported that they were completely or fairly confident in explaining the new law to patients and their family members. This, however, varied by group, with NHSBT staff showing higher levels of confidence than the other professional groups (see Table 9 for breakdown of responses by group). The more experience the SNODs/SRs had in deemed consent, the more the process became clearer to these staff and the more they supported the changes.

Table 9: Confidence in explaining the new law to patients and family members, by professional group (First survey)

Professional group	Percentage within professional group					Total number
	Completely confident	Fairly confident	Somewhat confident	Slightly confident	Not confident at all	
NHSBT staff	77%	20%	2%	1%	0%	103
Adult intensive care unit staff	4%	37%	22%	18%	18%	49
Clinical Lead in organ donation	40%	42%	9%	5%	5%	43
Operating theatre staff	0%	0%	44%	0%	56%	9
Emergency care unit staff	0%	17%	33%	0%	50%	6
Other	21%	42%	11%	21%	5%	19
Total	102	66	25	16	20	229

Just under half of the respondents to the second survey (49%) felt that they needed additional support, professional development or training to help them carry out their tasks in relation to implementing or sustaining the new system of organ donation in practice. This varied by professional group, with NHSBT staff being most likely to state they did not need such support or training. In terms of the type of additional support and training needed, the majority (58%) requested training (or refresher training) on how deemed consent was intended to work in practice, followed by training on issues affecting families from minority ethnic and different faith groups (42%). Additional requests included guidance on families' decision-making powers as well as training on how to explain a diagnosis of death by neurological criteria to families. These concerns, about how the law was helping people work together were reflected in more detail in the interviews, below.

NHS staff

Many clinicians did reflect on how best practice was evolving during early implementation and the wider impacts NHSBT standard operating procedures might be having on realising the intended outcomes of the law change:

*"I sometimes am worried that the push towards decoupling conversations with SNODs leads to disengagement [with organ donation] from clinicians. If you can go in a room and go yes, you're going to die, over to you. But you never stay and find out what over to you is, and how you can help and influence the next stage. It is also a point about how we record data, sometimes its seen as a pre-approach, where the consultant has been in the room with the SNOD but said the words [organ donation]. In my mind that's not a pre-approach. The whole point of it is to get the experts in a room together and work as a team, and it's a very complex piece of team working because there is so much at stake. There's obviously doing the best thing for the patient, that's at stake. There's a lot of pride on both sides and it is not very helpful at times. I think decoupling doesn't always help because you create a very linear, my bit, your bit. Maybe its just a personal thing for me. I feel very uncomfortable with a true decoupling when I go in the room, and come out, and they go in the room. It is not really about the patient then is it. That's just trying not to p*** each other off. It is also an impossible thing to accurately capture. because NHSBTs view is reliant on one individual's presentation of how an interaction occurred, which is the SNOD/SR. And as we all know people interpret situations very differently from their different perspectives."* (CLOD, interview)

Similar inter-professional tensions were reflected by the nursing staff (particularly in London) earlier in the pathway:

"We 'suggest', [referrals] we are always told that we can make a call ourselves, however, it would be quite difficult to work in that team when you bypass the clinical lead and, kind of, they feel like you're going behind their back to make that call. Even though sometimes you actually see this person can save so many lives." (ITU nurse, interview)

NHSBT staff

SNODs/SRs continued prefer a highly personal and adaptable approach to potential donor families, but there were frustrations that the law had had little impact on typical issues they encountered on a daily basis. These are illustrated in Box 2.

Box 2: Typical issues the SNOD/SRs encountered on a daily basis identified in staff interviews

Increased frustrations due to confused and mixed messages in the law

“As much as your trying to tell them you don’t need to make a decision, we are still asking families to support it [organ donation]. One minute we are saying, ‘deemed’ but then we can’t deem unless they support it [organ donation]. You are trying to say to them they’ve not opted-out so we want to deem consent, they’re objecting it, you push and push, and the family say, “Well if I don’t have a say what do I do?” And you’re having to say, “No, actually you do have a say, and if you say no, then that’s that...” (SNOD/SR)

Demotivation due to the law not elevating the importance of organ donation

“When I come out of that room and I can’t get consent, nobody cares, it’s so frustrating, the reality is I’m the only one out here searching for organs, if I don’t get them people die, its that simple really, I wanted it [law change] to help, it hasn’t.” (SNOD/SR)

Deemed consent manifesting as nothing more than a tick box exercise

“A lot of families will come on board and go, ‘let’s go for it’, the deemed bit is only when I come to sign the form, so I’ll say something like, ‘the reason I’m signing this box is because your relative meets the criteria because they didn’t opt-out. But I’m still going to ask you to sign to say you’re supporting this’.” (SNOD/SR)

Explaining not opting-out is choice which now means you have no objection to becoming an organ donor

“I can remember in a few conversations, families were saying to me, “He hasn’t done that intentionally. He did not know about the law change, so although his decision is blank, we have not discussed it, he does not know anything about it – he just sits in his chair every day and reads his book. We don’t even put the TV on. I’m telling you he has not actively left himself as a deemed. He just is what he was before, which is not on the Organ Donor Register.” How can you argue, we are not there to argue are we’.” (SNOD/SR)

Potentially increased strain on professional relationships

“It’s tough we are trying to tell hospitals it’s [organ donation] normal but also ‘donation’, don’t talk about it. When I’m talking don’t speak, so is that the reason they are not backing you up, but then they [clinicians] come in with their own opinions and own level of comfortableness with deemed, and I think its hard, especially now when we don’t have the staff to man the units.” (SR/SNOD)

“My colleague who was with me [with the family], was like “I don’t know if you are aware [of the opt-out law now for organ donation] and she started explaining... Then one of the family reworded it, and said “she’s saying it is against the law if you don’t want to be a donor”, the family blew up, went mad. I wasn’t shocked [they were smoking, it stank of drink, I knew I needed to tread so carefully]. I would never have mentioned the law in front of this family because it looked like they wouldn’t have respected that, and they didn’t, they refused to speak to us again, it is hard families are so different aren’t they”. (SR/SNOD)

“We do have to mould them [clinicians] a little bit, some of them are a little bit green. It’s [mentioning organ donation] never done to wind us up or to push our buttons or anything like that. It’s done where they’ve thought they had a good inroad as part of the conversation when, actually, they should have just stopped that conversation there and allowed the family to digest it. Or the classic [the family say] “what happens next”, so again the over thinkers [clinicians] go, oh my god, I’m going to have to be honest and say it...organ donation...then we need to wind everything back.” (SNOD/SR)

Disillusionment due to the lack of impact on highly individual and emotive situations

“We are dealing with irrational people, they are in crisis and grieving, trying to make a decision at that time is so hard, a sound decision, trying to apply the law at times of emotions, I would never ply it as a legal thing, I’d never leave them to believe they had no choice, or that it was happening irrespective of their suffering. The most authentic thing you can offer – is my experience, its comfort, giving hope and in time its [organ donation] meant something to so many, it’s about opening up that conversation and see how we do.” (SNOD/SR)

Irrelevant nuances in practice

“It feels a bit ridiculous, because Wales have a deemed law and we have a deemed law so the fact that you die on the wrong side of the border means you don’t apply the law [due to the residency status not allowing deemed consent to apply if people die outside their country of residence] if you’d been transferred to another hospital, it’s a bit frustrating, it seems stupid.” (SNOD/SR)

Concerns about (increasing) mistrust in the health system

“That’s the other dynamic we’re getting at the moment, since Archie Battersbee. We’re seeing a lot more resistance from families over withdrawal of treatment. The conversations that we’re having are so intense, lengthy conversations, far more questioning from families over decision making, treatment, length of treatment. Families are picking it apart, “How do you know he’s not going to get better? I’ve Googled it and this should be treated for 12 days!” (SNOD/SR)

The lack of clout in the law in traversing unyielding families

“The ones who are for it [organ donation] you’re just paying lip service to it [the law] by saying, thank you very much, obviously, you might be aware that the legislation supports you in this decision. And they’re just going, yes, get on with it, we want it, why are you telling me this, that’s lovely, bring out the forms. And the ones who are absolutely not going to entertain it [organ donation] are the types of families that it doesn’t matter what you say they will have an answer for everything. Oh you’re concerned about the operation, tell me about that. Actually, they wouldn’t want to do it for this reason, oh tell me, well actually, we’re not bothered, we’re not doing it!” (SNOD/SR)

Reconciling the law with acutely bereaved families

“I think law is a scary word for people and I know some colleagues of mine have used strong language when it comes to the law. Using the word law to people suggests there is going to be some sort of consequence should you not do it, so it becomes almost a threat. And on balance at a time of somebody’s acute grief that’s quite strong I think.” (SNOD/SR)

NHS and NSHBT staff

On the whole, we found a consensus that getting the donation conversation with the family right for everybody was a matter of the right staff coming together in the right ways and that this is something that is not easy to regulate, replicate or even articulate since the conversation has the capacity to shift and change course without warning with results which often remain uncertain and highly variable.

The general sentiment expressed was that this depended on the culture of the unit (often reliant on the embedded SNOD and a senior and enthusiastic CLOD), who else is on duty on the day and the limitations imposed by a permanently overstretched and overwhelmed

workforce resulting in missed donation opportunities and lapses in best practice. Most continued to feel that until the public were more informed, their jobs would be no easier. Generally, work related to organ donation was perceived as above and beyond the normal standard of care:

“You see with organ donation you have to have that drive and go over and above. We are asking people [NHS staff] to go over and above what they do, you’re asking favours, that’s how it feels a lot of the time and people are very nice about it and very kind but they’re obviously very, very busy with other patients. Then you get staff who say, this patient has died they’re not my priority, but I still need them [clinicians] to prescribe this, that and the other. So I do think from the hospital engagement side it’s just getting those powerful people who have that bit of a passion. From me what works really well, I’ve seen that there is a passion and there is a real interest and then that interest is fuelled in those [board] meetings and they just get really creative and they’re a strong force, they take it up and up and that’s what works best.” (SNOD/SR Interview)

Reflexive monitoring: appraising the impact of the law and system changes on NHSBT and NHS staff, and the system

NHS and NHSBT staff receive regular feedback in terms of routine donor audit data (see Box 3). These audit data showed that the law change was not having the desired impact on organ donation consent rates in the initial implementation period. When comparing the two surveys, there was a corresponding decline in the percentage of respondents in the survey who perceived that the changes would result in an increase in consent rates, and an increase in those who believed the changes would reduce consent rates (see Figure 3). A similar trend was observed in relation to the perceived impact on the number of donations (see Figure 4). Support for the law in general also decreased over time (see Figure 2). When we asked respondents to indicate the main perceived benefits of the changes, the promotion of family discussions about organ donation was the most frequently selected (selected by 58% of respondents), followed by the perceived facilitation of organ donation discussions among staff (selected by 46% of respondents). Perceived downsides to the changes included that it made conversations difficult if relatives were not aware of the change in law. Almost half (49%) also selected the option that the law was too ‘soft’:

“I don’t think it [law change] has had the desired impact on consent rates. In the deemed [consent] overrides that I have been [involved] in the law has been inconsequential to the family, as it is a soft law and cannot be enforced. The law needs to be hard and re-educated to the general public if it is to make a difference.” (Second staff survey, NHSBT staff)

Figure 3: Perceived impact of initiatives and changes on consent rate for organ donation (first and second surveys)

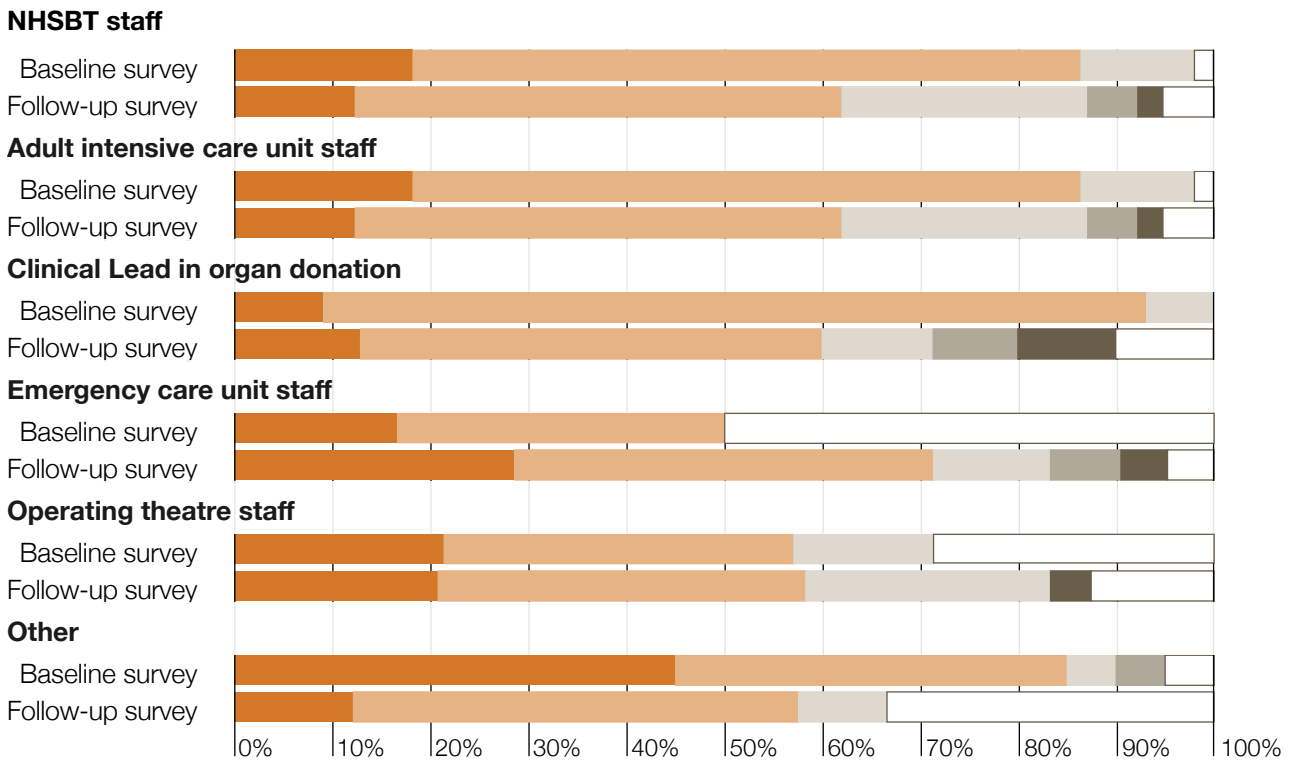
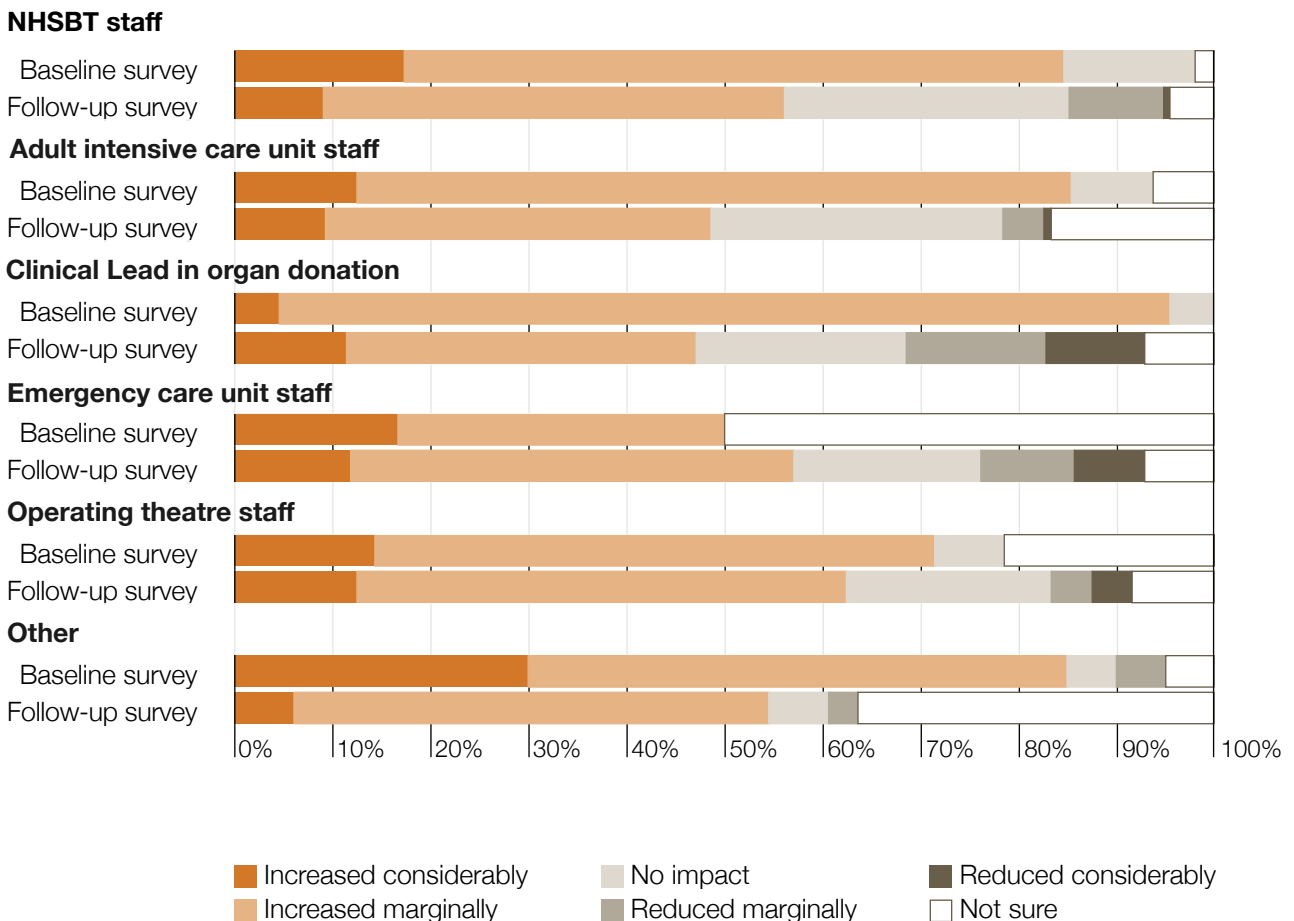


Figure 4: Perceived impact of initiatives and changes on number of organ donations (first and second surveys)

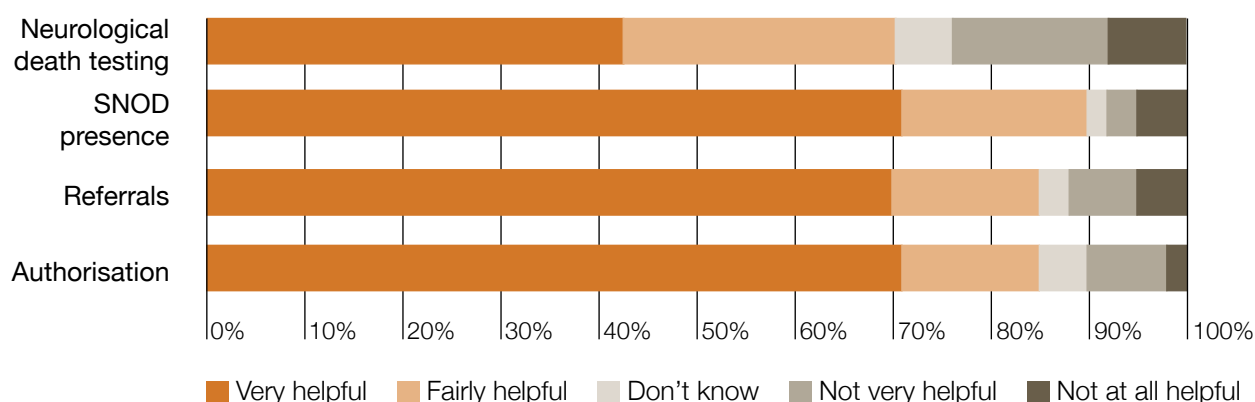


From a list of the top ten reasons identified in the 2021 NHSBT Annual Report on the Potential Donor Audit, the top three reasons why staff felt families still declined donation were that families felt that the length of time for the donation process was too long (46% of respondents); families were divided over the decision (45%); and the patient had previously expressed a wish not to donate (42%). To address these issues, staff most frequently advocated a media campaign to raise awareness among the public, as well as streamlining or shortening the processes involved in organ donation:

“The amount of time it takes for SNODs to process potential organ donations is unacceptable and a reflection of serious under-staffing and increasing demands on their vetting procedures/work up required (screening and checking for organ donation potential).” (Second staff survey, Adult intensive care unit staff)

The majority of respondents indicated that all of NHSBT’s routinely collected performance indicators were helpful (see Figure 5 for details). In response to a follow-up question in the same survey, asking how these indicators could be changed, the highest number of responses received was in relation to neurological death testing, where respondents felt staff should not be penalised for not performing these tests when there was a valid reason not to do so (e.g. the patient was unstable). These decreasing trends in support for the law change and increase in frustration with the system were also prevalent in the interviews, as described below.

Figure 5: Views on NHSBT key performance indicators (second survey)



NHS staff

Some staff reflected a dilemma with trying to encourage brain death testing independently from organ donation as the two are so intertwined in practice and there were frequently frustrations on how death testing is captured in the audit data, its accuracy and relevance to missed organ donation potential.

There was a move towards organ utilisation as a priority area during the course of the study (due to the recent publication of recommendations on ways to maximise organ transplant from living and deceased donors). There was a consensus that poor utilisation dissuades wider NHS staff from engaging with organ donation (especially in hospitals) and that the law would do nothing to help this. Others reflected that devolved implementation is already causing problems in what are always evolving end of life practices and establishing national consensus and keeping guidelines up to date.

Staff in general felt that in order for anything to change, the impetus needed to come from a change in the public who would come to expect organ donation as a part of end of life. Many also reflected on the possibility that the law change was out of step with some sub-cultures in

society as well as wider societal expectations and views on deceased organ donation, *“If you want to do something in 10 years, interventions might (if you are lucky) get you there in 8-9 years, we basically asking people to be less religious, less sectarian less everything and this takes time.”* (clinician interview)

Others discussed the quality of Organ Donor Register decisions, judging the extent to which decisions were adequately informed and proxy decision making, and that judging the quality of those decisions remained challenging. The decisions recorded on the register and the views of the family were viewed as integral to withdrawal of treatment and best interest conversations – nonetheless switching the law had done nothing to help these complex discussions on the pathway to organ donation. Some felt that in some ways NHS guidelines and NHSBTs standard operating procedures had gone too far by involving families too much in end of life decision making, and there was a genuine unease around declaring death using neurological criteria, related to some recent media cases around withdrawing treatment and declaring brain death (12, 17). Some interviewees particularly in the Northwest on reflection felt that despite unpromising early evidence were reserving judgement because they thought it was too soon to reach a clear verdict on what difference the law change was making. Many in the Northwest were also concerned that the law was losing clout every time a potential organ donor case was overridden by the family and reflected that an order of priority should be:

“We need to stop organ donor [register] overrides first, period. They [the deceased person] are on the [organ donor] register, there they are, not your [the family] decision, it’s happening. Then we can look into [verbally] expressed decisions and what they are or what not. We [SNODS and SRs] can’t do much about them at the moment, but it’s the deemed [consent] that’s the trouble. We are at least 20 years away from deemed[consent] being understood as a decision.” (Clinician, interview)

Most continued to feel that if there was no clear decision, then people would still take a cautious approach to organ donation irrespective of the change in law. Others highlighted that the law was never going to be good enough for such a diverse population:

“We have the low hanging fruit as it were, the remaining 20-25% were always going to be a challenge, will the law [change] help, no, and we should accept that some families will continue to say no, no matter what we do.” (Clinician, interview)

NHSBT staff

SNODs/SRs felt the law change had quickly faded into the background and some were increasingly worried about the public’s knowledge of the changes and the messages to the public:

“The message is now that you [the potential organ donor] do not have to do anything [to donate your organs] but families still don’t know [about deemed consent] and that really worries me, it feels like we are so far behind from Wales.” (SNOD, Interview)

Those who had been working in organ donation for a longer time (especially in the Northwest) were, however, disappointed at the lack of impact across the system and at an individual level:

“It [law change] doesn’t give anymore reassurance to approaching [family members], we were nervous twenty years ago and we are nervous now. We wanted it to be a stronger more forceful, direct vehicle for change, but that hasn’t happened, I suppose in reality it all just takes time.” (NHSBT, interview)

Most could see little change and felt, “that grief-stricken families can only take in so much, it is completely pointless to even try to explain the variables in consent, I mean ideally we want to be taking pressure off the families at really difficult times”. (SNOD/SR interview)

SNODs/SRs continuously reflected that the issues they were encountering were the same as before the law change and they continued to use their own individual interpersonal skills to “*schmooze and work with and around the various personalities*” they encountered (SNOD Interview). It also remained very important to be seen as a supportive and helpful presence on the intensive care units:

“At the start of my shift I’m supposed to go down and ask if there is anybody thinking about withdrawal of treatment. In the years I have been there is absolutely no way I would do that, I go down ask how everybody is, is there anything I can help with, would they like a cup of tea etc. then I can see what is going on and get invited into the discussions and get invited back, and that’s what changes things!” (SNOD/SR interview)

Everybody we interviewed said that the system issues were the same if not worse than before. Theatre space, funding, staffing, resources, training, reminding staff etc. remained untouched and were perceived to be at least if not more important than changing the law.

Impact of COVID-19

The COVID-19 pandemic impacted every aspect of implementation and the organ donation service as a whole. The media campaign and formal launch were cancelled, all staff education and training was paused, all SNODs/SRs were redeployed to COVID-19 related activities and transplant services were severely disrupted. Unsurprisingly, our first survey (conducted between 08/2021 and 01/2022), indicated that over three-quarters of respondents (77%) said the pandemic had affected their ability to perform organ-donation-related tasks, to a great extent, or to some extent. A similar proportion (75%) indicated that the pandemic had affected their ability to perform their wider role within their organisation.

“The roll out to staff not directly involved in organ donation was hindered by the pandemic, which dominated everything in ICU. No engagement with what SNODs could provide at the time in terms of training during the first COVID wave at it’s peak – which was sometimes held virtually and was poorly attended. It led to a largely misinformed workforce – heard a lot of “everyone’s a donor automatically now.” (First staff survey, NHSBT staff)

In our second survey (conducted between 11/2022 and 01/2023), although most suggested that end of life care had returned to the pre-pandemic state, there were continuing disruptions, such as staff burn-out (including PTSD) (reported to be an issue by 26 respondents), reduced opportunities to interact with families, as a result of the restrictions that were still in place (reported by 25 respondents). An equal number, however, also identified positive changes, in the form of innovative adaptations to help with implementation (for example, videocalls with family members) that were facilitated as a consequence of the pandemic. Interview data reflected similar sentiments over time.

“I do think we’re coming out the other side [of the pandemic]. I do think the nation’s returning to some kind of normal, but I think the hospitals and the staff are still terribly broken. And it feels like it’s just something that’s going to just explode, if I’m honest with you. The staff are broken, so everyone else has moved on but then there’s no recognition for the people who worked right the way through it. It’s now like, “Well you’re not meeting these targets, you’re not doing this, you’re not doing that.” (SNOD/SR, interview)

Discussion

Principal findings

Although most staff felt prepared for the law change, losing SNODs' embedded time within NHS hospitals was considered detrimental to relational work prior to (but exasperated by) COVID-19. There were mixed messages and views about when SNODs/SRs should or should not be mentioning the 'soft' opt-out law change during their conversations with family members. SNODs/SRs shared that they often had negative experiences with families when talking through the law change and what it meant, which significantly affected their perceptions of the practicability of the law change. NHSBT staff sometimes found it challenging to make sense of, and distinguish, old from new practice, especially as the 'soft' opt-out was implemented into the existing opt-in system, neither system had universal coverage. After receiving initial training and education concerning the law change, many staff in the NHS and NHSBT were redeployed to help treat severely ill patients with COVID-19. This meant that there was an overall loss of opportunities for collective cognitive participation in implementing the law change because organ donation was not the priority during the pandemic. Overall, the Northwest region seemed to find it more straight forward to implement the change in law, in part because the SNODs/SRs in this region covered North Wales and had been working with the Welsh 'soft' opt-out system since 2015 and there were very active organ donation committees supporting implementation.

Many felt that the continued requirement from NHSBT imposed on other NHS staff not to mention organ donation to family members was harming collective action and caused frustration when staff felt punished for doing so, especially when they were trying to facilitate organ donation. Despite this frustration amongst NHS staff, SNODs'/SRs' confidence with implementing the deemed consent pathway increased with the number of deemed approaches they had made.

There are many ongoing opportunities for reflexive monitoring in the organ donation system as NHSBT routinely collects a mass of data, which is fed back to all those involved in organ donation. On the one hand, NHSBT appeared to be reassured that there was little difference in practice and consent rates following implementation of the law, due to anxieties that the law change and implementation during COVID-19 would make things worse, and on the other disillusioned that nothing had changed in their practice or their consent rates. They faced the same challenges as before – the law gave them no new tools to navigate the complexities of speaking to the acutely bereaved or influencing the family's behaviours in regard to deceased organ donation. NHS clinicians too felt that NHSBTs standard operating procedures did not easily reflect reality on the ground, and were not always helpful in what were unique and complex, discussions and negotiations.

Meaning of this study

Our study has shown the complexities of trying to bring about change in a system where the key implementers (SNODs/SRs) are sometimes only in post for a short-term, have less time and resources than in the recent past to promote an activity (organ donation) which, for the majority of NHS staff, is very rare. This means that it is difficult to achieve coherence, cognitive participation and collective action to support implementation that is meaningful and sustainable across the NHS and NHSBT. This was made especially challenging to achieve in the unique context of the COVID-19 pandemic.

Over time, support for the law change decreased as did any perceived positive impact the law might have on consent or the organ donation system. In their reflexive monitoring and appraisals, staff continued to feel that the reasons for refusals were the same (processes too long, family divided or had previously said they did not want to donate). The lack of clout of

the law, its limited capacity to cope with population heterogeneity, irrelevant nuances in the law in practice, and the lack of impact on end-of-life proxy decision-making gave no more reassurance to anyone that the law would work in a practical help anybody in the system. Organ donation remains relatively rare even for ICU staff and sits outside clinical care of patients and thus requires staff involved to go to great efforts to secure donations, and within a permanently overstretched system and overworked workforce, making organ donation a priority outside NSHBT continued to prove challenging.

Introducing an opt-out policy in England automatically switched the default position of nearly 45 million adults to one that, in principle, should have positively supported organ donation. However, in practice, this has resulted in a series of standard operating procedures trying to cover a whole range of processes and scenarios and are now standing in direct opposition to the aims of the changes, which were to make organ donation a routine part of end-of-life care. While staff on the frontline remained highly motivated and engaged with organ donation and the good it might bring about, the lack of evidence of a positive effect on consent rates contributed to staff becoming disillusioned with the law change and any potential good it might bring about.

Implications for policy and practice

The findings presented in this paper are consistent with similar research in other countries which indicates deemed consent has had positive impacts on consent rates in some countries and negative impacts in others.[12, 18] Due to the mixed evidence, it is too soon to tell whether England is likely to be one of the positive cases but without the additional implementation strategies (discussed above) impact (on consent rates) will likely remain marginal.

It seems appropriate now that the crisis phase of the pandemic is over to take stock and consider what would further enhance implementation of the law change. When thinking about further changes and enhancements that could be made to the current ‘soft’ opt-out system three years after initial implementation, findings suggest that it would be helpful to revive the programme of support for the law change, which was cancelled due to the pandemic, with a focus on rebuilding and stabilising the NHS and NHSBT workforce involved in organ donation in the wake of COVID-19, revising and relaunching training and renewing the public media campaign. It will likely be challenging to move organ donation up the NHS priority list when there is an ongoing staffing crisis, staff are striking for more pay and there is a huge backlog of patients requiring treatment, but it is clear that unless organ donation becomes a higher priority, it will be difficult to bring about the required changes. NHS staff outside NHSBT, in particular, need to become more involved in deceased organ donation, to be encouraged to believe that it is their business to be involved in organ donation and to be provided with more stimulating work processes (e.g. examining the NHSBT veto on clinical staff becoming more involved in organ donation conversations) in order to stay motivated to maximise organ donation opportunities. Operational processes need to adapt to the intentions of the new legislation and ‘soft’ opt-out, rather than compete with it. Markers of success need to be individually tailored and more meaningful (e.g. number of lives saved or improved) and not just on establishing what is and is not deemed consent. Overall, current processes and operating procedures need to be changed such that they make implementation of the ‘soft’ opt-out easier and create simpler work processes for everyone.

Strengths and limitations

Some of our data collection was hampered by COVID-19, in particular the response rate to the first survey, but we recruited a high percentage (approximately 52%) of relevant NHSBT staff (SRs, SONDs and managers) and CLODs (approximately 70%) to the second survey. Some follow-up interviews were paused as there was very little evidence of impact or change over time. NPT was helpful in visualising and integrating data and explaining why the ambitions of the Act were not yet coming about in practice.

Conclusion

Implementing the law change at the height of the pandemic and in a crisis situation when many staff were retrained and redeployed elsewhere has meant that implementation strategies were ineffective, diluted or did not happen. Although broadly supportive of the law changes as morally the right thing to do, NHSBT staff were not generally convinced that the 'soft' opt-out system would deliver the expected increased consent rates as envisaged by legislators. NHS staff, in particular, were not able to fully consider or process the required changes to implement the 'soft' opt-out legislation during the pandemic due to other competing priorities and general disruption to care as usual. The NHS now needs to reprioritise organ donation (although this will be challenging given the current pressures on the NHS) and relaunch and revise the continued implementation of the 'soft' opt-out system with a largely (albeit slowly) replenished workforce. Nonetheless, even with a relaunched implementation a 'soft' opt-out system is always going to be difficult to implement if the main goal is to significantly increase consent rates.

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8

Potential donor families' behaviours and experiences following implementation of the Organ Donation Deemed Consent Act 2019

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Summary

Background

In May 2020, England implemented “deemed consent” legislation to reduce barriers to consent for deceased organ donation. We aimed to learn more about the experiences, behaviour and decisions of families who were approached about organ donation after their relative died.

Design

A qualitative study informed by a health systems perspective and utilitarian theory.

Methods

Semi-structured interviews with people involved in organ donation discussions, feedback from nurses, comparisons with NHSBT routinely collected audit data, stakeholder feedback and public involvement. Framework analysis informed by theory.

Findings

103 participants were interviewed representing 83 cases. 31/83 (37%) cases fully supported organ donation, 41/83 (49%) supported retrieval of some organs, tissues and procedures, 11/83 (13%) cases declined completely. Overall consent rates have fallen since implementation. Irrespective of the decision made by the deceased in life, most families still thought they were the decision makers. Families struggled to comprehend the highly complex and multiple processes involved in organ donation that they were presented with. Specialist nurses were critical in supporting families through these confusing processes. Families most frequently asked themselves if their relative would have wanted to donate (i.e. have a surgical procedure) rather than whether the person who died wanted to save lives. Families frequently unpicked the decision of the deceased and superimposed their own values, preferences and judgements to challenge and overturn consent, especially when consent could be deemed.

Conclusions

Despite a change in legislation, family behaviour did not appear to align with the utilitarian assumptions implicit in the Act to benefit people requiring transplants. Family members not supportive (of deemed consent, in particular) believed that donation would cause them and

their deceased relatives additional harms. They opted for what they thought would benefit them or their family the most rather than to provide the maximum benefit to unknown others.

Introduction

In this chapter, we turn to the experiences, behaviours and decisions of family members of potential donors, close friends and nominated representatives (who were involved in the decision-making process) and whether these are now aligned with the behaviours expected in the new opt-out system. In particular we wanted to know whether:

- the family members (and others involved in the decision) understood the changes and their changed role;
- the changes were well explained to them;
- they had confidence in the new system;
- they overrode the organ donation decision made by the deceased, and, if so, why they did so; and
- if they had enough support during and after the donation process.

Methods

Theoretical perspective

We conceptualised the Act as an intervention that was implemented into a complex and dynamic health system at the point of an equally complex aspect of human behaviour – acute bereavement. We therefore framed the study from a health systems perspective. A health systems perspective enabled the exploration of the impacts of the intervention on the whole system (rather than specific parts), with a focus on the interactions between components and their respective contexts.[14–16] In order to illustrate these wider contexts we developed a logic model (see logic model) and health systems map describing ex ante how the ‘soft’ opt-out was meant to work and to help conceptualise the changed role of the family within this dynamic system. (See within the appendices of the PIRU published protocol (Appendix 1 Figure 2) .

Utilitarianism is a consequentialist ethical theory that has been applied to the law change and organ donation.[17] Utilitarianism holds that actions should only be judged on the basis of their results, irrespective of the motives driving the decisions that lead to the results. Utilitarianism does not differentiate who or what should benefit, only that overall happiness (utility) should be maximised. Thus, from a health system and potential organ donor perspective, the goal implicit in the Act is for potential donors (and their families) to make decisions that maximise happiness by taking into account the potential benefits to other members of society (e.g. by making altruistic decisions), thereby saving and improving as many transplant recipient lives as possible in a cost-effective way. A recent position paper by Morris and Holt applied utilitarianism to the new ‘soft’ opt-out system of consent and the role of the family in the UK NHS. They hypothesised that family members would not act in line with the utilitarian ethics underpinning the legislation to increase the benefits to transplant recipients, but would often tend to make decisions to suit themselves (and their own utility), thereby discounting the decisions that their deceased relatives made in life to donate their organs.(18) We therefore felt that it would be useful to test the hypotheses of Morris and Holt in this analysis. See Figure.1 for a brief summary of the core principles of utilitarianism applied to deceased organ donation from the perspective of the donor family.

Figure 1: Utilitarianism and organ donation – from the perspective of family members**Utilitarianism and organ donation from the perspective of family members****Definition**

States a person's decision is morally right if and only if it produces the best possible results in that specific situation. Utilitarianism does not differentiate who or what should benefit-only that the consequences increase/ maximise collective wellbeing.

The 'soft' opt-out to organ donation advocates the saving and improving of (multiple) lives through making it easier for people to donate their organs resulting in more transplants and patients who benefit and additional resource savings for a public health service.

Core principles

Greatest happiness: pleasure or positive utility, such as improving well-being, should be maximized.

Family members may agree that the greatest benefit is to save lives, or they may feel that they gain more benefit from making different donation decisions to their deceased relative.

Impartiality: each decision should be without bias or prejudice. The assumption of the legislation is that the family will put their own views aside and support the decision of the deceased.

Family members can still decide not to support their relative's decision, as the law allows them to do so without prejudice or bias.

Consequentialism: the morality of actions should be judged by their outcomes.

There is morally no right answer from the perspective of family members.

Overall design

This was a theory-informed qualitative study using Framework analysis of semi-structured interviews with potential donor family members, close friends and nominated representatives who were involved in the organ donation decision-making process at end of life. Interview data from the aforementioned were supplemented by anonymised feedback from SNODs/SRs on cases where organ donation was declined, complemented by a high level of public involvement and input from a multi-disciplinary expert advisory group, which included donor families. We report the study using the Consolidated Criteria for Reporting Qualitative Studies (COREQ).[19]

Data collection

Interviews: A topic guide and interview protocol were further evolved from a previous study [3] and used to explore family members' personal views on organ donation, the Act, media campaigns, their personal experiences when approached about organ donation, minority ethnic perspectives and amended processes during COVID-19 (as the Act was implemented at the height of the pandemic). The initial topic guide (individualised to explore specific phenomena as appropriate) was shared with the advisory group and selected key stakeholders (e.g. NHSBT staff involved in implementing the Act) for their input, and can be found in the protocol.[13] Detailed fieldnotes were recorded, participants were interviewed once and audio-recorded. Transcripts were not returned to participants. Interviews lasted 55-130mins with 1-6 family members (and sometimes included close friends) who were involved in deceased organ donation decision-making.

SNOD/SR feedback: We requested that SNODs/SRs complete a brief free text box on their iPads for cases where the family declined organ donation so they could document their perceptions as to why they thought this might have happened, and anything they thought could help change or influence families' behaviours, and to see if there were any differences between the SNOD/SR interpretations and the families' own narratives (Supplemental file 2).

Sampling

For the qualitative interviews, all family members, close friends and nominated representatives (>16 years) where the person who died was a potential organ donor following the law change were eligible for inclusion. We aimed to recruit a minimum of 60 participants. As the study progressed, we developed an additional sampling framework (Supplemental file 4) in order to address key gaps in knowledge. We specifically aimed to target behaviours associated with families who declined organ donation and especially complex cases; e.g. where family members disagreed and cases from minority ethnic families as well as those which fitted the criteria for deemed consent.

Recruitment for interview

We recruited in two purposively selected NHSBT regions – there are nine regions which cover England – selected to cover a wide geographical area, high proportion of ethnic minority populations and variation in consent rates. We recruited directly through the SNODs/SRs who sought consent to contact (name, address, number, email) while speaking to family members about organ donation. We also organised recruitment via SNODs'/SRs' routine follow up calls, and via a postal mailing to families whose relative had been eligible for organ donation. Recruitment opened as planned in one region in September 2021, and closed in July 2023 (22 months), and opened in April 2022 and closed in July 2023 in the second region (15 months). In July 2022, we stopped recruitment of families who had consented to organ donation and purposively sampled only families who had declined (for any reason), and people from ethnic minorities. The consent to contact forms were digital, kept on SNODs'/SRs' iPads and transferred to the research team via a secure NHS email. Seeking consent to interview followed a straightforward protocol (wait a minimum of 4 weeks to contact, initial contact via phone, with a follow up email) but was adapted whenever necessary to the potential participants' needs.

Interviews were offered initially virtually (Teams, Zoom, telephone – due to COVID-19) and then opened up to include face-to-face, in a way and at a time the participants chose, and undertaken by an experienced female researcher with a PhD (LM) (two interviews were undertaken by another experienced female researcher with a midwifery qualification (LW)). We received 148 forms and 136 had contact details of potential participants.

Data analysis

We used the Framework approach by creating an a priori index for coding transcripts and analysed data using the selected theories (charting, mapping and interpretation).[20] Codes included, for example, personal motivations to donate or not, views on the law and what difference it made for them, the organ donation bedside conversation, what the deceased did (e.g. registered on the organ donor register, discussed organ donation or did nothing) and what the family did in relation to that decision, end of life processes leading into organ donation, family dynamics, the retrieval processes, tipping points, comfort and care, views on media campaigns or other nudges in the system (e.g. drivers' licence renewal). Interviews were transcribed verbatim, uploaded to NVivo 12 and coded by three female researchers (AJ, LM, SJ).[21] The SNOD/SR free text responses were also uploaded to NVivo, using the four questions asked (Supplemental file 3) as initial codes and reviewed for themes.

Validity, reliability and rigour

Discussion of data meaning and emerging themes started as soon as data collection began and these were shared at fortnightly team and separate analysis meetings via detailed fieldnotes, supplemented by possible patterns and explanations of behaviours. The core research team had varied experiences (clinical, academic and personal) and were able to offer additional insights into the emerging data. We used four well-established quality criteria (credibility, dependability, confirmability and transferability) [22] throughout. Presenting findings to a multi-disciplinary advisory group, regular updates and presentations to NHSBT staff,

ongoing engagement with SNODs/SRs, purposive sampling, attending organ donation committee, management, performance and training meetings and events at a local and national level, provided additional markers of rigour.

Reflexivity

The research team included a mix of male, female and ethnically diverse academics and lay representatives with a mix of experiences in health services research, health economics, social care, clinical and policy contexts. Two members of the research team had previous experience evaluating a similar policy change in Wales, were members of the Wales Kidney Research Unit, and had worked on several studies of organ donation and transplant (LM, JN). Potential biases were acknowledged through discussion, as well as taking opportunities to develop a much wider patient and public network of various groups and individuals not directly involved in organ donation or the clinical context.

Ethics

Ethical approval for the study was obtained (LSHTM ethics committee (Ref: 26427) and HRA (Ref: 21/NW/0151). Informed consent was obtained before each interview. Members of the research team had undertaken previous similar research and were experienced in recruitment to studies which included sensitive interview topics e.g. pregnancy loss, degenerative chronic conditions and complex decision making. We adapted a framework for ethical decision-making used successfully in these previous studies which focused on things like respect, compassion, options and choices, support and inclusion.[3] We partnered with two independent bereavement care charities and signposted to these during the interviews. Interviews included a distress protocol and we worked closely with SNODs/SRs (who routinely approach families for organ donation) and delivered bespoke training to support them to recruit and provide information to potential participants. Researchers (including those processing and coding data) were offered additional support, regular opportunities to debrief and encouraged to access bereavement care services if they felt the need.

Patient and public involvement (PPI)

We adapted a well-established PPI network from previous research and expanded it with a focus on individuals, groups and charities supporting the organ donation agenda from a minority ethnic perspective, as well as additional services involved in bereavement care and supporting potential donor families in England. We followed the UK national standards for patient and public involvement throughout,[23] involving PPI in every element of the study. We also arranged separate bespoke input from wider experts such as educational trainers and specialists in legislation drafting and implementation.

Findings

Of the 136 forms received, we made initial telephone contact with 104 potential participants, and undertook 84 interviews, representing 83 potential organ donation cases. Of the 20 cases contacted and not interviewed, the main reasons were forgetting the arranged interview and not finding a convenient time to rearrange. Three consented to interview but did not attend and we were unable to recontact directly, and three declined an interview after hearing more about the study. Two felt they did not have time for an interview whilst managing current life events.[11]

Across the 83 cases, 103 people were interviewed and in total a wider number of approximately 245 people were involved in some aspect of the organ donation discussion with SNODs/SRs after their relative died. Participants were predominately, white 83/103 (81%), female 74/103, (72%), not religious 72/103, (70%) and were a spouse/partner or a parent or child of the deceased 80/103, (78%). See Table 1 for detailed demographics of interview participants.

The 83 cases represented 39/83, (47%) opt-ins on the ODR, 17/83, (20%) verbally expressed decisions, 24/83, (29%) fitting the criteria to deem consent, and 3/83, (4%) were family consent due to mental incapacity and residency status. Of the 83 cases, 31/83, (37%) fully supported the organ donation, 41/83, (49%) supported some organs, tissues and processes but not others, and 11/83, (13%) refused any donation. Further details of the decision pathway are available in Table 2. We received additional contextual information from a further 23 cases from family members who declined organ donation (any pathway) via the SNOD/SR free text questions. To provide context, it is worth noting that there was an overall decline in officially recorded consent rates in England from 67% in 2019 to 61% in 2023.[24]

We developed two high level themes: 1. Family behaviours and decisions; and 2. Family experiences of navigating and following organ donation systems and processes; and nine sub-themes explaining how and why the law was not yet bringing about the desired increase in consent rates to benefit more transplant recipients.

Family behaviours and decisions

1. Understanding and agreeing the family member role

The implementation media campaign was cancelled in March 2020 (due to COVID-19), and recent (and ongoing) domestic and global events continued to overshadow NHSBT's public communications, e.g. COVID-19 anti-vaccination campaigns, the Ukraine war, the death of Queen Elizabeth and the murder of George Floyd. Unsurprisingly most people had little to no memory of the implementation campaign when shown prompts. Most people agreed with the sentiments of the follow-up media campaign messaging, 'Leave them Certain' but almost nobody had seen the latest campaign or anything to do with organ donation in the recent media. Campaigns themselves were framed in a value-neutral way, informing rather than promoting organ donation. Their messaging was unlikely to prompt or encourage any immediate actions. Overall, the implicit utilitarianism of the Act that assumes the best consequences will be brought about by donating organs were lost on family members. Most family members still thought that the decision was theirs to make. As Morris and Holt predicted,(18) this resulted in tensions between family members and SNODs/SRs who were trying to balance honouring the decision of the deceased person with the family members' perception that they had the right to make decisions that suited them best (rather than the deceased person). In the following sub-themes, we explore these tensions in more detail.

"Families are complicated aren't they, death causes tensions, brings out the worst and the best in people, and there are countless things to organise in death I can't see how this [law change and introduction of deemed consent] is likely to infiltrate or help such matters to be honest." (076, Partner, verbally expressed, partially supported)

2. Overall confusion about deemed consent

The only new consent pathway introduced under the 'soft' opt-out legislation was deemed consent. Deemed consent applied when the deceased person had not registered or conveyed their organ donation decision during life and it was then presumed in law that they had no objection to being an organ donor. The deemed consent rate in England was 57% in the period April 2022-March 2023 and far lower than the other consent pathways. All those interviewed were asked about deemed consent. Overall, families' understanding of deemed consent was confused and many did not see that deemed consent equated to a real decision. Although family members struggled with the information provided on all the consent pathways, it was especially so with deemed consent as the family members had to process a lot more questions in order for consent to be deemed.

"You see we were not switched to receive this information at all, we really didn't know what to do." (026, Spouse, Deemed consent, declined)

Common misconceptions included deemed consent being associated with giving families more decision making powers, or conversely taking away individuals' (potential donor and family members) decision making powers, or that deemed consent would somehow undermine the excellent care the family had received hitherto. Common words to describe deemed consent from less supportive families included: *"ambiguous, lacking clarity, unhelpful with such big decisions; a sneaky approach by politicians to take organs without permission; slippery and oily approach to politics; too apathetic, untrustworthy; and something and nothing."*

Some people felt that the new default would bring about protests and therefore might encourage people to opt-out of organ donation, especially within the UK cultural context. *"[British people], do not like being told what to do and do not like doing things they did not choose to do, and this is the real threat or danger of presumed consent – it can be a knee jerk reaction or a protest against other things often completely unrelated to organ donation – and there is really no way to distinguish between the two."* (018, Parent of adult child, on the ODR-In)

Families were involved in 24/83, (29%) cases where deemed consent applied when their relative died. Of those 24 cases, 3 families supported deemed consent, 12 families partially supported it, in that they supported the donation of some organs and tissues but not others, and 9 families overrode the deemed consent. We explore supporting and not supporting deemed consent in the following two sub-themes.

A. Not supporting deemed consent

Deemed consent was the pathway most frequently overridden by family members. They created a narrative based on what they knew about the person, unrelated to organ donation (e.g. views on being in hospital, surgery, death, burials and rituals associated with end of life). It was their views about processes involved in retrieval (and not whether the person wanted to save lives) that families were wrestling with when they were taking decisions.

Families struggled to view deemed consent as affirming that their relative would have supported organ donation on the basis that it would benefit transplant recipients. The following quote illustrates both the problem of not knowing their relative's organ donation decision but also that for them in their unique situation, the uncertainty of whether the person would become a donor and the value placed on that by some family members, tipped this family towards ambivalence. The uncertainty – for the family – was not worth the additional steps necessary to retrieve organs.

"I suppose it was that we didn't know whether she would or wouldn't [be able to donate]. It wouldn't have mattered to her because she would have been dead anyway. But it mattered to [daughter] and therefore it mattered to me and that mattered then to the family, which then included me, so that was the decision that was made." (028, Spouse, deemed consent, declined)

For many families, the actual processes involved in organ retrieval were used by families to create new narrative(s) about why the deceased person would not have wanted the surgery.

"We didn't discuss it, but if you knew her, she even put on make-up for zoom calls with the kids, hated having her photo taken, didn't want to go to hospital or be exposed bodily ever in that way. I know the benefits of it [organ donation] the hard thing is when it comes to someone who you know so well and you know their views on their own privacy, not wanting to be exposed or seen to lose their dignity, and also the images for the children of what it means, the images that you have in your head of what's happening to your loved one that is the barrier...to making that decision at that time." (059, Spouse, deemed consent, declined)

Families' views were often based on statements unrelated to organ donation but were rather based on their opinions about the deceased's state of mind, as if they were still alive. When

discussed within the family, this could develop into a (very) negative position towards the organ retrieval.

“They explained it [organ donation and retrieval] quite well. They also explained the myriad of controls before they can even look at an organ never mind take one. And then the timing and how critical that was as to whether they were going to be able to take an organ, would it be any use. At the end of it all, we went off for a little chat and apart from the messing about for the NHS to try and get an organ out of her body, sadly we were probably at an emotional low and a bit – not obstructive but a bit self-centred, but she always said that, in all sorts of circumstances she would never want to be messed about with. And as a women who wouldn’t be messed about and someone to literally mess her about in the worst possible way, I just thought no, let her be, it’s been too long, you did all this and nothing helped, leave her be.” (029, Spouse, deemed consent, declined)

Morris and Holt also suggested that the opt-out system involving family members could allow for families to project their own values and preferences rather than those of their relatives. Although this can also occur in opt-in systems, we saw this happening in several cases including the following example:

“When you think about it of course she would be kept alive so that the organs don’t die – but that is not where your head goes. You think, that person is dead; they’ve died. They can donate their organs.” The technicality and medical side of it have keeping them physically alive, while the organs are harvested, is a different thought process once it’s given to you. They walked us through the process of how it would happen, I know it sounds awful but I didn’t want it for her.” (022, Daughter, deemed consent, declined)

When asked at the bedside, families struggled to remember a ‘last known decision’ (this is a requirement before deemed consent can be applied in the UK system), and when they could not, deemed consent did not help as it was not considered a valid decision.

“That’s exactly what they asked me [did she express a view], I’ll tell you the truth, I don’t remember her view, whether that is she didn’t give it to me or I don’t remember because I’m very good at selective memory, and if it didn’t suit me I wouldn’t remember, but I think not. We were talking about my views. I don’t feel as though I could make that decision for [deceased]. It needs to come from the individual to determine whether you want to give up any organs, as opposed to giving up the organs of somebody that you love dearly.” (029, Spouse, deemed, declined)

Some families who declined organ donation via deemed consent felt that the entire process was too value neutral (our interpretation). They had recommendations to make organ donation more personal by knowing a bit more about who the organs are going to, and were less comfortable with the anonymity of an entirely altruistic gesture. At the same time, this also represented the subtle ways in which families were able to substitute the validity of the deemed consent for their own values and preferences, and create a legitimate and defensible alternate narrative as to why the organ donation was not going to proceed.

“The explanation we got about how organs could be taken and used, it was explained on a legal basis, how it could be done, when, time, timings and everything else. They didn’t expand on how many people would be available for the organs. Obviously by that point they had taken many, many bloods so they could have explored who was in range and available. I mean maybe it’s a terrible admin exercise, but for me it would be, “right, this is a person in the area, we have a consultant on call to do the operation and if you agree this could go ahead literally within hours and we can guarantee that organ would be going to that person and be beneficial.” Now it’s on a personal level...you’re actually very subtly putting pressure on because you’re saying, “look you could literally help Joe Plug who is down the road!”. I

mean I don't think it is beyond the wit of a man to have a computer programme to match up people to organs and just put it on the table, that would be far more effective, than how it came to us." (026, Spouse, deemed consent, declined)

B. (Ambivalent) support for deemed consent

The families who supported deemed consent still struggled to understand that the consent had in fact been deemed. This was often due to the consent processes (discussed later). They said they would have behaved exactly the same way and made the same decision without the deemed consent option. The utilitarian values implicit in the Act, were only helpful in supporting deemed consent if the family supported organ donation, there was a relatively distant relationship between the family members and the deceased person, and if there were fewer family members present to discuss the organ donation. Most families could not identify any benefits that deemed consent brought or would have brought to their very recent experiences.

"I was like hang on you are telling us that all of this is going to happen, I did ask what happens if I say no here, I don't really think we got an answer, they probably didn't want to answer that [laughs], I mean it was fine we were going to do it anyway." (017, Ex-husband, deemed consent)

3. Not supporting the deceased person's expressed decision

The overall rate of expressed opt-in overrides by family members in England was 11% in the period April 2022-March 23. In our sample, 2 families overrode their relative's decision to opt-in on the ODR, and we did not recruit any families that had overridden a verbally expressed decision, although as reported elsewhere, SNODs and SRs generally found it difficult to unpick whether family members were expressing their own preferences or the final expressed decision of their deceased relative.

In the case of the 2 families who overrode an opt-in decision on the ODR, being presented with the ODR registration created conflict and confusion. These family members pieced together events, scenarios and conversations (often over a very long time, having lived with the person for many years) into a narrative shared with the SNOD/SR that they believed indicated their relative did not want to be an organ donor. Often decisions were recorded a long time ago on the ODR, or as a passing remark, without any substantial detail, and often only one family (vaguely) remembered hearing such remarks. This started to create doubt, often in one family member, of what their relative really wanted and this began to dismantle their trust in the expressed decision. Again, the decision the deceased person had made in life to benefit transplant recipients was gradually unpicked and transformed into another decision that had what the family perceived to be greater benefits for the deceased person (i.e. they would be saved from a wrong decision on the ODR), or which turned the situation into one of most benefit to family members (such as closing down the potential for conflict and lasting relational damage amongst family members by refusing donation).

Although no verbally expressed decisions were overridden by the family members interviewed, the verbally expressed pathway created more problems for families in that there were more opportunities for families to disagree when there was no ODR decision, to question the relative who recalled the decision, to put that relative under pressure, or to claim that the deceased was unaware of the implications of what they were saying at the time, thereby challenging the validity of the expressed consent, and turning it into an opt-out (it is a requirement that the SNODs/SRs establish if there was a verbally expressed decision, before they can proceed on a deemed consent pathway). This was not necessarily because family members were trying to stop the organ donation but because (some family members) genuinely believed they were acting in the best interests of their relative, and other family members (where there was disagreement) believed that their deceased relative had changed their mind when alive.

4. Organ donation as too much of a harm

The Act assumes that family members will support the organ donation decision that their relative made in life, whether that person registered it on the ODR, discussed it or did nothing, thereby opening up the deemed consent pathway. In reality, family members were in unique, emotionally charged, often chaotic and traumatised states, often having experienced sudden, catastrophic and premature loss of a loved one. They had been faced with an unexpected loss of the person and now they could feel that they were being asked to ‘lose a bit more’ of the person in the form of organ donation. The visualisations of the surgery, the mechanics of retrieval, the currently ventilated state of the deceased person and the circumstances which would lead up to donation, were too great for some, who believed they would be haunted by visions of their loved one ‘being cut up’, ‘butchered’ or left ‘as an empty shell’. Within the deemed consent pathway, in particular, where family members did not know the organ donation decision of their deceased relative, families most frequently asked themselves whether their relative would have wanted surgery, to be ‘splayed out’, ‘under the lights’, ‘messed around with’, ‘hacked to bits’, etc. This undermined the assumptions underlying the Act, which were being trumped by some family members’ squeamishness, disgust and general (imagined) horror of organ retrieval.

Declining organ donation was however a cumulative process and multiple factors influenced family members to refuse to support the decision to donate organs, including:

- **Getting mixed information from other staff.** *“I did mention it [organ donation to the doctor], all they said was it would just prolong all this [ventilation in ITU], I just couldn’t bear to keep seeing them like that”.* (079, Spouse, ODR-In, declined)
- **Being overwhelmed with guilt.** It was common for families to find their relative, e.g. attempted suicide or found unconscious alone sometimes after a long time. Families worried about what they saw as potentially getting something else wrong at end of life. They elected to err on the side of caution by saying ‘no’, letting their relative go in what they saw as a peaceful and traditional way.
- **Avoiding family conflict and obeying family hierarchy.** *“Part of me would have maybe donated certain things such as liver, kidney, more like organy but not brain or eyes. But my brother had such a strong reaction to it, that then did change my view completely listening to him. I still didn’t want her messed with, but then I think after a conversation with the bereavement nurses, I could have agreed to some form of donation, but my brother was like “absolutely not, I’m putting my foot down, this is what I want. As your elder brother I need you to listen to my wishes, and that’s where we ended up going down and saying, “no””.* (022, Daughter, deemed consent, declined)
- **Perceiving that they were causing additional and unnecessary ‘handling’.** Many families witnessed the traumatic injury, accompanied their relative in the ambulance, through A&E and into intensive care, observed intubation, frequent observations including multiple tests, and being moved back and forth for specific scans and treatments. Organ donation was perceived to add to a long list of (unhelpful) processes, which when combined became too much on top of the organ donation which would delay the process of letting them rest and be at peace. *“Weirdly I think the worst part or most emotional part was when they took her jewellery off her, that was horrible. It was cold blooded as well – what a cow – the words she used to justify it was something like, “not everybody in these wards is honest”, I was thinking “oh that’s not nice”, I said “we’re going back to Edwardian time are we? You go around chopping peoples fingers off for their rings.” God. That was a difficult visit, you see the air of finality about it as well, seeing rings taped up and the like.”* (076, Spouse, deemed, declined)

In the following sub-themes, we move onto evidence from family members who supported organ donation. These sub-themes are briefer as a lot is already known from previous research as to why organ donation is supported.

5. Supporting their relative's expressed decision to be an organ donor

The overall expressed consent rate (Opt-in ODR and telling a relative) in England was 89% in the period April 2022-March 2023. Amongst the cases interviewed, families fully supported their relative's verbally expressed decision in 5 cases and partially supported (in that the family said "yes" to some organs, tissues and processes but not others) in 12 cases. Families fully supported their relative's decision to opt-in on the ODR in 21 cases, partially supporting it in 16 cases.

Although it has no legal status, the Organ Donor Register (ODR) was highly valued by families. For most it helped, and created a sense of pride and even opportunities to celebrate their relative's decision to donate their organs to benefit others. However, many people did not know that there was a register, how it worked, or that their relative was on it when the SNOD/SR came to discuss organ donation.

"I was just so so proud of them, I had no idea [they were on the register], it was only when the nurse came and said it, I remember just feeling completely overwhelmed with pride, I would have done it anyway [if they were not on the register] but I don't think it would have felt the same." (018, Mother, ODR-In)

"If I made a decision to donate I wouldn't think anybody would have the right to override that. But you've got to have gone on and filled the appropriate form out, or whatever it is you have to do, and then if you've done that a husband or a child can't override that, no, that is wrong." (15, Husband, ODR-in)

When the deceased was not on the ODR, but families recalled a conversation where their relative said they wanted to be a donor, in order to help families support the organ donation, the decision had to be recent, heard by more than one family member, aligned with the family's own views on organ donation and what they intuitively felt their relative would have wanted.

Family experiences of navigating and following organ donation systems and processes

In all of the sub-themes reported below, we also see a rejection of the utilitarian benefit of organ donation to transplant recipients and, instead, a focus on what was best for the family or the family's interpretation of what would now benefit the deceased person most.

6. The different experiences of DBD and DCD

Of the 83 cases, 34/83 (41%) were DBD, and 49/83 (59%) were DCD. There was a difference for families being told their relative had died (DBD) versus being told their relative was not going to survive (DCD). DCD was associated with more confused and mixed messages from staff, overwhelming and difficult decisions, and increased family burden. It was common for families to initially say "yes", but then withdraw consent completely as the situation evolved, especially if there were perceived delays in withdrawing treatment and progressing to funeral arrangements, often combined with no guarantees of a successful organ retrieval, and, if they saw other family members in (increasing) distress. In these situations, we also saw a rejection of the utilitarian benefit to transplant recipients and a shift towards what was best for the family.

"She [daughter-in-law] was in pieces, it was just going on and on, and seeing them both there now suffering, they kept saying just wait a bit longer and they will be here, but she was in a state, its Christmas, 2 kids and a new-born, enough was enough." (019, Mother-in-law, deemed consent, declined)

Families equally wrestled with DBD, which sometimes quickly became associated with an unnatural death, e.g. ‘hooked to a machine’, ‘heart still beating’, ‘dying too quickly’, ‘not at peace’ or ‘undignified’ and especially ‘without the family present’. Families also started to overlay the original decision with a narrative of what the deceased would have wanted for the family in their situation given what they were going through. This narrative again prioritised the family over the benefits of organ donation to others who were waiting for organs, *“It was important to be there in the end, as he took his last breath, that is what he would have wanted and what he would have wanted for us as well”*. (042, Spouse, deemed consent, declined)

Losing an adult child was overwhelming. Parents, in particular, struggled with the latter stages of the donation process which involved letting their relative go for organ retrieval. *“They were getting ready for it [organ retrieval] but I just couldn’t do it, I couldn’t give him up, not like that, that was my baby, I couldn’t let him go, not like that, I had to keep him beside me.”* (080, Parent, deemed consent, declined)

7. Experiences of the transition from end of life to organ donation discussions

Many families were surprised when the topic of organ donation was first brought up, especially when it came out of sync with the family’s understanding of the likely order of events. In these cases, some families experienced a sudden switch from them and their relative being cared for to, ‘they want something’. Some family members became very suspicious, very quickly, about what lay ahead which they (as yet) knew nothing about.

“I remembered a group of them [professionals] walking past and pointing [at the deceased], and I thought they must have been thinking about it then...I just think there is something sneaky about everything in the NHS at the moment.” (064, Parent, Verbally expressed, said yes)

At the same time, families frequently described the topic of organ donation coming too late, getting confused with end of life discussions, and thus became too much to bear on top of preceding events and decisions.

“It was just day by day, you went in and something else has stopped working, or something else they were saying, it was horrible to suffer. She was not suffering, allegedly, but that’s when we had the big conversation. It was basically, if we’re going to desert her as far as treatment and the rest of her life is concerned, then we don’t really want anybody else interfering. You’re not going to mess her about, because the neurosurgeons didn’t want to mess her about so I thought well fair is fair, if you don’t want to touch her, then you don’t get to touch her.” (029, Spouse, deemed consent, declined)

“It’s a difficult choice to make when you’re left in charge – not in charge, but you are, making a choice like “we’re turning off machines”. So then it is giving you that responsibility and handing it over to you. Then when they try to find matches, she’d be kept alive for all intent purposes, but we already made the decision, and the decision was turning off the machines and we’d said our goodbyes, the thought of her being kept alive after the parting, was too much.” (020, Daughter, deemed consent, declined)

“We were holding their hand saying “goodbye”, watching them go, and they came in, my mother ending up screaming at them, “they are not going to donate!!” she never screams, it was awful. That [organ donation] should have been mentioned when they were admitted.” (081, Son, deemed consent, declined)

8. Experiences of consent and associated paperwork and processes

Family members described the consent processes and then the wait for organ retrieval as long, overwhelming, difficult, challenging and generally not a conversation they wanted to have at the time.

“Christ, I mean to try and manoeuvre all the pieces into the right places and the time, to actually make the donation worthwhile, I was sitting there shaking my head. I mean basically they’ve made it virtually impossible, they have, they’ve made it virtually impossible.” (029, Spouse, deemed consent, declined)

“No its not nice, I mean it felt like he was still alive and here we were talking about taking body parts from your loved one, but they said obviously it was his wishes so I thought we will just have to go with that.” (016, Partner, ODR-IN)

Due to only the commonly donated organs being covered by the new ‘soft’ opt-out legislation, family members frequently moved in and out of scenarios where the Act applied and where other consent processes were required. They had no idea when this happened.

“It is only the fact that I took a picture of that form, [shows on phone] and talking to you, you see I would never remember that [slsets] I don’t even know what these are, but yes we said yes.” (077, Sibling, deemed consent)

“[SNODs/SRs] came along and said can we take this, can we take that, to be honest it got to a point where you can’t really see the sense in differentiating one bit from the other, it didn’t seem to make sense to me at least to say yes to some bits and pieces and no to others, so we just said take the lot.” (035, Partner, verbally expressed)

Despite changing to an opt-out system, all processes were exactly the same for every consent pathway (ODR, verbally expressed or deemed) and this was just the beginning of a very long paper trail.

“It was genuinely mad, it was like, “did mum have HIV, did she live in South America, was she a prostitute?”... I mean we just burst out laughing at that point, like what the actual f%K is going on! Don’t get rid of those questions – they were the only good thing about it all.”* (052, Daughter, ODR-In)

The consent process was dehumanizing, frequently conjuring up images of mutilation and the macabre. Families were basing decisions on their own levels of comfort and understanding of what was presented to them at the time. Family members’ most common behaviour was saying “yes” and “no” to potential deceased organ, tissue and scheduled purposes (processes and procedures that fall outside of life immediate lifesaving or life improving treatment), as they went through the list of potential options for retrieval. Even when families felt very supportive of organ donation themselves, were united as a family and knew exactly what their deceased relative wanted, families were commonly picking and choosing options (which organs and tissues that they would donate and which ones they would not), as they were presented to them. Often family members volunteered to go through the paperwork when others were finding it too much to manage.

“You are preaching to the converted, we’ve all signed up, we said yes to everything except the eyes, she had the most beautiful eyes you can imagine everyone said it from the day she was born...by the time we had got through it all...were all exhausted...there for days, and then waiting to see if they would take her, it was awful...I guess we felt by that point we had given enough really.” (045, Multiple family members, ODR-In and discussed, non-proceeding organ donor, cremated)

“I mean they asked about her hands, I was like really they can do that wow, it sounds awful but she had such chubby fat fingers I couldn’t imagine the thought of them on someone else, so I said no to that one.” (067, Daughter, Deemed consent, thinks said no to some tissues, hands and some research)

“I mean Jesus Christ when they started going through the whole thing, it sounds weird but I just didn’t want her to end up as a skinned chicken, so I said no to that and a few other things that I didn’t really understand.” (058, Daughter, verbally expressed, no to skin cannot remember details)

“I was like, hang on a second what is coming back, am I burying a coffin or a shoe box, do you know what I mean, [laughs] it was absolutely mental, but they were great, it was just a few things I wasn’t sure about so I said no.” (071, Daughter, deemed consent, cannot remember thinks said no to skin, eyes and research which might involve animals in the future)

“It was only when they said “skin” she [mother] jumped up screaming and had to leave, I understand why they have to do it that way, as they have to check, but yes it was absolutely horrific, and she [mother] was obviously struggling to cope so I finished it off.” (009, Son, Opt-In, no to skin unsure about everything else)

All of these factors got worse or were at the very least amplified on a deemed consent pathway.

In the small number of ethnic minority families interviewed, some additional factors at the bedside included translation. Often younger family members were tasked with translating to older more distraught relatives. This increased the scope for confused or incorrect information being shared due to the number of people and, therefore, the number of perspectives involved in discussions. Sometimes, family members lived overseas (and would not have been exposed to the changes, or even general organ donation campaigns in the UK). Sometimes, family members elected not to tell wider family that they had proceeded with organ donation in order to avoid upset. *“There was no way [grandmother] would have allowed it, it was better she didn’t know, but we were happy with our decisions.”* (044, Daughter, deemed consent)

All families, irrespective of ethnicity, said education was needed, even more now, to explain the changes and how organ donation comes about, to better prepare families, to replace outdated or misinformation, which were either causing people to opt-out on the ODR or families to say “no” at the bedside.

9. Valuing SNODs and SRs

All family members commented that the care and support received from the SNODs/SRs was outstanding. This included families who went on to not support the organ donation. Families noticed an increase in support once the SNOD/SR arrived for them and their relative. Most felt that they would not have been able to get through the process without the SNODs/SRs. Aftercare and follow-up (e.g. telephone calls) and direct lines of communication and support were frequently cited and valued. Some families who declined organ donation were surprised not to see the SNOD/SR again, some wanted to apologise and to explain that their decisions were no reflection of the work of the SNODs/SRs, and some wanted opportunities to ask more questions, in hindsight, out of genuine interest in what was possible, but not necessarily anything that would have changed or influenced their behaviour regarding the organ donation.

Perspectives of the SNODs and SRs

The SNODs’/SRs’ free text responses indicated that families were declining due to the length of time, and processes involved in retrieval, as well as when there were family disagreements, in the aftermath of especially traumatic and violent deaths, in chaotic (family) circumstances, and related to religious beliefs, but often noted that the last was used as an excuse or easy way for families to shut down or disengage from the organ donation conversation before it started. In some cases, the SNODs/SRs were unable to speak to the families and so had very limited understanding of why they were refusing. Most could not identify anything that would have helped in a specific situation. Some stated that the law was too soft and so families were not respecting or interested in the Act or able to process the information and how it applied to them at the time.

Discussion

Summary of findings

Overall, the legislation was intended to make it easier for people to donate their organs to benefit transplant recipients. In doing so, the Act tries to reconcile two competing perspectives – respecting the donation decision of the potential organ donor made in life AND respecting the right of family members to override their deceased relative's decision on their death. The result is a long and complex process that tries to reconcile these two perspectives but satisfies neither. Consent rates have gone down since the implementation of the Act during the pandemic though it is perhaps too early to tell whether they will recover.

Despite the change in legislation, family behaviour at the bedside was generally not aligned with the utilitarian values implicit in the Act to benefit as many transplant recipients as possible. Irrespective of the deceased decision pathway (ODR, expressed or deemed), many families still felt that they were the decision makers. Those that did not support donation made decisions that brought about the best outcomes for themselves, and/or reinterpreted the donation intentions of the potential donor. For many families, in a utilitarian sense, not supporting organ donation had the most benefits for them as they were able to end what they saw as a long drawn out and distressing situation and avoid the distressing thoughts of their relative going for organ retrieval.

The 'soft' opt-out legislation did not appear to make difficult decisions any easier and families did not seem any more reassured in their decision making with regard to deceased organ donation than would have been the case under the previous legislation. While most people supported the law change in principle, very few understood it, especially what it meant for them in their specific circumstances. The majority of family members were making different decisions (yes/no) for different organs, tissues and scheduled purposes. The Act did nothing to shift these micro decisions within the consent process in favour of a greater number of donations from their relative. Officially, consent is considered to have been successful if there is support to donate one organ or tissue out of the long list of potential options but this overlooks the potential for more organs to be donated or lives to be improved.

Families reported that situations where consent would be deemed made their situation more difficult than if the deceased was on the ODR. For families, overall, the organ donation conversation was too long and convoluted, and they retained very little detailed knowledge of what they were asked or had done. Deaths are often traumatic and family members are in various states of turmoil. Changing the law did nothing to help SNODs/SRs better support the pragmatics of acute bereavement. It was unclear for most families how deemed consent could be helpful given their very recent experiences. Family members were frequently unpicking the decisions of the deceased and subtly superimposing their own values, judgements and preferences to challenge and overturn the consent given in life by the deceased person. They did this most often when consent was deemed. Most families had never even been in an ITU before, or ever seen what death looks like for a potential organ donor. As a result, many families struggled to comprehend the processes involved in organ retrieval. They most frequently asked themselves (and questioned) if their relative would have wanted organ retrieval, and not whether the person who died wanted to save lives (the utilitarian principle underpinning the Act). On the other hand, families greatly valued the guidance, support and reassurance provided by SNODs/SRs throughout the difficult process.

Families who declined donation generally became increasingly ambivalent about organ donation during the process. This was especially the case when families did not know what their relative wanted, which created a specific barrier to seeing the benefits of organ donation for recipients. This was amplified by the context of the bereavement and other external factors such as trust in health care, the circumstances of the death and wider family perspectives. The processes involved in organ retrieval were leading many to question their

relative’s donation decision, as if they were still alive. Families are thus creating alternative (and new) narratives at the bedside, completely at odds with the utilitarian values in the Act and thus overturning the deceased person’s decision.

Nonetheless, irrespective of whether the families say “yes” or “no”, most found the process(es) too long, distressing and exhausting. For families who supported deceased donation, they were enduring the process for the benefit of others. This is also likely to be part of the reason why DBD consent rates are still consistently higher than DCD consent rates. There are no guarantees of organ retrieval on a DCD pathway and families do not want to put their relative through what they see as a harmful process.

Meaning of this study in relation to other research

The factors reported by families as influences on their decisions to agree to deceased organ donation are summarised in Table 1 below, and match well with evidence elsewhere,[25,26] but gaps remained as to why families declined which this study fills.

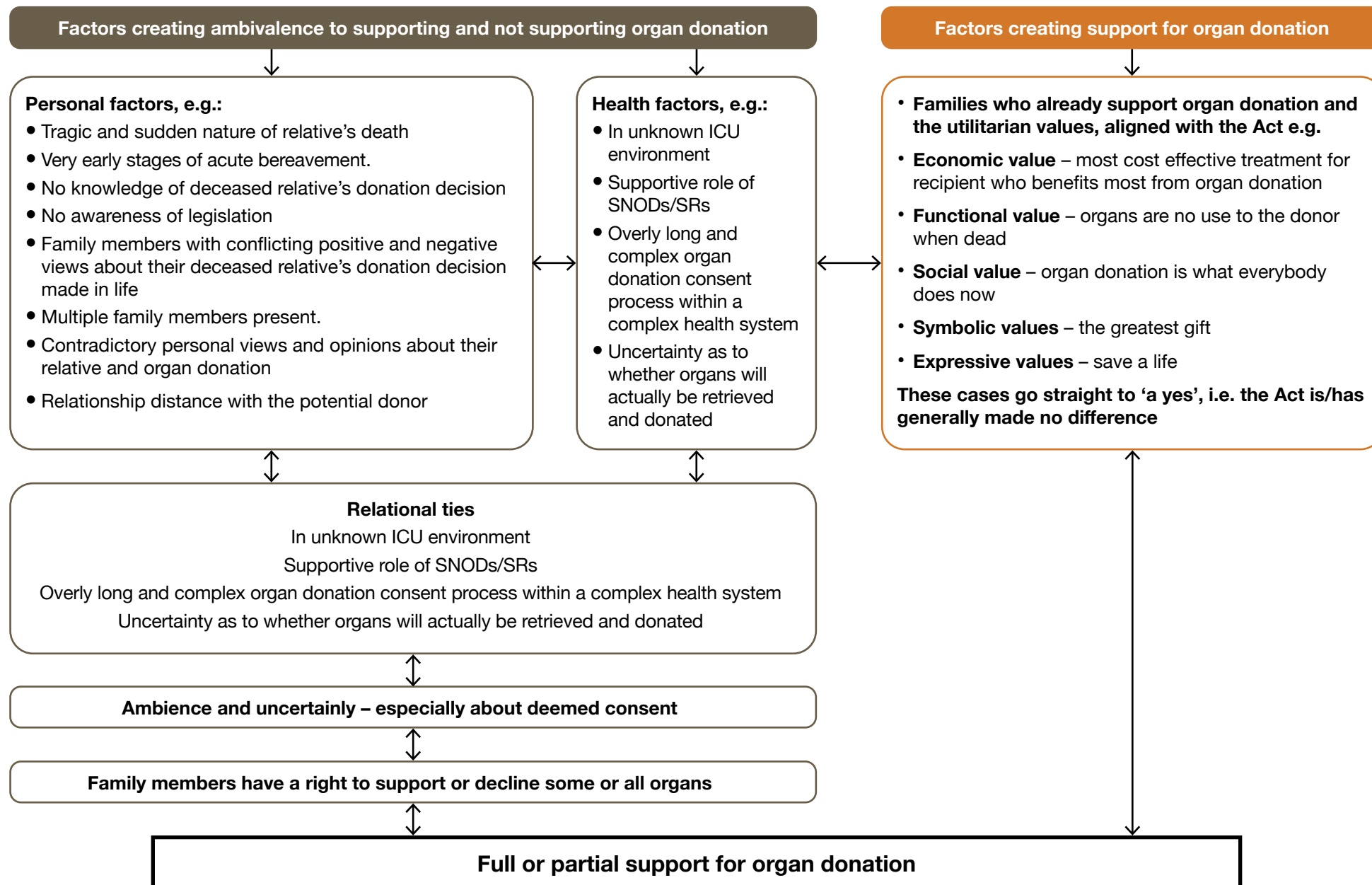
Table 1: Summary of factors reported as influencing agreement to deceased organ donation

Health system factors	Personal factors
<ul style="list-style-type: none"> • Trust in the care and support they and their relative received. • Rapport and interpersonal relationships with the clinical, nursing and organ donation team(s). • Clarity in terms of communication and processes leading to end of life and organ donation. • Feeling like they could ask questions. • That there was always someone around to help with anything. • Overwhelming support and admiration for the staff who cared for them, and what they did day in day out. • A feeling a pride towards the NHS. 	<ul style="list-style-type: none"> • Supporting organ donation themselves. • Wanting to help others. • Not wanting others to be going what they are going through. • United families. • A general position that organ donation is right, good and something amazing. • Knowing that their relative wanted to be an organ donor.

Sque et al’s seminal work on sacrifice as an alternative conceptualisation of gift theory in organ donation also resonated with aspects of our findings that illustrated how difficult it was for some to support organ donation. Gift theory shares a common conceptual foundation with utilitarianism, although, of note, ‘the gift of life’ slogan is no longer used to underpin organ donation media campaigns.[27]

In another workstream of this study looking at the attitudes of the public, we found that the broadly utilitarian social values underpinning the Act aligned well with many (but not all) individuals’ in principle support for organ donation;[2], i.e. people do want to save and improve lives of others and are aware that this happens after they no longer have any use for their organs (“take what you like, I’m dead!”) when they can give a gift to the living. This fits well with presumed consent; i.e. a form of implied consent which represents one fewer thing for people to have to do in a busy world, and it can be seen as logical to introduce legislation which switches the default to align with these values. However, as described above, these utilitarian principles fail to hold up in the circumstances of the acutely bereaved having to support their relative’s organ donation decision made in life. Families do not base their decisions on what is assumed will happen in the legislation. Many families do something completely different, and slowly create alternate narrative(s) to unpick the deceased’s decision or implied decision made in life, to the point where the end goal to save lives (so easy for the living to endorse as a matter of principle) can disappear completely from bereaved families’ decision making and subsequent behaviour. This behaviour and attitudes are summarised in Figure.2.

Figure 2: Factors creating support and or ambivalence to organ donation



A recent analysis of the impact of the legislation on SNODs/SRs found that the Act gave them no new tools to help families support the decision at the bedside, and showed that the balance of power from families to the deceased person had not shifted following implementation.[28] We also found multiple examples of the old opt-in system's, processes and values working in confusing ways, and a culture of practice which only allows organ donation to be mentioned in specific ways, by specific people, at the very end of life. From the families' perspective, these standard operating procedures are adding to the difficulties they face, particularly since they are overlaid with the requirements in the Human Tissue Act to gain consent for every organ, tissue, scheduled purpose, and all processes involved in any part of organ retrieval.[29] A comparative analysis of consent processes in Spain – which has remained the world leader in consent for deceased organ donation (also undertaken as part of this study) – revealed a much simpler, shorter, adaptable and personally tailored consent process and associated standard operating procedures.[30] Options and choices are minimised in favour of a more supportive, directed pathway towards organ donation and initiated much earlier, to ensure families are able to do what they need to do to support the decisions of the deceased, thus ensuring their behaviour aligns more closely with the core principles of utilitarianism – and Spanish law.

Implications for policy and practice

The legislation was implemented in a neutral way rather than being biased towards promoting organ donation. Although there were hints about sharing decisions, via the 'pass it on' message, this did not specify to whom or why this might be critically important. Deemed consent is more uncomfortable for family members compared to when a deceased person has expressed their decision during life and has potentially made things even more uncertain for acutely bereaved family members. Our evidence suggests that families would benefit from further reassurance of the decisions of the deceased in the form of more, and more frequent opportunities to register organ donation decisions, prompts and reminders to update decisions embedded throughout day to day life, and more general education campaigns about the nature of organ donation and the circumstances which are likely to bring about organ donation. This in turn, may also help health care professionals feel more secure and reassured that it is their right and business to discuss organ donation (following agreed protocols to ensure consistent messages) and to help reassure and promote the rational choices of potential organ donors in life, reduce the risk aversion and related bureaucracy around establishing decisions, and promote a more positive culture towards the benefits of organ donation. This should help families see the benefits to them of enabling the gift of organs which can save lives and improve treatments.

Nonetheless, reforming the protocols governing pathways from end of life to organ donation is unlikely alone to bring about the desired outcomes. In a broader health systems context, additional policy and practice factors are also known to influence the availability of organs for transplant. These include: developed and efficient healthcare systems; (long) established, integrated and well-resourced donation and transplant programmes; positive public attitudes towards organ donation; general health of the population; care and support for the acutely bereaved; availability of healthcare specialists, including specialist nurses; inequalities in overall health, innovations and research to preserve and prolong (organ) life; and sufficient ICU capacity.[31, 32]

Strengths and limitations

We did not interview any nominated representatives. We were limited to recruiting family members through the SNODs/SRs at the bedside which meant that not all eligible participants were given full opportunities to decide if they wanted to take part or not. We were able to include a wide range of perspectives, including, crucially, families who declined organ donation, not included in previous research.

Conclusion

Given the traumatic circumstances which often precede organ donation, the (very) 'soft' opt-out policy in England was unlikely to help families at their most vulnerable to any great degree to increase their support for deceased decision. New public ongoing media campaigns crafted to be more supportive of organ donation as a benefit to transplant recipients, could help (some) families overcome the many difficulties they encounter at the bedside, help them through the processes and lessen the perception of harm to their deceased relative. At the same time, public communications need to refocus and emphasise the changed role of the family to one of supporting their relative's organ donation decision made in life. This will also help create a new context for families, where, although very difficult, they are there to do what they can to ensure that what their relative wanted happens. If families become more aware of their changed (but essential) role, this may create new narratives for families, less about processes involved in organ retrieval, and more about what they are able to do to help those in need of an organ transplant.

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9

A qualitative content and discourse analysis comparing the current consent systems for deceased organ donation systems in Spain and England

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Summary

Introduction

Since England switched to an opt-out system of consent in May 2020 consent rates to deceased organ donation have remained much the same. However Spain also operates an opt-out system yet has almost twice the organ donations per million population compared to that in the UK.

Methods

We aimed to identify both differences and similarities in the consent policies, documents and procedures between the two countries using comparative qualitative content and discourse analysis.

Findings

The Spanish system had more simple and locally tailored consent documents, the time taken for bereaved families to support organ donation was shorter, there were more pathways leading to organ donation in the Spanish system, and more robust legal protections for the decisions of individuals.

Conclusion

If England's ambition is to achieve the consent rates consistently seen in Spain, greater legal protection is required to honour the decision of the potential organ donor made in life and also a shift in culture, from being impartial and risk-averse, to promoting organ donation.

Aim

The purpose of this chapter is to identify differences and similarities in the consent policies, documents and procedures between England and Spain, and to consider what works well in Spain to see if there are opportunities to further increase the consent rate of organ donation and improve current practice in England and the rest of the UK.

Research question

What are the differences in roles, processes, consent forms and practices between the Spanish and English systems of organ donation and how do any identified differences begin to explain the higher consent rates in Spain?

Methods

Data collection

We identified and obtained key policy and procedural documents and consent forms from websites of the ‘Organización Nacional de Transplantes’ (ONT) in Spain and NHS Blood and Transplant (NHSBT) in England. Documents published in Spanish were translated into English for analysis using the computer software ‘Transperfect’ Table 1 (Appendix 6) lists the documents included in the analysis. The documents were read, reread, compared and coded. Coding involved assigning attributes to words, sentences, or paragraphs to compare and contrast content, process and meaning. The consent forms were compared for structure, content, and length.

We worked with a Spanish intensive care doctor (co-author) via email and two on-line Teams sessions to clarify the correct interpretation of the documents and donation system. It also enabled us to ensure if current practice was in line with written protocols. We also gained further understanding and copies of Spanish consent forms through face-to-face engagement at key meetings with academics and clinicians through the European Society for Organ Transplantation (ESOT) to establish the context of the English and Spanish organ donation systems within which the documents for analysis were produced. We also consulted with a UK senior nurse (co-author) involved within the English NHSBT education programme and UK legislation. A summary flow chart was made of the Spanish and English organ donation structure and processes for comparison (Appendix 6 Figures 1 and 2).

Via the two Teams sessions, as well as through face-to-face engagement at key meetings and events, we discussed the analysis plan, emerging results and additional contextual details. These opportunities helped confirm and further clarify aspects of the written documentation and their interpretation in practice in Spain and England. They also helped build a better understanding of cultural factors, such as religious beliefs, ethnic diversity, family dynamics, the reaction of families to the system (including if they had ever challenged the law), and how these might be underpinning any differences observed in the documents analysed in detail.

Data analysis

Qualitative content analysis was used to code, analyse, compare and interpret the textual data and diagrams in the included documents to gain insight into the meaning and context of the policy, and links between content, process and outcome.[1]

Principles from critical discourse analysis were used to make additional interpretations of the text, supplemented by engagement with experts on the Spanish and English systems. This was to systematically explore the ‘often opaque’ relationships between what is written (i.e. policies, guidance) and what happens in practice, with multiple stakeholders – each with their own goals. This process helped to check, for example, who or what the subjects

and objects were in the respective structures, discourses and processes, and how and why the two systems manage to generate and sustain different forms of language (rhetoric). The flow charts constructed (Appendix 6 Figures 1 and 2) helped to show where objects such as the Organ Donor Register, role of the staff e.g. clinicians, transplant co-ordinators, nursing staff and the role and hierarchy of the family etc., fitted together in a complex system. The rhetoric analysis specifically searched for opportunities to give or decline consent within the process. This enabled us to understand more about the mechanisms underpinning the Spanish consent pathway, and thus extrapolate learning and recommendations which may be applicable, with adaptation, to England and the UK more widely.[2]

Once we had a good understanding of the two systems, we had further discussion with the Spanish consultant and Senior UK nurse co-authors to validate the interpretation of the two systems.

Results

Direct comparison of systems, processes, and cultural and linguistic styles between Spain and England in relation to consent for deceased organ donation are described below. Table 2 highlights similarities and differences within the process with specific reference to consent. The mechanisms which are bringing about the desired outcomes, or not, in relation to consent are described in Table 3.

Overall system

England has a diverse population with deep rooted Christian traditions and multi-faith communities. England switched to opt-out in May 2020. Organ donation in the UK exists solely within the NHS and does not involve the parallel private sector. Deceased organ donation is considered in those who die from brain stem or controlled circulatory death. Donation is therefore only possible from those who are admitted to an intensive care unit (ICU), but ICU admission is for clinical purposes, not organ donation. England has an intensive care bed capacity of around 6.6 per 100,000 people.[3] Organ donation is possible in every acute NHS hospital. When the patient is identified as a potential donor the clinical team caring for the patient will refer the patient to the organ donation team via a national referral number, the regional NHSBT team will assess the patient and mobilise a Specialist Requester (SR) or Specialist Nurse in Organ Donation (SNOD) – depending on whether a specialist member of staff is available. After checking the national Organ Donor Register (ODR), the SNOD/SR attends the unit and approaches the family for donation – this is a nurse-led process and care pathway. The ODR has various options (e.g. opt-in, opt-out, or nominate a representative). There are also opportunities to specify a small number of organs/tissues people want to donate or not after they die. But the ODR has no legal status and family members have the ability to override deceased decisions in practice.

Spain is a majority Catholic country whose organ donation system has been in place for 44 years.[4] The organ donation system is overseen by the ONT. It is possible to be an organ donor whilst being treated privately, by being transferred into the public health system purely for donation purposes. In addition to the pathways in England, deceased organ donation can be obtained from sudden unexpected circulatory death and for those undergoing euthanasia. All patients in all pathways will need to be ventilated in preparation for organ donation. Spain has an intensive care bed capacity of around 9.7. per 100,000.[5] In Spain, patients admitted to the Emergency department with catastrophic brain or cardiac damage in which treatment has been considered futile, can be intubated, and admitted to ICU for the purpose of organ donation,[6] also, those who are suspected to develop or are already declared brain dead in private institutions or the Emergency Room, can be admitted to ICU solely for the purposes of organ donation, unlike in England.

Spain has dedicated hospitals where deceased organ retrieval can occur, with designated transplant co-ordinators (TC) in each of these hospitals (approximately 70% being physicians and 30% nurses). Often in hospitals with no TC, there will be proactive ICU staff that can identify donors. They can request support from a dedicated hospital who will usually send a TC to aid in speaking with the family. Any health professional can contact the TC regarding a potential donor. Once alerted to a potential donor the TC will attend the potential case, check the medical records, and identify whether or not there is a 'prior instructions document'. This document has legal status.

System processes in relation to consent to deceased organ donation

In England *'the individual leading the family approach for organ donation must be suitably trained and qualified with sufficient knowledge and skills to sensitively answer any questions and have the time to support the family'* (7, pg. 9). In practice, this is always a SNOD/SR, anybody outside of this role is actively discouraged from discussing organ donation.

As illustrated in Figure 1 (Appendix 6), the English system has many pathways to consent. If the deceased opted in to organ donation during their lifetime, this is discussed with the family to ensure this was the last known decision. If the deceased person opted out on the Organ Donor Register *'providing work load allows, the SNOD should also discuss with the family if this was the last known decision'* (8, pg. 11). If they are unable to do so due to workload, the SNOD/SR will *'coach the clinician in the discussion to have with the family and agree actions'*. If the clinician feels unable to do this, the family will have to wait for the arrival of the SNOD/SR. In practice, detailed discussions with the family when the deceased opted out rarely happen due to limited resources and concerns about NHSBT been viewed as pushing for organ donation when the deceased had opted out.

Another pathway, although rare, is the 'nominated representative', whereby prior to death, a person nominates another to make a decision on their behalf. *'If despite all reasonable efforts the nominated representative cannot be contacted in time or to make a decision, then consent may be deemed'* (7, pg. 19). Nonetheless in practice donation can only proceed after also speaking to the family.

Only after the SNOD/SR has established that none of the above pathways apply, can they check if consent can be deemed. If the family cannot agree, despite being given time and further information, then *'the hierarchy of consent i.e. highest qualifying relationship', applies, but the final decision to proceed lies with the [SNOD/SR]'*. In reality, it is the family member with the strongest voice (either for or against donation) whose wishes are followed. In addition, the SNOD/SR cannot proceed with donation unless they have the full support (and permission) of the treating clinical team(s). In the event that the family cannot be contacted and there is no prior expression of a decision, then although *'consent could be deemed it is advised that donation must not proceed'* (7, pg. 17).

To override a decision, families only need to provide a *'level of information that would lead a reasonable person to conclude that they [i.e. the deceased] did not want to be a donor'* (7, pg. 24). This can be verbal or written. Any evidence from any family member at this point can be taken into account (7, pg. 18). The SNOD/SR will make a judgement about the reliability of the information and whether it is right for donation to proceed. *'Sometimes clinical staff will reach the judgement that although there is a legal basis to proceed with the donation, the human considerations involved mean that it should not go ahead. While the presence of appropriate consent permits organ and tissue donation to take place, it does not mandate that it must....(and) where the risks to public confidence might outweigh the benefits of donation proceeding, donation should not proceed even though the law permits it'* (7, pg. 7).

In Spain, there is no organ donor register but a ‘prior instructions’ document available from the patient’s GP. Patients can register consent or decline consent for organ donation within the document and it will be made available on the local Advance Directives Registry. Families will be approached and be informed of the decision recorded. If a ‘No’, to donation has been recorded, the family is still asked if there has been any more recent change to this decision. There would have to be substantial evidence to overturn this notion since the prior instruction is a legal document and signed by a witness.

It is advised that the health professional who mentions organ donation be different to the professional who has discussed the likelihood of the patient dying to avoid a conflict of interest for the TC who may also have a role as an intensivist, etc. It is mandatory in some hospitals that the TC be contacted before withdrawal of treatment in ITU, a condition introduced by some hospital medical directors.

The consent forms

The English consent form is seven pages long, with all organs, tissues and retrieval processes listed as yes/no tick boxes. The family will need to answer ‘Yes’ or ‘No’ to everything irrespective of what the deceased registered and what organs they wanted to donate while they were alive, and this will include donation to research (not just for therapeutic purposes). The family is made aware that the decision can be revoked until *‘knife to skin’* (8, pg. 24). The family ‘are encouraged to sign the consent form’ even though there is no legal obligation to do so. The process can take hours to days. The SNOD/SR will document the conversation in the patient’s notes and on NHSBT’s national digital system, also verified by a witness. If the family override the decision or revoke consent this is respected, and the reasons acknowledged and documented by the SNOD/SR.

Each Spanish region has its own form based on examples from the ONT protocols. Often they are a single page requesting the name and relationship of the relative and date. Some do have a free text space to write which organs or tissues the family believe the deceased would not have wished to donate. Other times, these wishes are documented in the medical notes instead. Once a decision is reached from the discussion with the family, it is mandatory that the consent form is signed by the family member.

Consent approach and language

In England, when families are approached, they are asked, *“what the potential donor’s last decision would have been and whether the deceased expressed any thoughts on becoming a donor”*. Standard operating procedures suggests that SNODs/SRs should establish who is the next of kin (as per established highest qualifying relationship guidance) and approach this relative about organ donation. Although the opportunity to help others is often mentioned, standard operating procedures suggests that the SNOD/SR remain impartial.[7]

In Spain, if there is no recorded decision in life, the family are generally asked *‘what would have been the willingness of the deceased to donate their organs to help other people?’* (9, pg. 197). *“If the family are in doubt, the TC can assist in decision-making, reinforcing positive verbalisations to donation and courage in those moments, and conveying ideas of generosity and proximity and enquiring whether the deceased gave to charity or donated blood during their lifetime etc.”* (9, pg. 126).

Where there are large families, the TC seeks to speak to the ‘key family’ member. The key family member is highlighted through discussion with the family and the knowledge of the staff caring for the patient. Should a family be divided over the matter of donation, it will not proceed. When no family are present, the TC *‘strive(s) through links with social services and the police to find a family member’* (9, pg. 120) but they can still consider organ donation if no family can be found.

Should the family decline donation, *'it is important to make it clear that the decision is respected and understood but that, however, it is advisable to think about the matter more slowly without the presence of a TC'* (9, pg. 126). The TC also explores the reasoning behind the refusal and correcting misunderstandings. The TC can approach the family as many times as required.

During the consent process, the family are usually asked which organs they believe the deceased would not want to donate. The conversation aims to combine *"speed and effectiveness in communicating with families, with respect for ethical principles and transparency that must preside over the process"* (9, pg. 116). On average, the process of gaining consent takes 30 minutes.

Discussion

This is the first detailed documentary comparison between the Spanish and English opt-out systems of consent to organ donation. The biggest differences observed were that the Spanish system was less complex, evidently pro-donation with willingness to take some risks, likely to take less time, better resourced, with better access to ICU beds and a more locally tailored opt-out system with some legal protections for the potential organ donor's decisions in life. This appears to work better than a more complex centralised system with risk adverse protocols, implemented into a country where there are fewer ICU beds, with no legal protections for the potential organ donor.

The Spanish system covers both public and private hospitals. In England, for deceased organ donation, NHSBT only covers NHS hospitals so some potential donors in the private sector will be lost. Organ donation accompanying euthanasia is legal in Spain (illegal in England) and although it is relatively recent the pathway has created an additional platform to embed organ donation as a routine end of life process – the initial requests for this pathway having come from people who had requested euthanasia and not in the initial euthanasia protocols. Potential organ donors with neuro degenerative conditions requesting euthanasia also tend to be younger without underlying co-morbidities and a single donor could potentially decide to donate all their organs and tissues to help others.

Families are as involved in decision making in Spain as they are in England, yet the consent process is much shorter in Spain. The language used with family members and staff was also observed to be different in tone and meaning. The English system focuses on establishing the last known decision of the deceased whereas the Spanish system aims to establish the will of the potential organ donor to donate their organs as well as the will to help others. In England, current guidance and codes of practice reflects the human tissue authority's position on consent for retrieval of organs and tissues, which appears to be more in line with the old 'opt-in' system and thus introduces unnecessary risk aversion that is contrary to the spirit of the opt-out legislation and appears confusing and impartial.

Organ donation appears to be more ingrained within the Spanish healthcare system being an integral part of end-of-life care, with many healthcare professionals being aware of it and being encouraged to be involved with it. Thus, it is possibly more likely to be discussed by families as there may be a healthcare worker in the family or someone they know to have been through the process before.

The legally binding prior instructions document is also available through the GP or local hospital and is signed with a witness present. Therefore, the witness i.e. an accompanying family member is likely to be able to verify the document. Once it is filled out it is part of the person's local health records meaning that there is a more complex process if family members want to challenge their relative's organ donation decision made in life.

The structure of the hospitals – i.e. that specific hospitals manage deceased organ donation, that patients can be admitted to ITU purely for the need to ventilate organs and drug infusion in preparation for donation – is also very different to England. Matching the Spanish approach would undoubtedly cost the NHS more at the expense of another area within the health service. However, Spain states that *‘the social value of organ donation justifies staff efforts and the economic cost involved’* (11, pg 195), indicating an overall difference in priority in terms of deceased organ donation between the two countries.

In addition to the marked differences in ICU bed provision required for organ donation to proceed, in 2019, Spain had 3 hospital beds per 1000 population whereas the UK had 2.5 beds per 1000 population. In 2019, Spain had a bed occupancy rate of 76%, whereas in England the rate was 92% for overnight general and acute beds.[10] Given the relentless pressures on NHS staff to continuously manage such a high bed occupancy rate, it becomes clearer as to why a centralised system of organ donation was implemented via a separate NHS body (NHSBT) with its own governance and management structures. NHSBT was created in 2008 and to a certain extent, this centralised opt-in system was successful in that consent rates steadily increased in the ensuing decade before the law change. Nonetheless, NHSBT was unable to replicate the consent levels of Spain. In 2020, the opt-out was implemented within the existing centralised national system alongside the existing opt-in system, and the two systems have been operating together in a complex way ever since. In Spain the law appears more consistent across the organ donation pathway. Spain does also offer the ability for patients to opt-in through their decision on the prior instructions document, however this is rarely seen since the Spanish public trust the organ donation system, knowing that their families will always be consulted so do not see recording their decisions in life as important.[11]

Recommendations for policy and practice in England and the UK

In England, if SNODS/SRs were able to openly emphasise the benefits of organ donation and encouraged to do so with families, i.e. reflected (without ambiguity and risk aversion) in the written protocols, this would align more with the legislation of presumed consent. By remaining impartial, this may potentially be more likely to instil fears within public confidence of the system.

The ODR also lacks legal status. Anybody can go onto the ODR and register a person’s decision – there continue to be cases where families opt-out on behalf of their relatives while the latter are being ventilated in intensive care. Around 10% of families override their relatives’ opt-in decision but the same rates are not observed in opt-out decisions. Despite having an ODR, it is not mandatory that the organ donation decision on the register is followed. If the ODR was given greater legal status and the decisions in it used as the basis of the conversation with the family after death (preferably by simplifying the latter to align more with the Spanish approach to consent after death), it might make it easier for the family to support the potential donor’s decision. It may also create a context where people are more likely to discuss what they want in terms of organ donation. Aligning language, processes and guidance with the legislation of presumed consent may generate a more positive initial response towards organ donation and help reconcile doubt or concerns common in these complex discussions at end of life.

The linking of the ODR with a patient’s health record may also make it easier for health professionals to discuss with the patient if they still stand by their recorded decision should anything life-threatening happen during their admission, similar to a ‘Do Not Attempt Resuscitation’ form.

Although organ donation has expanded, over 44 years, the legal standing, guidance and protocols have not changed substantially in their underlying principles in Spain. Since 2021

the latest NHSBT consent manual has had six updates. The last updates are included in Figure 3 (Appendix 6) for reference. The consent forms and associated documents have had many revisions in recent years, with each iteration adding further layers of complexity and processes. We recommend that documents are revised, simplified and provide a more positive emphasis to cope with change and promote a more sensitive approach to consent that is aligned with the intention of opt-out legislation.

Limitations

Due to resource constraints, we were not able to back translate very long policy documents from English back to Spanish. We relied on software to translate Spanish documents and then verified key concepts and processes with a small number of Spanish experts.

Policy documents alone are unlikely to be entirely reflective of actual practice and there is likely to be variation in the implementation of processes across a health system. We acknowledge this limitation and mitigated this by engaging with organ donation practitioners in Spain and England, as co-authors, to supplement our documentary analysis with their perceptions, experience and knowledge. We also acknowledge that the UK has much higher numbers of live donors than Spain, emphasising the complexity of organ donation and the fact that there are more ways to increase donation than merely increasing consent to deceased donation. Furthermore, deceased donor consent rates are not the only measures of a successful organ donor system.

Conclusion

The Spanish system gives more opportunities to gain consent from family members for organ donation and the system actively encourages donation. If England's ambition is to achieve the consent rates consistently seen in Spain, greater legal protection is required to honour the decision of the potential organ donor made in life and also a shift in culture from being impartial and risk averse to promoting organ donation. Significant investment in staff and resources would also be required to match the ITU bed availability seen in Spain. However, there are potentially modifiable issues that appear to work better in Spain such as a shorter and simpler consent process and much more positive language throughout the process that could be fairly quickly resolved in England.

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Discussion and recommendations

In this final chapter we summarise the findings of the evaluation with a view to providing an overall picture of implementation of the ‘soft’ opt-out system of consent to organ donation in England since May 2020. We assess the strengths and weaknesses of the study and relate our findings to the evidence from other countries about the impact of different legal frameworks for deceased organ donation. Finally, we set out the implications of our findings for policy and practice in England and where relevant, the whole of the UK, including specific recommendations where this seems appropriate. We take a health systems perspective on what we think needs to change to bring about the desired outcomes of the 2019 Act.

Summary of findings of each component of the evaluation

How the law change came about (Chapter 3)

England had been debating changing its organ donation system from an opt-in system to an opt-out system for over 15 years before 2019. During this time, there was shift from a dominant position, which gave primacy to the evidence of likely effects, towards a more normative position in which the deemed consent option was viewed as the ‘correct thing to do’, and the limited and conflicting evidence of its likely positive effect on consent rates viewed in a generally more optimistic light, leading to little opposition and strong cross-party support for the change in law. Parliamentarians wanted a law that would reflect what they saw as largely favourable public opinion, with most people reporting that they would be happy to donate their organs after death. They also wanted to demonstrate a response to the pressing need for more organs to save more lives. There was evidence of misconceptions about how organ donation actually works in the UK during the debates, and much weight was given to the perceived successful opt-out countries, especially Spain. Once Wales’s similar law change of 2015 had been implemented for a few years with no obvious disruptions, the argument gained ground that opt-out was correct in principle and could be introduced with minimal risk if framed in a ‘soft’ form. As a result, the bill passed with little opposition in 2019 (see Chapter 3, Figure 1). It was felt by many also to be a route to creating a positive culture towards deceased organ donation.

Publicity and media coverage of the law change (Chapter 4)

A condition of implementation was a media campaign to ensure the public was aware of the changes. The Government-led campaign was neutral in tone, but parallel campaigns and coverage led by the Daily Mirror predominately featured children (who are excluded from the Act) and emotive human-interest stories, creating a dominant narrative which suggested that deceased organ donation is a moral good, as are any measures to help increase the number of transplants. But in order to work (to increase consent to deceased organ donation), the change in law needed to be not only successfully communicated by the media but correctly understood and supported by the public. An important aspect of the new law, and left out of campaigns, was the changed role of the family to one of supporting organ donation

decisions, rather than making them. Despite consistent messaging of the moral good in the mainstream media, reader-generated content was mixed towards organ donation in general, and mostly negative towards the law change (Chapter 4, Figure 4). Concerns about the expanding role of the state, loss of individual freedoms and rights, the potential for the change in the law to be abused for financial gain, and uncertainty about how death is defined and verified created a counter-narrative to that expressed by the mainstream news media. This narrative suggested that neither the Government nor the NHS could be trusted to act in the best interests of individual patients.

The views represented in online comments likely contributed to what manifested as a very cautious approach to publicising the law change – NSHBT did not want to be seen to be taking organs without consent despite the fact that families were no longer the decision makers in law. To add to the difficulties faced in promoting the law change to the public, all campaigns were suspended in March 2020 due to the COVID-19 pandemic, and an agreement reached between the mainstream media and NHSBT to stop all communications related to organ donation. This was to avoid any possibility that NHSBT could be viewed by the public as capitalising on the excess deaths caused by the pandemic. Implementation of the publicity campaign as intended thus did not happen.

Trends in consent rates (Chapter 5)

The analysis of trends in consent rates shows a reduction in family consent/authorisation rates in England since implementation of the law change in May 2020, from 68% in 2019 to 63% in 2023 (Chapter 5, Figure 3). Despite the short-term negative impact of the pandemic on the donation and transplantation system, the fact that consent rates in 2023 have yet to reach 2019 level casts some doubt on the hoped for emergence of the positive culture and process of organ donation that would lead to a marked increase in consent rates and donations propounded by Parliamentarians in support of the law change.

Before the law change in 2019, consent rates in England had, in fact, been steadily increasing for a decade, especially in the period 2014-2019. A similar upward trend was observed in Wales and Scotland. When the English law was passed, the consent rate in England was the highest it had ever been. However, it is difficult to conclude that the implementation of the law has caused the decline in consent rates since, in May 2020, at the start of implementation, England was between lockdowns, was experiencing ongoing variations in social distancing guidance, and preoccupied with containing the pandemic and investigating drug therapies for COVID-19. At the same time, in order to keep transplantation in operation, at some low level, major changes were made to the organ donor system, including substantial changes to the criteria for assessment of potential organ donors, making discerning any impact of the law change on consent rates challenging.

Although the UK organ donation system now shows signs of recovery from the pandemic, donation rates, the number of eligible potential donors and consent rates remain below their pre-pandemic levels. While this is more likely to be attributable to the pandemic than the switch to deemed consent, at least in 2020-22, the fact that consent rates in England had been increasing steadily before COVID-19 and the law change calls into question, to some degree, the assumed need for the change to deemed consent in the first place, especially since this was accompanied by warnings from experts that the change would be unlikely to be beneficial and could harm the organ donation system.[12-15]

Another important factor observed was that, although over the long term, consent rates in deceased organ donation had been steadily increasing, this figure was volatile year-to-year. Unexplained dips have on the whole been attributed to various causes celebres within the NHS such as the controversy about the Liverpool Care Pathway and the Alder Hey children's organs scandal, as well as more specific cases such as the transplant of two kidneys infected

with a rare disease in which both recipients died. Most agree that a system based on altruism depends on donors trusting the system of organ donation and the NHS as a whole. Given the extraordinary context in which opt-out was implemented (a pandemic), and particular events which followed, affecting public opinion in England (e.g. the Black Lives Matter Movement following the murder of George Floyd in the US, vaccine hesitancy, “Party gate” and other scandals) that reduced public’s trust in Government. It is perhaps unsurprising that consent rates have not yet returned to their pre-pandemic levels or, indeed, increased (as it was assumed the Act would bring about).

Views of the public with a focus on views among ethnic minorities and religious faith groups (Chapter 6)

Changing the law has had little impact on the general public’s support for the principle of organ donation which has remained high and stable over time (80+%). However, it does not appear to have influenced people’s willingness to become deceased organ donors, which is lower at 56%, with considerable variation in what people wish to donate after they die. Non-white ethnic minorities’ support and willingness to donate remain lower (20+%) than in the white population. At the same time, we also found that individuals from minority ethnic groups could potentially be supportive of organ donation, but family and cultural factors sometimes prevented them from doing so. Thus, it was not always the individual’s decision to make, contrary to the assumptions implicit in the 2019 Act.

We also found (very) low levels of understanding of deceased organ donation and how it comes about in ethnic minorities, as well as concerns about whether the processes of organ retrieval aligned with people’s cultural and religious beliefs and preferences. This can lead to individuals making decisions that they perceive to be perfectly rational, but which are often seen as irrational and misinformed by professionals and at odds with the principle underlying the law, which assumes that people will make a personal rational choice based on public information campaigns and official sources of information in favour of donation. We observed the consequences of misleading campaigns against organ donation which rapidly and easily spread due to social media in minority ethnic families and communities who frequently used WhatsApp to talk to their relatives overseas as well as to access community information. This tended to encourage people to opt-out of organ donation, which was a rational choice in the face of misinformation and in an atmosphere of mistrust of the Government and the NHS.

While awareness of organ donation publicity was relatively low and unstable, averaging around 36%, awareness of the law change was (surprisingly) higher at 58% in the white population but again lower in ethnic minority populations (31%) (see Chapter 6 Figure 3 and Appendix 4 Supplementary table 3). But minority ethnic group members were often unaware of, and shocked by, their longer waiting time for organs, and frequently wanted awareness of the impacts of organ donation on their communities to be increased. This information was needed to inform their rational choice to donate their organs. The lack of information and level of misinformation were exacerbated by frustrations with inconsistencies and lack of consensus on organ donation on the part of people in positions of leadership, whom many felt should take a more positive role in addressing these inequalities. People in leadership positions can control the narrative and knowledge which community members use to make their decisions about organ donation.

The number of people registering on the organ donor register has stagnated. Of those registered, 89% have opted in and are predominately white; about 10% have opted out and are predominately non-white. Nonetheless, these findings relate to the early period of the implementation of the new law which was marked by a series of extraordinary events which contributed to a narrative of Government conspiracies directed at harming members of ethnic minority groups, including, by implication, the NHS, and resultant mistrust.

Latent class analysis was used to identify four population sub-groups in terms of their attitudes to deceased organ donation: supportive donors (24%, the subgroup of the population who are the most supportive of organ donation); unsupportive (9%, the subgroup of the population who are the least supportive of organ donation) who are unlikely to respond (positively or negatively) to interventions designed to raise the consent rate; unengaged donors (22%, defined as a subgroup least aware of organ donation publicity) who displayed the most uncertainty about organ donation and may respond to targeted interventions to promote and raise awareness of organ donation; and uncommitted donors (46%, who would consider organ donation, since they were broadly positive in principle but less so when faced with the practicalities) who may also respond to interventions to promote and raise awareness of organ donation. Apart from the supportive donors, most in the other three groups had not discussed their organ donation views or preferences and might benefit from more opportunities to talk or register on the organ donor register (especially uncommitted donors – the subgroup who are supportive of organ donation but not registered). This is important as, although most people supported the changes, the presumption of consent left gaps in people’s knowledge, they wondered what they needed to do while alive, what would happen if they or their relative who died were eligible for organ donation and, critically, what they would do if they did not know what their relative who died had wanted.

Views of specialist and other NHS staff of the deceased organ donor system (Chapter 7)

This part of the evaluation was undertaken informed by Normalisation Process Theory (NPT), a theory for understanding the factors influencing the implementation of a policy or service change, widely used in health care research. Although most staff felt prepared for the law change, losing SNODs’ embedded time within NHS hospitals was considered detrimental to relations between specialist NHSBT staff and clinical staff in NHS trusts, prior to (but exacerbated by) COVID-19. There were mixed messages and views about when SNODs/SRs should or should not be mentioning the ‘soft’ opt-out law change during their conversations with family members (see Chapter 7, particularly section on cognitive participation). SNODs/SRs reported that they often had negative experiences with families when talking through the law change and what it meant, which significantly affected their perceptions of the law change. NHSBT staff sometimes found it challenging to make sense of, and distinguish, old from new practice, especially as the ‘soft’ opt-out was implemented into the existing opt-in system, with some organs, tissues and processes involved requiring family consent and others not.

After receiving initial training and education concerning the law change, many staff in the NHS and NHSBT were redeployed to help treat severely ill patients with COVID-19. This meant that there was an overall loss of opportunities for collective engagement and participation in implementing the law change because organ donation was not the priority during the pandemic.

Many felt that the continued requirement from NHSBT for NHS clinical staff not to mention organ donation to family members was harming the collective action needed to bring about organ donation, and caused frustration when NHS clinical staff were criticised for doing so, especially when they were trying to facilitate organ donation. Despite this frustration amongst NHS clinical staff, SNODs’/SRs’, confidence with implementing the deemed consent pathway increased with the number of deemed approaches they had made.

There were many ongoing opportunities for monitoring the perceived effects of the law change in the organ donation system, as NHSBT routinely collects a mass of data, which is fed back to all those involved in organ donation. On the one hand, NHSBT staff appeared to be reassured that there was little difference in practice and consent rates following implementation of the law, due to anxieties that the law change and implementation during

COVID-19 would make things worse, and, on the other, some disillusionment that nothing had changed in their practice or consent rates. Despite receiving training in the approach to families, specialist NHSBT staff faced even more challenges than before the law change – the 2019 law gave them no new tools to navigate the complexities of speaking to the acutely bereaved or influencing the family's behaviours in regard to deceased organ donation (Chapter 7, particularly section on reflexive monitoring). NHS clinicians too felt that NHSBTs standard operating procedures were not always helpful in what were often highly varied family contexts and complex discussions and negotiations.

Over time, support for the law change appeared to decrease among staff, as did any perceived positive impact the law might have on consent or the organ donation system (Chapter 7, Figures 1 and 2). In their reflections and appraisals, staff continued to feel that the reasons for refusals were the same as before the law change (processes too long, family divided or had previously said they did not want to donate, etc.). The lack of clout of the law, its limited capacity to cope with population heterogeneity, irrelevant nuances in the law in practice (such as devolved implementation and residency status), and the lack of impact on end-of-life proxy decision-making gave staff no more reassurance that the law would work in a practical way to help them make more organs available for transplant. Organ donation remains a relatively rare even for ICU staff and sits outside the clinical care of patients, and thus requires staff involved to go to great efforts to secure donations, and within a permanently overstretched system and overworked workforce, making organ donation a priority outside NSHBT continued to prove challenging.

Experiences of family members approached about organ donation after the law change (Chapter 8)

Despite the change in legislation, not all family behaviours at the bedside were aligned with the utilitarian values implicit in the Act; i.e. that the goal of the legislation is to maximise the number of organs available for transplantation, thereby providing the greatest good to the greatest number of those on the organ donor waiting list. Irrespective of the deceased decision pathway (via the Organ Donor Register (ODR), expressed or deemed), many families still felt that they were the decision makers. Those that did not support donation made decisions that brought about the best outcomes for themselves and/or reinterpreted the intentions of the potential donor. While most people supported the law change in principle, very few understood it, or what it meant for them in their specific circumstances (see Chapter 6). This was echoed in the accounts of family members of potential deceased donors.

For many families, the soft- opt-out legislation did not appear to make difficult decisions any easier and families did not seem any more reassured in their decision making with regard to deceased organ donation than they would have been previously. The majority of family members were having to make different decisions for different organs, tissues and scheduled purposes, but the Act did nothing to shift these micro decisions within the consent process in favour of a greater number of donations. Families reported that situations where consent was intended to be deemed made their situation more difficult not less, because families felt that deemed consent was not really a 'consent' decision at all. For families, the organ donation conversation was too long, complex and convoluted and they retained very little detailed knowledge of what they were asked or did at the time. Changing the law did nothing to better support the realities of losing a loved one so suddenly, dying in intensive care and being identified as a potential organ donor. As deaths are often so traumatic and families are in various states of turmoil, it was unclear for most families how deemed consent could be helpful given their very recent experiences. Families were frequently unpicking the decisions of the deceased and superimposing their own values, judgements and preferences to challenge and overturn the prior consent. They did this most often when consent was deemed. Most families had never even been in an ITU before, or ever seen what death looks like for a

potential organ donor. Families struggled to comprehend the processes involved in retrieval. They most frequently asked themselves (and questioned) if their relative would have wanted the retrieval, and not whether the person who died wanted to save as many lives as possible. Families consistently leaned on the SNODs/SRs for guidance, support and reassurance, and appreciated and needed the high-quality care that they provided.

How the current findings relate the experience of other countries

Findings from cross-country comparisons

Changing the way that people are able to indicate their decisions in relation to deceased organ donation has become a global trend in recent years as more countries move to a system of 'opt-out' in order to increase donation rates. On the face of it, the evidence in favour of shifting to some form of opt-out system would appear clear: of the top ten countries across the world with the highest number of deceased organ donations in 2022, eight had opt-out systems.[1] In Europe alone, 19 out of 27 European Union Member States currently implement opt-out organ donation systems, with those exhibiting the highest rates of donation having opt-out systems of consent.[2] Taking one example, Iceland implemented an opt-out system in 2018 and subsequently jumped from mid/low global rankings to having some of the highest rates of donation in the world by 2022. Taken in isolation, these findings all suggest that opt-out is an obvious solution to a very important problem. However, on closer investigation, the situation is far from straightforward. Opt-out systems are usually implemented alongside, or as part of, a package of changes. Unpicking what difference legislation makes in isolation from wider system changes and factors such as healthcare resources (specialist staff, ICU beds, etc.), culture, media coverage, trust in health and government agencies, end of life care practices, and population characteristics such as general health and ethnic composition, remains challenging. Recent evidence continues to illustrate that taken in isolation legislation makes little or no discernible long-term difference to making more organs available for transplant.[3]

Studies to understand and compare organ donation systems across countries find that the public are generally unaware of the legal framework of organ donation in their own country, but that people in opt-out countries are generally more confused in terms of what role the family has, and while there remains division as to what role families should have, there is substantial opposition to giving families full authority in any system.[4] Research looking at the impact of opt-in and opt-out policies on deceased donation rates, indicates that the assumptions underpinning opt-out legislation should be treated with caution. Legislators, in particular, seem fairly consistently to overvalue the change in default that opt-out brings about, while at the same time to underestimate the de facto role (and power) given to the family in a deceased organ donation context.[5]

In order to be able to make more valid cross-country comparisons to enable learning about how best to increase consent and donation rates, there needs to be greater similarity in the data collected.[6] Analyses focused on ways of increasing the rate of organ donation across the globe suggest that the focus needs to be on bolstering the existing health care infrastructure, and essentially what matters is the health care system rather than the precise terms of any particular legislation.[6, 7]

Given the trend towards opt-out systems, a recent international consensus forum looked more closely at the relationship between the opt-out system and the mechanisms available to enable individuals to make their organ donation decisions known (i.e. organ donation registers). Registers appear to be even more variable in design and operation than the opt-out systems in place. The forum concluded that registries need to work across the three core elements that embody any functioning health care system (legal, societal and economic). The forum also stressed that keeping these structures working well is a complex task, demands

on them will vary and change over time and the task of maintenance is resource-intensive.[8] More research is needed to identify which forms of register best fit which type of health care system, especially when thinking about bringing about a change in consent policy.

A recent comparison between England and the Netherlands, which has implemented a mandated choice policy (every person over 18 is required to register on the organ donor register), is especially illuminating in that it focuses on two policies, which are aiming to do exactly the same thing, but implemented in very different ways: a mandated choice policy (Netherlands) in which citizens must make a decision in advance, by law, versus a default choice policy (England) in which people are presumed to support being a deceased donor unless they say otherwise. The authors concluded it was too soon to identify the impacts of either system, but the comparison highlights the variability in terms of how opt-out systems manifest in practice, and reinforces the point that neither policy is likely to work in isolation from other health system support structures.[9]

Finally, a very recent investigation across the European Union into the translation of organ donation policies into approaches made to the family to discuss donation found that pathway(s) to organ donation are a highly varied mix of law, regulations, guidelines, or combinations of the aforementioned, and even, nothing at all. The authors conclude that practice rarely conforms to the content of formal policies due to culture, the make-up of societies, traditions, beliefs and values, and the context of acute bereavement. The authors conclude that more research is needed to better understand the way that policies are intended to operate and ways of enhancing their impact in practice.[10]

Comparison of England with Spain as world leader in deceased organ donation (Chapter 9)

Aware of the likelihood that factors other than legislation were implicated in differences in consent rates, and the fact that Spain is frequently held up as epitomising the benefits of an opt-out system, we took the opportunity to add an element to the evaluation in the form of a comparison between the consent protocols and documentation used with families in Spain and England.

Despite similar legal frameworks, Spain has a less complex, more evidently supportive of deceased donation (with willingness to take some risks), likely less time-consuming, better resourced (with better access to ICU beds), and more locally tailored opt-out system, with some legal protections for the potential organ donor's decisions in life. This stands in contrast to England's more complex, centralised system with protocols focused on risk minimisation, implemented into a country where there are fewer ICU beds and with no legal protections for the potential organ donor's decisions in life (Appendix 6, particularly Tables 2 and 3).

The Spanish system covers both public and private hospitals. In England, for deceased organ donation, NHSBT only covers NHS hospitals, so some potential donors in the private sector will be lost. Organ donation accompanying euthanasia is legal in Spain (illegal in England) and, although it is relatively recent, this clinical pathway has created an additional platform to embed organ donation as a routine end of life process – the initial requests for this pathway having come from people who had requested euthanasia, and which were not in the initial euthanasia protocols. Potential organ donors with neuro-degenerative conditions requesting euthanasia also tend to be younger without underlying co-morbidities and a single donor could potentially decide to donate all their organs and tissues to help others.

Families are as involved in decision making in Spain as they are in England, yet the consent process is much shorter in Spain. The language used with family members and staff was also observed to be different in tone and meaning. The English system focuses on establishing the last known decision of the deceased, whereas the Spanish system aims to establish the

willingness of the potential organ donor to donate their organs as well as their willingness in general to help others (Appendix 6, Table 2). In England, current guidance and codes of practice reflect the Human Tissue Authority's position on consent for retrieval of organs and tissues, which appears to be more in line with the old 'opt-in' system and thus introduces a degree of risk aversion that is contrary to the spirit of the opt-out legislation, and confusing to staff and family members.

Organ donation also appears to be more ingrained within the Spanish health care system as an integral part of end-of-life care, with many health care professionals aware of it and encouraged to be involved in it. Thus, it is possibly more likely to be discussed by families as there may be a health care worker in the family or someone they know who has been through the process before. More clinical staff are trained to discuss organ donation in Spain and are able to initiate a conversation with relatives about potential organ donation while the patient is still alive which potentially gives family members more time to prepare. This practice is discouraged in England.

A legally binding prior instructions document is also routinely available through the GP or local hospital and is signed by a witness (who may be a family member) in Spain. Therefore, the witness, i.e. an accompanying family member, is likely to be able to verify the document when in ICU. Once it is completed, it is part of the person's general health records meaning that it is more difficult for family members to challenge their relative's organ donation decision made in life.

The structure of the hospitals – i.e. that specific hospitals manage deceased organ donation and that patients can be admitted to ITU purely to ventilate organs and for drug infusion in preparation for donation – is also very different to England's. Matching the Spanish approach would undoubtedly cost the NHS more at the expense of other clinical priorities. However, Spanish policy documents state that 'the social value of organ donation justifies staff efforts and the economic cost involved' (Chapter 9 – Discussion section) indicating an overall difference in the priority given to deceased organ donation between the two countries.[11]

Implications and recommendations for policy and practice

We recognise the multiple agencies and stakeholders which already work together to deliver organ donation and transplant services in the UK. Our recommendations reflect a highly complex and dynamic system. Table 10.1, below, sets out in detail the changes that we think are justified in relation to each of the key health system requirements for an effective consent system when one compares the goals of the opt-out legislation with the experience of its implementation analysed in the preceding chapters of this report. We also identify the agencies responsible and some indication of the sequence of events needed to bring about the desired outcomes set out in the opt-out legislation. We recognise that some changes may take longer to come about in practice than others. In addition, we recognise the complexities and political sensitivities of the fact that there is subtly different legislation in each of the countries of the UK. Nonetheless, our findings have UK-wide implications, and we recommend an aligned UK-wide approach to any changes to the implementation of the current laws and to any changes to legislation that may be determined in future.

Brief summary of implications and recommendations

To help navigate the detail of Table 10.1, this section summarises the main changes recommended if there is a wish to increase consent and donation rates. Given the traumatic circumstances which often precede deceased organ donation, the (very) soft opt-out policy adopted in England was unlikely to help families at their most vulnerable support organ donation decisions. New public ongoing media campaigns crafted to be more supportive of organ donation as a benefit to transplant recipients, could help (some) families overcome some of the many difficulties they encounter at the bedside. At the same time, communications need to refocus and emphasise the changed role of the family. This should

help make more prominent and better understood the new but essential role for families in the context of opt-out legislation, in which they are expected to do what they can, albeit in very difficult circumstances, to ensure that what their relative wanted in life happens.

At the same time, more organs, tissues and processes could be added to the 2019 Act to help further simplify and align policy and practices. As families greatly value the ODR, it could be given greater legal status to further legitimise and protect individuals' decisions and increase support for the aforementioned family behaviours. In order for any changes to the ODR to increase consent rates, health system processes need to adapt, and consent needs to be completely reimagined as an assent mission. Steps need to be taken in the form of regular reminders to those on the ODR so that decisions are kept up-to-date, thereby helping SNOs/SRs in their roles. Documents and processes that the family have to assist in completing need to be reduced to cover only the essential details in terms of ensuring an evidence-based approach to safety and efficacy of transplant.

SNODs/SRs need further training (and tools) to help with their new assent mission. The concept of deemed consent needs further clarification, and a greater public understanding to ensure that it is considered by family members to be a legitimate pathway by their deceased relative. This has not yet happened because the legislation was implemented in a neutral way to promote sharing decisions between the family and the state, rather than being biased towards promoting organ donation on behalf of those waiting for organs. Deemed consent is far from being widely seen as on a par with a decision made by the deceased during their life. This has made the donation process even more uncertain (and ambiguous as families are being given mixed signals as to whether they are the decision makers or not), for acutely bereaved family members, who our research suggests would benefit from further reassurances, such as the more, and more frequent, opportunities for family members to register their organ donation decisions, with reminders embedded throughout day to day life mentioned above, accompanied by more general education about organ donation and about the circumstances which are likely to bring about deceased organ donation.

This, in turn, should help health care professionals to feel more secure and reassured that it is their role to discuss organ donation and to help promote the personal choices of potential organ donors and help the family to support the organ donation. If the processes and protocols around establishing decisions could be reimagined and then revised to promote a more positive culture towards the benefits of organ donation, then this would help staff. It would also help families see these benefits but most importantly, the consequences of their behaviours denying potential beneficiaries awaiting lifesaving and life improving treatments. If families were more reassured that they were supporting what their relative wanted (e.g. by more up-to-date entries on the ODR), then the ambitions of the Act might be easier to implement in the real-world context of deceased organ donation. Finally, we need to acknowledge that the UK NHS consistently operates over and above maximum capacity. This is different to other countries which are better resourced. NHSBT and in particular the SNODs/SRs are essential to the organ donation service which is currently operating in a context that is permanently overstretched and consistently understaffed.

Table 10.1 Recommended changes to the consent process for deceased organ donation in England in light of the evaluation of the implementation of the 2019 Act

Key system input: The organ donor register				
Findings and issues to be resolved	Step(s) 1	Step(s) 2	Step(s) 3	Risks, benefits and resources
<p>We found that:</p> <ul style="list-style-type: none"> • People generally have no idea that their organ donation decision made in life can be overridden by their family members upon death. • There is a significant disconnect between what the potential organ donor is asked to do while alive and what the family members are asked to do after their relative has died and organ donation becomes an option. <p>Problem:</p> <ul style="list-style-type: none"> • The UK has expanded the organ donor register as a key part of implementing the opt-out legislation, but it has no legal status and family members can override a person’s decision to donate their organs made in life. 	<p>Give the organ donor register legal status. <i>Lead agency: Parliament</i></p> <p>Better align the organ, tissues and scheduled purpose options on the ODR with the actual organ donation processes after death. <i>Lead agency: NHSBT</i></p>	<p>Create more opportunities for people to register and reaffirm their decision on the ODR in any interaction with the NHS (e.g. GPs, prescription services, NHS app etc.) <i>Lead agency: Department of Health</i></p> <p>Explore new opportunities to register and reaffirm decisions on the ODR in contexts with high digital footfall (e.g. ordering food, pizza, Deliveroo, taxis, QR-code table ordering e.g. Wetherspoons, Brains etc.) <i>Lead agency: Department of Health</i></p> <p>Ensure that there are regular opportunities to update and/or refresh ODR decisions (e.g. most services now require annual reviews, subscriptions, parking permits, insurance, TV licenses, the gov.uk portal etc.) <i>Lead agency: Department of Health</i></p>	<p>Develop (or utilise an existing) integrated platform with NHS services where the ODR can be immediately linked to patients on admittance to ED and ITU. <i>Lead agencies: NHS & NHSBT</i></p>	<p>Risks and benefits:</p> <p>Legalising the ODR would maintain the ‘soft’ opt-out system while at the same time give greater reassurance to the public (that their decisions are taken seriously and endorsed by law) and signal a legitimacy of the ODR to staff and family members by raising it to a legal status ODR, which is highly valued in bereavement conversations. Linking the ODR to hospital admissions, would remove the current (highly manualised, labour intensive and problematised) referral system and free up resources to be utilised elsewhere.</p> <p>Resources:</p> <p>The ODR is already maintained, utilising existing services/partners to increase sign-ups and identifying existing integrated platforms (e.g. from another country) that work well should result in overall time and cost savings.</p>

Key system input: General knowledge and understanding				
Findings and issues to be resolved	Step(s) 1	Step(s) 2	Step(s) 3	Risks, benefits and resources
<p>We found that:</p> <ul style="list-style-type: none"> While support for organ donation in principle is high, people have very limited knowledge of what can be donated, offered and retrieved as routine practice in the UK. <p>Problem:</p> <ul style="list-style-type: none"> The acutely bereaved are too ill-informed and shocked by what is discussed and involved in organ retrieval at the bedside and are declining (some parts of) organ donation. 	<p>A new media campaign to accompany the changes to the register. <i>Lead agency: Department of Health</i></p> <p>Initial media campaigns should focus on consequences i.e. your family might override your decision/speak for you if you do not register your decision. <i>Lead agency: Department of Health</i></p> <p>Until the ODR has a legal status, potential organ donors should be made aware that their family members can override their recorded decision on the ODR or shared with their family members. <i>Lead agency: NHSBT</i></p>	<p>Review (new) school education materials esp. young adults turning 16-18 and create pathways to inform them that they are in the new opt-out system (and their parents no longer consent on their behalf). <i>Lead agency: NHSBT</i></p> <p>Develop more personalised messaging which speak to a sudden traumatic loss of (young) life, e.g. organ donation happens at the end of life but not at the end of a long life. <i>Lead agency: Department of Health</i></p> <p>In general campaigns need to be less passive have a more actions/ consequences approach and highlight rarity and the need and benefit from family perspectives. <i>Lead agency: NHSBT</i></p>	<p>New opportunities created and taken to demystify organ donation to better align public awareness with what is actually possible to retrieve as routine in practice today. This may involve re-configuring staff to more outward/ education facing roles and/or developing new/ hybrid posts. <i>Lead agencies: NHS & NHSBT</i></p> <p>Ensure well established public health resources have an up-to-date deceased organ donation module (e.g. HealthTalk). <i>Lead agency: Department of Health</i></p>	<p>Risks and benefits: Acutely bereaved families will be more informed, receptive and expecting of an organ donation conversation.</p> <p>Resources: The number of experts (i.e. SNODs) on deceased organ donation is decreasing in the system – it may be worthwhile reimagining new roles who could fulfil an increase in the publics desires to know more about end of life pathways leading to organ donation and/or partner with services with a view to train them to be ‘public experts’.</p>

Key system input: Consent documents, processes and procedures				
Findings and issues to be resolved	Step(s) 1	Step(s) 2	Step(s) 3	Risks, benefits and resources
<p>We found that:</p> <ul style="list-style-type: none"> Bereaved families find the consent process too long and overwhelming and are not reassured in their decision making since implementation. SNODS/SRs are constantly having to navigate in and out of confusing processes and documents, where opt-in, opt-out and HTA (amongst other) legislation(s) may or may not apply and are worried about getting things wrong. <p>Problem:</p> <ul style="list-style-type: none"> Both opt-in and opt-out systems continue to operate in parallel as neither has universal coverage. The consent process is too complex for everybody. We also do not know how useful related documents (e.g. the Medical and Social History Questionnaire (MASH)) are for anybody. The Human Tissue Act (HTA) requires that every organ and tissue for potential donation is discussed and agreed with family members. 	<p>Develop a more simpler consent form by initially removing all processes involved in itemising and listing organs/tissues/ processes/pathways etc. <i>Lead agency: NHSBT</i></p> <p>Turn the conversation around by re-framing discussions around what the person would NOT want, rather than asking acutely bereaved families to imagine what their relative wanted. <i>Lead agency: NHSBT</i></p> <p>Enable SNODs/SRs to suggest innovations and develop ways to act on them in real time. <i>Lead agency: NHSBT</i></p> <p>Reframe the language of ‘consent’ more towards one of ‘assent’ across all documents and practices. <i>Lead agency: NHSBT</i></p>	<p>Reconceptualise the entire separate organ donation consent pathway and re-imagine it as a part of an end-of-life care pathway and dying process in order to help avoid the shock of families suddenly being exposed to the organ donation conversation. <i>Lead agencies: NHS & NHSBT</i></p> <p>- Redesign all consent processes/documents/ procedures and ensure that they are aligned with a mission of assent with flexibility to evolve within a dynamic system, likely to change rapidly and often. <i>Lead agencies: NHS & NHSBT</i></p> <p>Add more organs, tissues and processes to the deemed consent Act legislation, with the aim of universal coverage. <i>Lead agencies: NHS & NHSBT</i></p>	<p>Overhaul how the HTA Act applies to organ donation to create a new less bureaucratic process that ensures a culture of support, re-assurance and protection for those working to ensure that all people who want to donate are supported to do just that <i>Lead agency: Parliament</i></p> <p>Redesign digital services so that every potential organ donor is automatically linked to their medical history. <i>Lead agency: Department of Health</i></p> <p>Align the organ, tissues and scheduled purpose options on the ODR with the actual organ donation process with a view to minimise the need for family input into ‘consent’. <i>Lead agency: NHSBT</i></p>	<p>Risks and benefits: These changes are designed to enable NHSBT to be more explicit, visible and courageous in their role as a Special Health Authority and enable further alignment of or highlight the issues created by implementing an opt-out system into a well-established opt-in system that is intertwined with other legislations (such as the HTA Act) with competing and contradictory aims.</p> <p>Resources: There may be a need for additional research, evaluation and audit to determine the use and function of other documents used to determine safety and efficacy of organs, alongside a process of removing the burdens of consent on grieving families.</p>

Key system input: The (existing) system relationships and interfaces				
Findings and issues to be resolved	Step(s) 1	Step(s) 2	Step(s) 3	Risks, benefits and resources
<p>We found that:</p> <ul style="list-style-type: none"> • The existing opt-in system was relatively inflexible when implementing a soft-opt-out system into it. • The implementation of the ‘soft’ opt-out wasn’t observed to be a radical policy change as suggested by law and policy makers. • Very little changed – only the addition of the deemed consent pathway added as a new section to the existing opt-in consent form. <p>Problem:</p> <ul style="list-style-type: none"> • We have a highly protocolised, multiple layered and complex bureaucracy, resulting in a model of practice so restrictive and risk adverse it is stopping the spirit of the ‘soft’ opt-out legislation being realised. 	<p>The status and content of SOPs could be more aligned with how the ground staff actually conduct themselves (as flexible and adaptable) with bereaved family members to provide more individually personalised care.</p> <p><i>Lead agencies: NHS & NHSBT</i></p> <p>Create new support, education and actual real life processes for NHS clinical colleagues who are eager to help and engage with organ donation to help them to do so.</p> <p><i>Lead agencies: NHS & NHSBT</i></p> <p>Create new and more opportunities for SNODs/ SRs to progress in leadership and research roles.</p> <p><i>Lead agency: NHSBT</i></p>	<p>Replace the culture of ‘don’t mention organ donation’ with one that champions an alternate philosophy that organ donation should be integrated with an end of life care pathway and everyone’s business due its rarity.</p> <p><i>Lead agencies: NHS & NHSBT</i></p> <p>Explore options to raise the profile of organ donation within the overall Trust’s agenda and improve visibility outside the SNOD/SR presence – e.g. wider charity/ corporate sponsored events.</p> <p><i>Lead agencies: NHS & NHSBT</i></p>	<p>NHSBT should be encouraged to move towards new models of working that are more aligned with the spirit of presumed consent and not a system that is trying to make every form of consent work for everybody and at the same time keep organ donation away from everybody else.</p> <p><i>Lead agency: NHSBT</i></p> <p>We need to ask if we created a presumed consent system from scratch what would it look like. (lead agency, Parliament)</p> <p><i>Lead agencies: Department of Health NHS & NHSBT</i></p>	<p>Risks and benefits:</p> <p>Although often unrelated to organ donation scandals (e.g. Alder hey), the HTA, common law changes in data protection (GDPR), and isolated yet high profile media cases (usually involving children) going to court over withdrawal of treatment have contributed to a systemic culture of risk aversion within NHS/BT.</p> <p>We need to learn from adverse events but at the same time legislating in the wake of scandals is in itself very risky. We need to protect our workforce and ensure that any interventions and how they come about in practice makes their complex and challenging roles easier and not more difficult.</p> <p>Resources:</p> <p>It remains unclear what the level of NHS/ NHSBT ambition was concerning the Act. There did not appear to be any great desire to match global leaders (Spain) but rather to facilitate an implementation that did not disrupt or harm the status quo. However if the ambition is to make organ donation an expected part of End of Life care then the focus needs to be on creating more seamless interfaces between NHSBT and NHS in the clinical setting, in the documents and in the overall system – and resourced accordingly i.e. organ donation is rare but when it is a potential option, everybody needs to be ready for it.</p>

Key system input: UK ethnic minorities specific perspectives				
Findings and issues to be resolved	Step(s) 1	Step(s) 2	Step(s) 3	Risks, benefits and resources
<p>We found that:</p> <ul style="list-style-type: none"> • UK ethnic minorities ‘base line’ of understanding about organ donation is even lower. • Family structures in terms of decision making can be (very) different. <p>Problem:</p> <ul style="list-style-type: none"> • There are specific more nuanced concerns often related to end of life beliefs, rituals and ceremonies and their relationship to organ donation. • Family hierarchies may need consideration alongside a ‘new’ ODR and its status. 	<p>In addition to the above for the ‘general’ public, there are much more nuanced and complex factors that are impacting ethnic minorities views and behaviours. Organ Donation needs to be couched in overall health inequalities which (at present) are contributing more to the need for organs for ethnic minorities than any issues in consent.</p> <p><i>Lead agency: Department of Health</i></p> <p>Finding the right leadership to address the lack of clarity from top down in the Muslim communities may help as well as more effective pathways to spread messages and innovations into the communities and families with a view to pre-emptively protect against harmful misinformation.</p> <p><i>Lead agencies: NHS & NHSBT</i></p> <p>Opportunities could be taken to start with more palatable ‘normalised’ options e.g. blood and breast milk donation to start conversations and the processes of engagement towards deceased organ donation.</p> <p><i>Lead agencies: NHS & NHSBT</i></p>			<p>Risks and benefits: Addressing overall health inequalities first may act as a starter to reduce inequalities on the waitlist and help balance limited resources with the comparatively small number of UK ethnic minorities who are currently eligible for deceased organ donation.</p> <p>Resources: Recent resources have focused on small scale projects delegated to community based innovations. But innovators have found measuring impact (i.e. number of people they get signed on the register) challenging and unhelpful to address the significant knowledge gaps, often clinically orientated questions. Answers to which at present are only creating more questions and uncertainties.</p>

Research, evaluation and audit

Routine evaluation and audit data can be used to monitor further changes and modifications to processes and procedures and may identify population level trends, patterns or tendencies that warrant (new) investigations.

We recommend:

- Additional research to better understand the current use and function of the remaining documentation presented to families at the bedside (e.g. MASH) with the purpose of simplifying whilst maintaining safety and efficacy of organs to transplant.
- We still need to determine the effect of the ‘soft’ opt-out system in England and to determine what works in the ‘soft’ opt-out system in a non-covid setting.

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Declarations

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Ethics and research approvals

The study received favorable ethics opinions from the LSHTM Research Ethics Committee (Ref. 26427 – 20/07/2021) and from the Health Research Authority (HRA) Research Ethics Committee (Ref. 21/NW/0151 – 03/06/2021). Research approvals were received from the HRA and Health and Care Research (HCRW) Wales (IRAS project ID 297313) on 3/06/2021, and from the Research, Innovation and Novel Technologies Advisory Group (RINTAG) (ODT Study no 113; NHSBT Change Control ref: cc/11164) on 11/06/2021.

Further information

You can find further information including a lay summary of this report on the website, <https://piru.ac.uk/projects/current-projects/evaluation-of-changes-to-organ-donation-legislation-in-england.html> as well as updates and any follow on research and dissemination.

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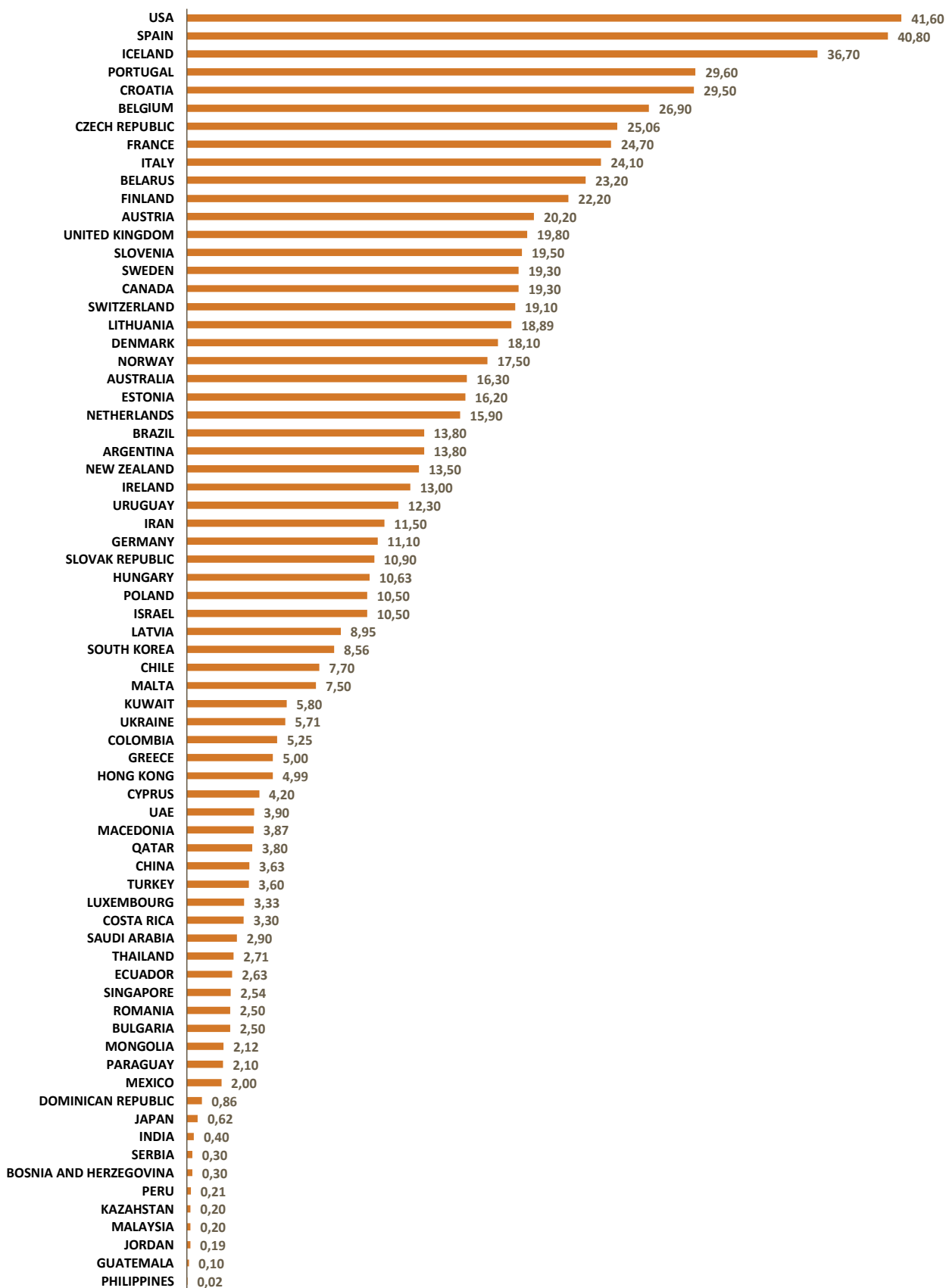
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Appendix 1: Chapter 1

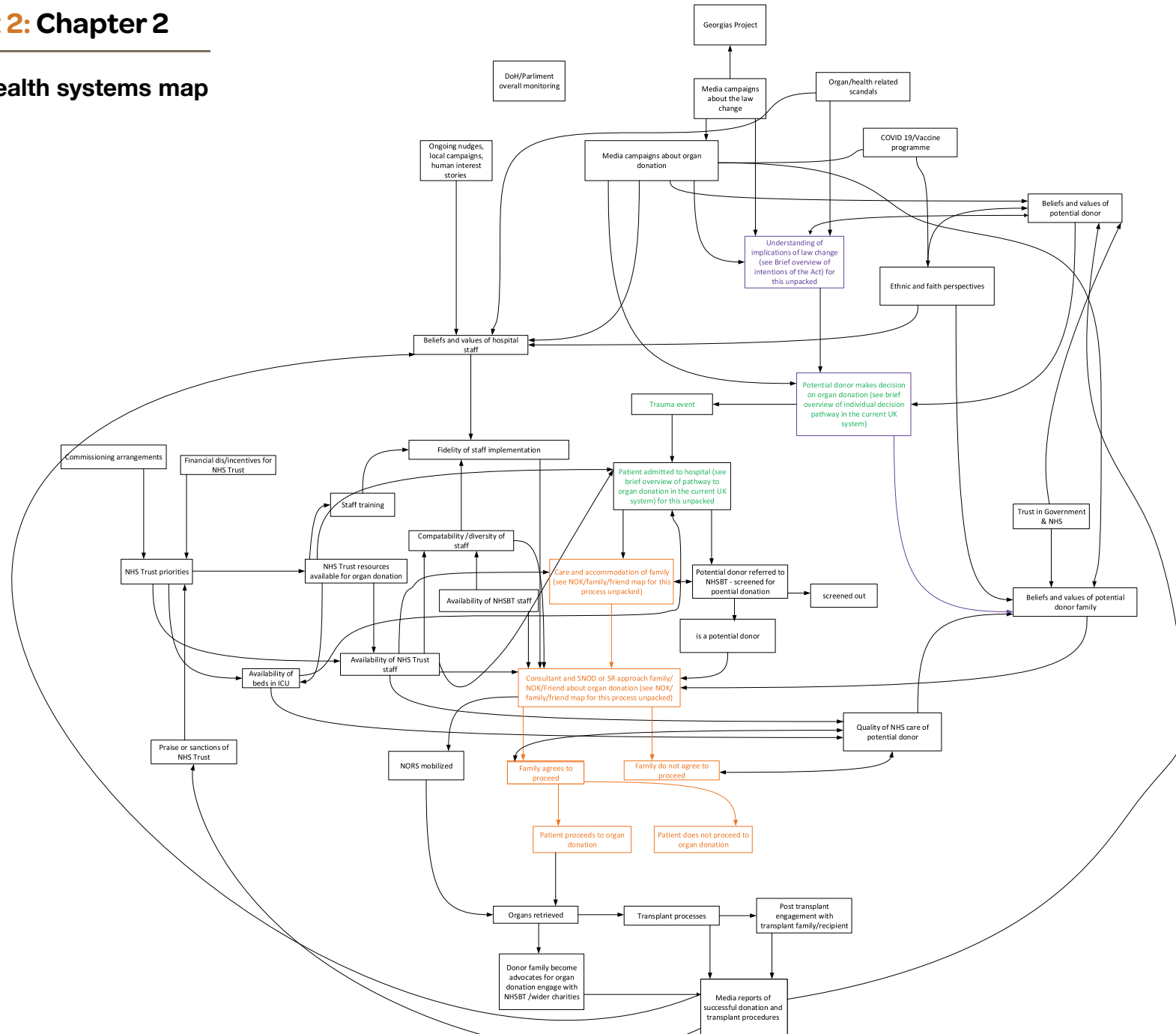
Figure 1: Deceased organ donation rate per million population, 2021



Source: IRODaT (International Registry in Organ Donation and Transplantation (www.irodat.org))

Appendix 2: Chapter 2

Figure 2: Health systems map



Appendix 3: Chapter 4

3.1: Publications with highest readership

Publication	Estimated number of readers (2020)
Metro	1,426,535
The Sun	1,250,634
Daily Mail	1,169,241
Evening Standard	798,168
Daily Mirror	451,466
The Times	368,929
Daily Telegraph	360,345
Daily Express	296,079
Daily Star	277,237
i	217,182
Financial Times	157,982
The Guardian	132,341
Daily Record	104,343
City A.M.	85,521
The Independent	55,193

Source: IRODaT (International Registry in Organ Donation and Transplantation (www.irodat.org))

3.2 Full list of media articles and tone and full list of comments on media articles and tone

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
iNews	20 May 2019	“I’ve just turned 30 – it’s a birthday I never thought I’d see”: Cystic fibrosis sufferer celebrates life after double lung transplant	Positive	Positive	119	57
Evening Standard	23 May 2019	Machine that keeps livers ‘alive’ could allow for more life-saving transplants in future	Positive	N/A	282	64
Daily Mail	28 May 2019	Mother of teenage organ donor says she ‘got a sense of Ben’ when she met the father-of-two given her dead son’s liver for the first time at the finish line of a walking challenge	Positive	N/A	3256	117
The Conversation	29 May 2019	Opt-out organ donation: presume kindness, not consent, to save more lives	Positive	Negative	248	73
East London Lines	4 June 2019	New campaign launched to encourage organ donation among BAME communities	Positive	N/A	1	1
The Star	8 June 2019	Three organ donors from Sheffield honoured for saving lives in posthumous award ceremony	Positive	Positive	26	25
Northern Echo	9 June 2019	Meet the nurse saving lives by encouraging organ donation	Positive	Positive	37	9
Daily Mail	10 June 2019	Breakthrough device that can keep donor organs functioning outside the body for 24 hours will revolutionise transplant surgery, experts say	Positive	N/A	3256	117
The Mirror	24 June 2019	Max and Keira’s Law: The story of how the Daily Mirror campaigned to change the law on organ donation	Positive	Positive	906	81
The Metro	26 June 2019	Boy, 10, died playing football when ‘blood vessel burst in his brain’	Positive	N/A	328	40
The Sun	26 June 2019	‘LOVED BY ALL’ Football-mad boy, 10, collapses and dies while playing with pals in the park after suffering cardiac arrest	Positive	N/A	1069	48
Windsford and Middlewich Guardian	29 June 2019	“Losing her was such a heartbreaking time but we are so glad we agreed to organ donation”	Positive	Positive	1	2

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
Leigh Journal	3 July 2019	Sisters of 19-year-old who became a life-saving organ donor after his sudden death 'honoured' to accept award in his name	Positive	N/A	1	1
Daily Express	7 July 2019	New figures reveal one in five organ transplants come from drug users	Negative	N/A	1351	50
Daily Mail	10 July 2019	Revealed: one in five organs used in transplants including kidneys, lungs and hearts have come from drug users	Negative	N/A	3256	117
The Times	10 July 2019	Woman died of HIV from donor's kidney	Negative	N/A	357	117
The Mirror	17 July 2019	Britain's longest surviving heart transplant patient makes plea for organ donors	Positive	Positive	906	71
Daily Mail	18 July 2019	People dying fatter and older is 'reducing the number of usable donated organs' as NHS reveals one in SIX body parts now get rejected by doctors	Positive	Positive	3256	117
The Independent	18 July 2019	Obesity and old age blamed as organ transplants fall despite record number of donors	Positive	Positive	937	287
The Telegraph	18 July 2019	Soaring obesity rates fuel doubling in the number of organs which cannot be transplanted	Neutral	Positive	609	107
Finchley and Barnet Times	19 July 2019	Patient visits Barnet school over change in law for organ donations	Positive	Neutral	1	9
The Metro	19 July 2019	Teen saves lives after 'mysteriously' becoming organ donor two weeks before dying	Positive	N/A	328	40
Essex Gazette	22 July 2019	Only 25 people eligible for organ donation in Essex	Positive	Neutral	13	4
Daily Express	26 July 2019	British Transplant Games poignant for Wilson family as Tom's memory lives on	Positive	N/A	135	50
The Metro	26 July 2019	The reality of having an organ transplant is not what you think	Positive	Neutral	328	40
London news	26 July 2019	Organ donations from St George's Hospital helps the UK reach its highest level of donors	Positive	Positive	6	19

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
The Sun	27 July 2019	FAMILY TORN APART Heartbroken mum loses son, 22, in freak hockey accident and husband, 56, from sepsis just weeks apart	Positive	N/A	1069	48
Essex Live	27 July 2019	Essex mum whose son and husband died eight weeks apart urges people to donate their organs	Positive	N/A	27	8
Lancs Live	29 July 2019	Posthumous honour for organ donor Pippa Astbury who helped save three lives	Positive	N/A	22	10
The Sun	30 July 2019	MUTANT MADNESS Plot to create ‘human-animal hybrids’ using controversial gene-editing science approved	Negative	N/A	1069	48
Financial Times	2 Aug 2019	Richard Thaler: “If you want people to do something, make it easy”	Neutral	N/A	268	45
Stone and Ecclesham Gazette	2 Aug 2019	Call for families in Staffordshire to talk about organ donation	Positive	Positive	1	1
Daily Express	10 Aug 2019	George Shelley sister: The tragic accident that killed his sister – but saved five lives	Positive	N/A	135	50
iNews	17 Aug 2019	Mother who lost her 22-year-old son holds hands with six-year-old girl who was saved by his liver	Positive	N/A	119	57
The Sun	17 Aug 2019	‘HE’S MY HERO’ Girl, 6, praises the “hero” who helped save her life through organ donation after he died of a brain haemorrhage	Positive	N/A	1069	48
The Telegraph	17 Aug 2019	Pig hearts ‘could be used in human transplants within three years’ after gene breakthrough	Positive	Positive	609	107
The Sun	18 Aug 2019	FRANKENSWINE Pig hearts could be used in human transplants ‘within just three YEARS’ says surgeon who performed first ever op 40 years ago	Negative	N/A	1069	48
The Telegraph	18 Aug 2019	How Britain’s first heart transplant almost didn’t happen due to medical ‘rivalries and intense hostility’	Positive	Positive	609	107
The Conversation	20 Aug 2019	Organ transplants: why so many people are put off donating	Positive	Positive	248	73

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
Daily Mail	21 Aug 2019	Mother whose son died aged 17 ‘after a sneezing fit triggered a stroke’ meets the man whose life was saved by his donor heart	Positive	N/A	3256	117
Financial Times	21 Aug 2019	Pig organs to be used in transplant operations	Negative	N/A	268	45
Daily Express	23 Aug 2019	Transplant breakthrough: Pig-to-human heart transplants possible ‘within three years’	Neutral	N/A	135	50
The Mirror	2 Sept 2019	Bereaved families objecting to organ donation is costing hundreds of lives	Positive	Neutral	906	81
The Telegraph	2 Sept 2019	“I didn’t want my sister to die for nothing: It just seemed such a waste”	Positive	Positive	609	107
Cambridge Independent	2 Sept 2019	Organ Donation Week: families urged to talk about their wishes	Positive	Positive	2	16
ITV news	3 Sept 2019	New law means organ donation will be automatic after death: What are the facts?	Positive	Positive	924	120
Romford Recorder	4 Sept 2019	Organ Donation Week 2019: Queen’s hospital doctor urges organ donors to make family aware of their wishes	Positive	Positive	3	7
The Mirror	5 Sept 2019	Mum who lost 5 relatives to kidney disease gets miracle donor alongside mum and sister	Positive	N/A	906	81
The Guardian	5 Sept 2019	Organ donations from BAME community at record high, data shows	Positive	N/A	3046	148
BBC news	6 Sept 2019	Hepatitis C-infected kidneys used in organ transplants	Positive	N/A	7781	152
Daily Star	6 Sept 2019	Tragic mum of eight-month-old-baby ‘took own life’ weeks before 25th birthday	Positive	N/A	348	16
Shropshire Star	6 Sept 2019	Organ Donation Week: “to give the chance of life to someone is the most precious gift”	Positive	Positive	16	13
The Telegraph	6 Sept 2019	Dozens more kidneys could be donated after doctors successfully cure transplant organ with hepatitis C	Positive	N/A	609	107
The Mirror	7 Sept 2019	Teenager with ‘heart of pure gold’ saves three lives with organ donors	Positive	N/A	906	81

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
The Sun	7 Sept 2019	DEATH SENTENCE Busy mum who went to the doctor with tiredness was told her liver was shrinking and she had 72 hours to live	Neutral	N/A	1069	48
The Sun	7 Sept 2019	BRIDE AND JOY Double transplant took diabetes suffering dad, 35, from contemplating last rites to tying the knot	Positive	N/A	1069	48
The Metro	9 Sept 2019	Man ‘wanted to die’ after rare illness caused belly to swell up like he was pregnant	Neutral	N/A	328	40
The Mirror	14 Sept 2019	Woman ‘slowly dying’ with months to live makes desperate plea for transplant	Positive	Positive	906	81
The Mirror	20 Sept 2019	Brave youngster Max Johnson to be celebrated as ‘Heart Hero’ at awards ceremony	Positive	Positive	906	81
The Telegraph	24 Sept 2019	Heart transplant waiting lists hit record high, with doubling in number waiting	Positive	Positive	609	107
The Times	24 Sept 2019	Longer wait for heart transplants as donor quality drops	Positive	Positive	357	117
Daily Mail	26 Sept 2019	Kind hearted teenager’s organs saved three lives after 18-year-old ran into path of oncoming Mercedes and was killed outside her school	Positive	N/A	3256	117
The Metro	26 Sept 2019	Schoolgirl ran over and killed ‘after bus driver signalled she could cross road’	Positive	N/A	328	40
Daily Express	29 Sept 2019	Have a heart and save us: Desperate parents plead for child donors	Positive	Negative	1351	50
The Mirror	29 Sept 2019	“Stranger’s heart saved my life – now my baby son needs a miracle donor too”	Positive	Neutral	906	81
The Sun	11 Oct 2019	School children blow bubbles and mourners dress in blue as ‘hit and run’ death girl Melissa Tate, 10, laid to rest	Positive	N/A	1069	48
Kent Online	15 Oct 2019	Tonbridge mum Gemma Ashdown hopes children will hear organ donor dad’s heart beat again	Positive	N/A	54	19
The Mirror	19 Oct 2019	Dad who had vital transplant shares ‘special’ bond with organ donor’s parents	Positive	N/A	906	81

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
The Mirror	20 Oct 2019	We put little Max in the public eye to change law – and find him a heart donor	Positive	Positive	906	81
The Metro	21 Oct 2019	Woman who survived kidney and liver transplants becomes athletics star	Positive	N/A	328	40
The Mirror	24 Oct 2019	Emotional mums who inspired organ donor campaign meet for first time 25 years on	Positive	Positive	906	81
The Sun	28 Oct 2019	‘MOWED DOWN’ Driver admits causing death of ‘beautiful’ girl, 10, in ‘hit-and-run’	Positive	N/A	1069	48
The Mirror	3 Nov 2019	“Our son’s death was not in vain after he gave organs to Team GB winner”	Positive	Positive	906	81
The Mirror	4 Nov 2019	Organ donor’s heartbroken wife makes tearful plea to person receiving his heart	Positive	Positive	906	81
The Guardian	10 Nov 2019	“I knew my son’s heart was out there”: why the families of organ donors would love a thank you	Positive	Positive	3046	148
The Guardian	13 Nov 2019	Overwhelming gratitude for the priceless gift of organ donation	Positive	N/A	3046	148
New Milton Advertiser	14 Nov 2019	Accidental death victim saved two lives with organ donation, inquest told	Positive	N/A	1	4
The Telegraph	15 Nov 2019	I gave you my heart: the surprising truth behind that Last Christmas organ donation twist	Negative	N/A	609	107
Daily Mail	21 Nov 2019	One NHS patient DIED and another became seriously ill after receiving infected organs from surgeon who failed to disclose his fatal mistake	Negative	N/A	3256	117
The Metro	21 Nov 2019	Patient died after surgeon spilled stomach contents onto donor’s organs	Negative	N/A	328	40
The Sun	21 Nov 2019	SURGICAL BLUNDER One NHS patient died and another left seriously ill after receiving infected donor organs	Negative	N/A	1069	48
Bristol Post	2 Dec 2019	The people spreading the word on organ donation to Bristol’s African Caribbean community	Positive	Positive	40	14

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
The Metro	3 Dec 2019	Baby desperate for new heart just months after his dad received a transplant	Positive	N/A	328	40
ITV news	6 Dec 2019	Nine-month-old baby desperate for new heart to spend Christmas in hospital	Positive	Neutral	924	120
Daily Express	8 Dec 2019	All I want for Christmas is a new heart – child donor appeal	Positive	Positive	1351	50
The Mirror	16 Dec 2019	Baby born with half a heart receives life-saving Christmas organ donation	Positive	N/A	906	81
The Mirror	17 Dec 2019	Incredible Izzy whose kidneys failed at birth rings ‘transplant bell’ for the first time	Positive	N/A	906	81
Daily Mail	20 Dec 2019	Moving TV advert encourages families to talk about organ donation this Christmas before the law changes to make EVERY adult a donor next year	Positive	Positive	3256	117
The Metro	20 Dec 2019	NHS urges families to share organ donation wishes before opt-out system hits	Neutral	Neutral	328	40
Daily Mail	22 Dec 2019	World’s first human HEAD transplant ‘could happen in next ten years’ due to advances in technology, says ex-NHS neurosurgeon and robotics expert	Negative	N/A	3256	117
The Mirror	30 Dec 2019	Girl, 12, saved by miracle heart transplant after nearly dying from rare disease	Positive	Positive	906	81
Daily Star	31 Dec 2019	Girl, 12, heaps praise on donor’s family following successful heart transplant	Positive	N/A	348	16
SW Londoner	8 Jan 2020	BAME lives to be saved as new organ donation law rolls out	Positive	Positive	2	17
Daily Mail	13 Jan 2020	Scientists develop a machine that can keep a donated human liver alive for a WEEK outside the body by pumping fresh blood through the crucial organ	Positive	N/A	3256	117
The Guardian	13 Jan 2020	Organ donation: new technique can preserve human livers for a week	Neutral	N/A	3046	148
Jewish Chronicle	22 Jan 2020	Survey finds ‘significant confusion’ over organ donation among Jews	Neutral	Neutral	5	1

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
Evening Standard	23 Jan 2020	First ever robotic heart could put an end to transplants, scientists say	Neutral	N/A	282	64
Daily Mirror	23 Jan 2020	World's first totally robotic heart will end need for transplants in 10 years	Neutral	N/A	906	81
Daily Express	24 Jan 2020	Iain Dale left in tears as heartbreaking call ends in the most beautiful way	Positive	N/A	1351	50
Hull Daily Mail	24 Jan 2020	The organ donation hero who had a miracle year then gifted life after death	Positive	Positive	47	12
Ely Standard	2 Feb 2020	Cambridge University Hospitals urge people to become life-saving organ donors	Positive	Positive	1	1
Lexology	2 Feb 2020	Give or take? The new law on organ donation	Neutral	Neutral	30	3
BBC news	7 Feb 2020	My newborn son – the organ donor	Positive	N/A	7781	152
Religion news	10 Feb 2020	Fighting taboos, British Sikhs work to demystify organ donation	Positive	Positive	11	158
Daily Mail	14 Feb 2020	Pioneering heart transplant device can keep donated organs alive for 24 HOURS, potentially saving thousands of lives	Positive	N/A	3256	117
Mobile Marketing	14 Feb 2020	NHSBT goes social to raise awareness of organ donation law change	Positive	Positive	1	4
The Sun	14 Feb 2020	HEART IN A BOX Doctors keep heart beating for 24 hours with new 'game-changing' device	Positive	N/A	1069	48
The Telegraph	14 Feb 2020	Hearts can be kept alive for 24 hours after death, scientists have shown	Positive	N/A	609	107
Daily Mail	17 Feb 2020	With a new opt-out donation law weeks away... DR MARTIN SCURR and DR MAX PEMBERTON question if the NHS should have the right to take our organs?	Positive	Neutral	3256	117
Lancashire Post	20 Feb 2020	People across the north west must ensure they get their facts straight about organ donation law change, warn health bosses	Neutral	Neutral	7	7

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
Leigh Journal	24 Feb 2020	Lifts at hospital trust given new look to encourage people to join organ donation register	Neutral	Neutral	1	1
The Mirror	25 Feb 2020	Everyone will be an organ donor by default within weeks – thanks to two special children	Positive	Positive	906	81
Nursing Times	25 Feb 2020	Exclusive: organ donation nurse network expanded ahead of law change	Positive	Positive	13	79
Sky news	25 Feb 2020	Max and Keira’s law: new ‘opt-out’ organ donor system to be introduced on 20 May, government plans	Positive	Positive	538	413
The Independent	25 Feb 2020	Adults to be automatically enrolled as organ donors under new law	Positive	Positive	937	287
The Telegraph	26 Feb 2020	All adults will be assumed organ donors unless they opt-out under new system	Positive	Positive	609	107
The Guardian	1 March 2020	New law on organ donations could save thousands like 12-year-old Max	Positive	Positive	3	148
The Sun	10 March 2020	My husband registered to be an organ donor and didn’t tell me... now I don’t trust him again	Negative	N/A	1069	48
Healthcare IT News	11 March 2020	Organ donation law seeing move to opt-out system to come into effect in England	Positive	Positive	5	14
The Moorlander	11 March 2020	Organ donation law to come into effect	Positive	Positive	1	1
BBC news	22 March 2020	Vinnie Jones welcomes organ donation change after wife’s death	Positive	Positive	7781	152
The Metro	22 March 2020	Vinnie Jones says wife Tanya’s heart transplant ‘saved his life’ as well	Positive	Positive	328	40
The Sun	22 March 2020	“IT GAVE US 32 YEARS” Vinnie Jones says wife’s heart transplant saved HIS life as well as hers – as he praises organ donor law change	Positive	Positive	1069	48
The Metro	23 March 2020	Mum listens to late daughter’s heart as it beats in another teenager’s body	Positive	N/A	328	40

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
Daily Mail	31 March 2020	Family of father, 27, who took his own life share their pride at knowing he saved SIX people by donating his organs and say it's a comfort to know 'his heart is beating in someone else'	Positive	N/A	3256	117
Daily Mail	31 March 2020	Every organ donor is being tested for coronavirus as NHS rejects transplants from infected patients to minimise risk to recipients	Neutral	N/A	3256	117
The Mirror	2 April 2020	Family shed tears for life-saving daughter crowned world's youngest organ donor	Positive	Positive	906	81
The Mirror	2 April 2020	Eddie Large helped change UK organ donation law after receiving heart transplant	Positive	Positive	906	81
Health Service Journal	2 April 2020	Exclusive: NHS trusts suspend life-saving organ transplants	Positive	N/A	3	68
Cambridge News	3 April 2020	Cambs family shed tears for life-saving baby crowned world's youngest organ donor	Positive	Positive	23	17
Daily Mail	3 April 2020	NHS bosses admit ALL organ transplants could be scrapped 'within days' over fears patients will catch coronavirus as outbreak overwhelms intensive care units	Positive	Neutral	3256	117
BBC news	9 April 2020	Coronavirus pressures 'put organ transplants at risk'	Positive	N/A	7781	152
Daily Mail	13 April 2020	Nursery worker, 21, who was waiting for life-saving liver operation dies after being taken off transplant list when she tested positive for coronavirus in hospital	Positive	N/A	3256	117
The Mirror	27 April 2020	Boy, 12, saved by 9-year-old donor vows to 'cherish your gift with all my life'	Positive	Positive	906	81
EurekAlert	6 May 2020	Study reveals impact of 'soft opt-out' system for organ donation	Positive	Positive	22	71
BBC news	12 May 2020	Coronavirus: low level of transplants sparks concern	Positive	N/A	7781	152
The Mirror	17 May 2020	Mum who nearly died after birth saved by miracle heart transplant	Positive	Positive	906	81
The Sun	17 May 2020	'WORRYING TIME' Transplant patients face anguish as number of organ donors falls during coronavirus crisis	Positive	N/A	1069	48

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
The Mirror	18 May 2020	Boy, 5, is symbol of hope that new ‘opt-out’ transplant system will save lives	Positive	Positive	906	81
iNews	19 May 2020	‘Game changing’ organ donation law means adults in England are deemed to have given consent to donate their organs when they die	Positive	Positive	119	57
The Guardian	19 May 2020	All adults in England to be deemed organ donors in ‘opt-out’ system	Positive	Positive	3046	148
The Jewish Chronicle	19 May 2020	Chief Rabbi backs new organ donation system in England	Positive	Positive	5	1
The Mirror	19 May 2020	Heart transplant hero Max, 12, says “You did it for me... now do it for Ethan”	Positive	Positive	906	81
Daily Express	20 May 2020	Organ donation update: every adult now an organ donor unless they opt-out	Positive	Positive	1351	50
Daily Express	20 May 2020	Lifeline for patients as organ donation by all becomes law	Positive	Positive	1351	50
Evening Standard	20 May 2020	New law will see adults in England automatically become organ donors in hope for patients awaiting life-saving transplants	Positive	Positive	282	64
iNews	20 May 2020	Organ donation opt-out explained: how to opt-out, why the UK law is changing and excluded groups in the NHS scheme	Positive	Positive	119	57
Sky News	20 May 2020	England moves to ‘opt-out’ organ donation system after change in law	Positive	Positive	538	413
The Independent	20 May 2020	Organ donation: how have the laws in England changed and do you still have a choice?	Positive	Positive	937	287
The Metro	20 May 2020	How has the law around organ donation changed today and what is the opt-out system?	Positive	Positive	328	40
The Metro	20 May 2020	From today every adult in England is automatically an organ donor	Positive	Positive	328	40
The Metro	20 May 2020	The new organ donation law will save lives, but it’s pointless if your family don’t know your wishes	Positive	Positive	328	40

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
The Sun	20 May 2020	TICKING TIME BOMB My baby boy needs a new heart... without it, he won't live to see his 2nd birthday	Positive	N/A	1069	48
The Sun	20 May 2020	MAX & KEIRA'S LEGACY Every adult is now an organ donor unless they opt-out – thanks to two inspiring children	Positive	Positive	1069	48
The Sun	20 May 2020	THE GIFT OF LIFE How does organ donation work and what is Max and Keira's Law?	Positive	Neutral	1069	48
The Sun	20 May 2020	ORGAN DON'TOR How to opt-out of organ donation in the UK	Neutral	Neutral	1069	48
The Times	20 May 2020	Every adult automatically an organ donor by law	Positive	Positive	357	117
Wired	20 May 2020	New organ donation laws could help fix the BAME donor crisis	Positive	Positive	56	128
Daily Mail	21 May 2020	I admit it, I feel queasy about the State having a claim on my organs... unless I choose to opt-out, writes Melanie McDonagh	Positive	Negative	3256	117
Halifax Courier	21 May 2020	Parents of Halifax boy who saved six lives through organ donation support new 'opt-out' law	Positive	Positive	3	15
Daily Express	22 May 2020	Organ donation opt-out: How do I opt-out of organ donation scheme?	Negative	Neutral	1351	50
Vatican News	23 May 2020	Bishop for Healthcare on England's new organ donation law	Positive	Negative	100	364
The Mirror	2 June 2020	Boy marks first birthday as donor law comes into force after his own transplant	Positive	Positive	906	81
The Mirror	2 June 2020	Every member of this choir has been touched by organ donation in some way	Positive	Neutral	906	81
Manchester Evening News	4 June 2020	Mum thanks kidney donor who saved her life and allowed her to have her "miracle" baby	Positive	Positive	346	119
Daily Mail	6 June 2020	We're all organ donors now – unless we opt-out. Katie Hind's moving story about her father's incurable disease and how a new heart saved his life shows why the new law is so essential	Positive	Positive	3256	117

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
The Telegraph	12 June 2020	Letter: a sceptical view of the ‘gods in white’	Negative	Negative	609	107
Daily Express	14 June 2020	Fear Brits died waiting for organ transplants during lockdown as ops plummet by two thirds	Positive	N/A	1351	50
Financial Times	17 June 2020	Letter: the patient is not the only transplant beneficiary	Positive	Positive	268	45
Daily Star	26 June 2020	Extreme sex killer caged in ‘Monster Mansion’ wants to donate his kidney	Negative	N/A	348	16
The Metro	28 June 2020	Boy waiting on organ transplant gets amazing rocket ship bed from grandad to fulfil astronaut dream	Neutral	N/A	328	40
BBC news	3 July 2020	Organ donation: “Mum said we don’t do it. So we don’t”	Positive	Positive	7781	152
The Sun	8 July 2020	TWO LITTLE MIRACLES My two little girls almost died from deadly heart condition but doctors’ brilliance and strangers’ kindness saved them	Positive	Positive	1069	48
Daily Star	10 July 2020	Dad who died after he was ‘punched in Screwfix queue-jumping row’ pictured	Positive	N/A	348	16
EurekAlert	10 July 2020	New study warns of misinformation about opt-out organ donation	Positive	Negative	22	71
The Mirror	16 July 2020	Our little princess urgently needs new organs – just like other children waiting for call	Positive	N/A	906	81
Daily Star	20 July 2020	F1 grid girl in coma after going blind in one eye and suffering kidney failure	Neutral	N/A	348	16
Daily Mail	6 June 2020	We’re all organ donors now – unless we opt-out. Katie Hind’s moving story about her father’s incurable disease and how a new heart saved his life shows why the new law is so essential	Positive	Positive	3256	117
Daily Star	10 July 2020	Dad who died after he was ‘punched in Screwfix queue-jumping row’ pictured	Positive	N/A	348	16
EurekAlert	10 July 2020	New study warns of misinformation about opt-out organ donation	Positive	Negative	22	71

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
The Mirror	16 July 2020	Our little princess urgently needs new organs – just like other children waiting for call	Positive	N/A	906	81
Daily Star	20 July 2020	F1 grid girl in coma after going blind in one eye and suffering kidney failure	Neutral	N/A	348	16
The Leader	21 July 2020	Increased public support for organ donation despite impact of Covid-19	Positive	Positive	9	5
Evening Standard	22 July 2020	Kidney transplant resume for patients who have isolated	Neutral	N/A	282	64
Bracknell News	23 July 2020	Berkshire families urged to talk about organ donations	Positive	Positive	4	3
The Sun	8 Aug 2020	ORGANS FOR SALE Kidney trafficker brags to The Sun about luring poor victims into selling organs to desperate Brits on Facebook for £85k	Negative	Negative	1069	48
Daily Star	10 Aug 2020	Formula One grid girl Khloe Atkinson dies after desperate kidney transplant plea	Positive	N/A	348	16
Daily Star	12 Aug 2020	Girl, 11, killed after being hit by car in horror crash as heartbroken family pay tribute	Positive	N/A	348	16
EurekAlert	10 July 2020	New study warns of misinformation about opt-out organ donation	Positive	Negative	22	71
The Metro	12 Aug 2020	‘Kind and caring’ girl, 11, dies two days after being knocked down in hit and run	Positive	N/A	328	40
The Sun	12 Aug 2020	HIT-&RUN HORROR Girl, 11, killed in hit-and-run crash while crossing road with friend in Bury	Positive	N/A	1069	48
The Mirror	22 Aug 2020	Miracle transplant patient whose organs were ‘kept alive in a box’ set for dream wedding	Positive	N/A	906	81
The Mirror	25 Aug 2020	Brave Thalia, 5, dies waiting for heart transplant as heartbroken family pays tribute	Neutral	Neutral	906	81
Bishops Stortford Independent	29 Aug 2020	Bishop Stortford man, Stephen Cooper, the 100th multi-organ patient at Addenbroke’s, salutes the surgeons and donor’s family who gave him a new life	Positive	Positive	1	1

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
ITV news	1 Sept 2020	The journey of organ donation: “Your son’s kidney saved my life”	Positive	Neutral	924	120
On the Wight	4 Sept 2020	Letter: Organ donation is now opt-out: let family know your wishes	Positive	Positive	2	6
Island Echo	7 Sept 2020	Local transplant recipient calls for families to talk about organ donation	Positive	Neutral	9	4
Northamptonshire Telegraph	7 Sept 2020	Kettering couple meet the boy who was given the gift of life by their daughter	Positive	Positive	7	11
Daily Express	8 Sept 2020	How to opt-out of being an organ donor	Positive	Neutral	1351	50
Daily Mail	8 Sept 2020	GP reveals how she offered to give her desperately ill baby son half of her own liver to save his life after struggle to find an organ donor – as she urges BAME community not to ‘opt-out’ of register	Positive	Positive	3256	117
Northampton Chronicle and Echo	8 Sept 2020	Northampton’s oldest transplant patient urges public to sign organ donation register after surviving for 30 years with new heart	Positive	Positive	8	11
The Metro	8 Sept 2020	Family camps by bedside of girl, 1, in hospital waiting for a heart transplant	Positive	Neutral	328	40
Evening Standard	9 Sept 2020	Organ transplant waiting list jumps to five-year high due to pandemic, new NHS figures show	Positive	Positive	282	64
Asian Image	10 Sept 2020	New website aims to give Muslims the facts about organ donation	Positive	Positive	2	7
The Mirror	11 Sept 2020	Organ transplants among BAME patients at record highs after Mirror campaign	Positive	Positive	906	81
The Telegraph	11 Sept 2020	My scars aren’t ‘sexual’ – so why did Instagram remove my pictures?	Positive	N/A	609	107
The Times	11 Sept 2020	Minorities more likely to opt-out of organ donation	Positive	Neutral	357	117
Yorkshire Post	11 Sept 2020	Organ Donation Week – meet the Yorkshire mum whose husband saved three lives	Positive	Neutral	16	28

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
The Metro	13 Sept 2020	Muslims encouraged to learn more about organ donation to help lack of donors for BAME people	Positive	Neutral	328	40
Plant based news	14 Sept 2020	Vegan TikTok star blasted for refusing to donate organs to meat eaters	Neutral	N/A	5	95
The Mirror	27 Sept 2020	Over half of pupils back organ donation after being inspired by Mirror campaign	Positive	Positive	906	81
Daily Star	11 Oct 2020	Fiancée of footballer, 25, who died in pub row gives birth to his baby daughter	Positive	N/A	348	16
Somerset Live	16 Oct 2020	29 Somerset people on the organ transplant waiting list have died in the past five years	Positive	N/A	16	11
The Mirror	18 Oct 2020	Couple who lost baby son after he received a new heart in favour of organ donation	Positive	Positive	906	81
The Mirror	21 Oct 2020	Mum, 26, desperate for life-saving transplant to see her girl, 5, grow up	Positive	Positive	906	81
Worcester News	3 Nov 2020	Organ Donation Memorial gathering at Royal Worcestershire	Positive	N/A	10	7
Exmouth Journal	7 Nov 2020	Socially distanced photo opportunity as ‘opt-in’ organ donation law comes into force	Positive	Positive	1	3
Daily Express	9 Nov 2020	New drive for donors as demand for organs reaches five year high	Positive	Positive	1351	50
Nursing Times	9 Nov 2020	‘2020 is the year of talking about organ donation’	Positive	Positive	13	79
BBC news	20 Nov 2020	Max and Keira’s law: mum’s ‘one comfort’ after son’s organ donation	Positive	Positive	7781	152
Birmingham Mail	20 Nov 2020	Nurse’s pride as son, 18, saves three lives after law change	Positive	Positive	141	22
The Mirror	20 Nov 2020	Heartbroken mum donates tragic son’s organs in historic first to save three lives	Positive	Positive	906	81
The Telegraph	23 Nov 2020	‘My life was on old’: how patients awaiting transplants were hit by the closure of units	Positive	N/A	609	107
The Mirror	30 Nov 2020	Boy, 9, with three hearts says he can’t wait for Christmas after second transplant	Positive	Positive	906	81

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
Eastbourne Herald	4 Dec 2020	Organ donation gives people the gift of life and their freedom back	Positive	Positive	5	9
Yorkshire Evening Post	4 Dec 2020	Man born with one kidney is campaigning to keep organ donor register open during pandemic	Positive	Positive	20	38
Daily Echo	10 Dec 2020	Bournemouth family issues organ donation appeal to save son's life	Positive	N/A	31	6
The Mirror	10 Dec 2020	"I almost died last Christmas – now I'll celebrate this one twice with two of everything"	Positive	N/A	906	81
The Sun	21 Dec 2020	WORST NIGHTMARE Mum whose two children need life-saving kidney transplants is a match for both – but can only donate one	Positive	N/A	1069	48
The Telegraph	24 Dec 2020	Ten ways to give to charity without spending a penny	Positive	N/A	609	107
The Mirror	25 Dec 2020	Girl asks Santa for new heart for sister, 4, who has already lost half her foot	Positive	Positive	906	81
The Metro	26 Dec 2020	Dad who needs transplant to save his life urges black and Asian people to be organ donors	Positive	Neutral	328	40
The Mirror	26 Dec 2020	Woman whose life depended on double lung transplant and new heart gets Christmas miracle	Positive	Positive	906	81
The Metro	31 Dec 2020	Woman finally receives two new organs after first seven attempts went wrong at the last minute	Positive	Positive	328	40
Daily Mail	2 Jan 2021	How many like Natasha Tiwari have to die before Britain tackles its black and Asian organ donor crisis? Singer loses her fight for life five years after pleading for a new kidney	Positive	Positive	3256	117
BBC news	7 Jan 2021	Organ donor mum wishes she could help her children in need of kidneys	Positive	N/A	7781	152
The Telegraph	13 Jan 2021	Organs ready for donation discarded as transplant centres close due to pandemic	Positive	N/A	609	107
The Mirror	18 Jan 2021	Little Evie, 8, gets life-saving transplant after only match in the world drops out	Positive	Positive	906	81

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
The Mirror	20 Jan 2021	Schoolgirl saved by heart transplant gets another 'perfect gift' from donor's parents	Positive	Positive	906	81
The Times	23 Jan 2021	Meet the people changing the world of organ transplants	Positive	Positive	357	117
Daily Mail	26 Jan 2021	Teenager who received a life-saving heart transplant reveals her donor's grieving family have sent her a ring belonging to their 19-year-old daughter	Positive	N/A	3256	117
The Mirror	30 Jan 2021	My son was beaten to death at a bus stop – now I listen to his heart beat in a stranger	Positive	N/A	906	81
Daily Star	7 Feb 2021	Heartbreak as teenager, 19, dies in 'freak accident' after going to bed with a headache	Neutral	N/A	348	16
Daily Express	10 Feb 2021	Mother's hope that daughter, 17, who donated organs, will inspire others	Positive	Positive	1351	50
Eastern Eye	10 Feb 2021	Donor family joins NHS campaign on organ donation	Positive	Positive	3	45
Telegraph and Argus	10 Feb 2021	The gift of life: Bradford backs campaign urging people to talk about organ donation	Positive	Positive	40	9
The Mirror	10 Feb 2021	Mum's sudden decision weeks before her death saved four people's lives	Positive	Positive	906	81
The Cumberland News	11 Feb 2021	NHS organ donor campaign is launched to get people talking	Positive	Neutral	15	6
Positive news	12 Feb 2021	Life-saving small talk: the hairdressers trained to chat about organ donation	Positive	Neutral	2	102
Cambridge Network	15 Feb 2021	Plea to leave no uncertainty on organ donation	Positive	Positive	1	3
The Metro	18 Feb 2021	Scientists regrow and repair liver from lab-grown cells in world first	Neutral	N/A	328	40
The Telegraph	18 Feb 2021	Lab-grown tissue repairs human organ for first time, Cambridge University scientists reveal	Neutral	N/A	609	107
BBC news	21 Feb 2021	Child heart transplants: record year for new-style operations	Positive	N/A	7781	152

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
Daily Mail	21 Feb 2021	'World first' as NHS doctors transplant hearts in children using organs brought back to life by ground-breaking machine that replicates conditions inside human body	Positive	N/A	3256	117
Evening Standard	21 Feb 2021	Children given reanimated hearts by NHS in world first	Positive	N/A	282	64
iNews	21 Feb 2021	UK teens given reanimated hearts in world-first transplants	Positive	N/A	119	57
The Guardian	21 Feb 2021	UK doctors pioneer use of 'heart in a box' transplant technique in children	Positive	N/A	3046	148
The Metro	21 Feb 2021	Children receive hearts 'brought back to life' by NHS transplant machine	Positive	N/A	328	40
The Mirror	21 Feb 2021	World first as NHS saves six children by making 'dead' donor hearts beat again	Positive	N/A	906	81
The Telegraph	21 Feb 2021	Hearts brought back to life by ground-breaking machine given to children in world first	Positive	N/A	609	107
Evening Standard	24 Feb 2021	Woman dies after receiving 'double lung transplant from donor with Covid-19', report finds	Negative	N/A	282	64
The Mirror	24 Feb 2021	Max Johnson says "I did not think I would make it" in moving film about transplant	Positive	Positive	906	81
Shropshire Star	26 Feb 2021	Family whose son died in a car accident back organ donation campaign	Positive	N/A	16	13
The Mirror	8 March 2021	"I'd given up all hope and I knew I was going to die – then a phone call changed my life"	Positive	N/A	906	81
St Helen's Star	10 March 2021	Violet-Grace posthumously recognised for organ donation which saved two lives	Positive	N/A	5	7
Daily Mail	11 March 2021	Snapchat partners with NHSBT to launch a body-tracking lens that lets you view your ORGANS through augmented reality	Positive	N/A	3256	117
Yorkshire Live	11 March 2021	Harrogate man 'forever grateful' to donor who saved his life	Neutral	N/A	81	20
Campaign	12 March 2021	NHS partners Snapchat to drive up organ donation awareness	Positive	N/A	7	7

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
Hampshire Chronicle	12 March 2021	Hampshire Hospitals backs organ donation campaign	Positive	Positive	5	2
Gazette and Herald	13 March 2021	Organ donation campaign launch	Neutral	N/A	4	1
Nursing Times	15 March 2021	Nurse recognised for work on organ donation law change during COVID-19	Positive	Positive	13	79
Jewish Chronicle	21 March 2021	Jewish doctors launch survey to raise awareness of organ donation issues	Positive	Neutral	5	1
The Mirror	30 March 2021	Teen declared dead ‘miraculously’ starts blinking just before his organs were donated	Negative	N/A	906	81
The Mirror	4 April 2021	Transplant tots are hidden victims of pandemic as they desperately await life-saving ops	Positive	N/A	906	81
Daily Star	6 April 2021	Footballer Jordan Sinnott ‘saves seven lives’ with organ donations months after tragic death	Positive	N/A	348	16
The Metro	11 April 2021	My sister died in front of me but there was nothing I could do	Positive	N/A	328	30
The Mirror	22 April 2021	Loving lad hit by uninsured driver saves three lives after he’s robbed of his own	Positive	N/A	906	81
The Mirror	9 May 2021	“Mum’s dying gift means she lives on through my amazing new friends”	Positive	Neutral	906	81
The Sun	13 May 2021	‘PERFECT SON’ Dad of Jordan Banks, 9, killed by lightning, says he had the ‘biggest heart’ and his donated organs helped save 3 kids	Positive	N/A	1069	48
Daily Express	14 May 2021	Boy killed by lightning saves three children by donating organs	Positive	N/A	1351	50
Daily Star	14 May 2021	Organs of boy killed in lightning strike have saved three other children’s lives	Positive	N/A	348	16
Evening Standard	14 May 2021	Jordan Banks: Boy who died when he was ‘struck by lightning’ to save three others after organ donation	Positive	N/A	282	64
The Metro	14 May 2021	Family of boy, 9, killed by lightning donate his organs to save three other kids	Positive	N/A	328	40

Publication	Date of publication	Headline	Organ donation tone	Law change tone	Viewer score	Engagement score
Sky news	14 May 2021	Jordan Banks: Boy who died after being 'struck by lightning' was organ donor and will save three lives, dad reveals	Positive	N/A	538	413
The Sun	17 May 2021	A TRAGIC nine-year-old boy died in hospital an hour after he was struck by lightning as he played football, an inquest heard today	Positive	N/A	1069	48
The Mirror	19 May 2021	Athlete saved by mystery heart donor after being on life support for nine days	Positive	Positive	906	81
BBC news	20 May 2021	296 people donate organs in first year of new consent law	Positive	Positive	7781	152
The Metro	20 May 2021	Hospital carries out three organ transplants in just 17 hours	Positive	Positive	328	40
The Mirror	20 May 2021	Max and Keira's 300 lifesavers who gave organs since donation law change one year ago	Positive	Positive	906	81

Full list of comments on media articles and tone

Publication	Date	Headline	Organ donation tone				Law change tone			
			Article	Positive	Neutral	Negative	Article	Positive	Neutral	Negative
Daily Mail	18 July 2019	People dying fatter and older is 'reducing the number of usable donated organs' as NHS reveals one in SIX body parts now get rejected by doctors	Positive	3	0	20	Positive	0	0	8
Daily Mail	20 Dec 2019	Moving TV advert encourages families to talk about organ donation this Christmas before the law changes to make EVERY adult a donor next year	Positive	14	1	12	Positive	11	1	23
Daily Mail	22 Dec 2019	World's first human HEAD transplant 'could happen in next ten years' due to advances in technology, says ex-NHS neurosurgeon and robotics expert	Negative	4	0	11	N/A	0	0	0

Publication	Date	Headline	Organ donation tone				Law change tone			
			Article	Positive	Neutral	Negative	Article	Positive	Neutral	Negative
Daily Mail	17 Feb 2020	With a new opt-out donation law weeks away... DR MARTIN SCURR and DR MAX PEMBERTON question if the NHS should have the right to take our organs?	Positive	20	0	13	Neutral	15	0	32
Daily Mail	31 March 2020	Every organ donor is being tested for coronavirus as NHS rejects transplants from infected patients to minimise risk to recipients	Neutral	3	0	1	N/A	0	0	2
Daily Mail	3 April 2020	NHS bosses admit ALL organ transplants could be scrapped 'within days' over fears patients will catch coronavirus as outbreak overwhelms intensive care units	Positive	7	0	3	Neutral	0	1	1
Daily Mail	13 April 2020	Nursery worker, 21, who was waiting for life-saving liver operation dies after being taken off transplant list when she tested positive for coronavirus in hospital	Positive	2	0	0	N/A	0	0	0
The Metro	20 May 2020	From today every adult in England is automatically an organ donor	Positive	19	4	8	Positive	18	1	24
The Metro	20 May 2020	The new organ donation law will save lives, but it's pointless if your family don't know your wishes	Positive	0	0	1	Positive	0	0	1
The Times	20 May 2020	Every adult automatically an organ donor by law	Positive	10	0	1	Positive	36	0	46
Daily Mail	21 May 2020	I admit it, I feel queasy about the State having a claim on my organs... unless I choose to opt-out, writes Melanie McDonagh	Positive	26	0	11	Negative	15	0	46
Daily Mail	6 June 2020	We're all organ donors now – unless we opt-out. Katie Hind's moving story about her father's incurable disease and how a new heart saved his life shows why the new law is so essential	Positive	3	0	1	Positive	3	0	5

Publication	Date	Headline	Organ donation tone				Law change tone			
			Article	Positive	Neutral	Negative	Article	Positive	Neutral	Negative
On the Wight	4 Sept 2020	Letter: Organ donation is now opt-out: let family know your wishes	Positive	6	0	4	Positive	3	0	6
Daily Mail	8 Sept 2020	GP reveals how she offered to give her desperately ill baby son half of her own liver to save his life after struggle to find an organ donor – as she urges BAME community not to ‘opt-out’ of register	Positive	2	4	1	Positive	0	0	1
The Times	11 Sept 2020	Minorities more likely to opt-out of organ donation	Positive	3	0	1	Neutral	1	0	2
The Mirror	27 Sept 2020	Over half of pupils back organ donation after being inspired by Mirror campaign	Positive	1	0	0	Positive	1	0	1
The Mirror	20 Nov 2020	Heartbroken mum donates tragic son’s organs in historic first to save three lives	Positive	6	0	0	Positive	1	0	1
The Mirror	18 Jan 2021	Little Evie, 8, gets life-saving transplant after only match in the world drops out	Positive	3	0	0	Positive	1	0	0
The Times	23 Jan 2021	Meet the people changing the world of organ transplants	Positive	12	0	0	Positive	2	0	0
Daily Mail	21 Feb 2021	World first as NHS saves six children by making ‘dead’ donor hearts beat again	Positive	43	1	20	N/A	0	0	8
The Mirror	20 May 2021	Max and Keira’s 300 lifesavers who gave organs since donation law change one year ago	Positive	2	0	2	Positive	2	0	2

3.3: List of codes

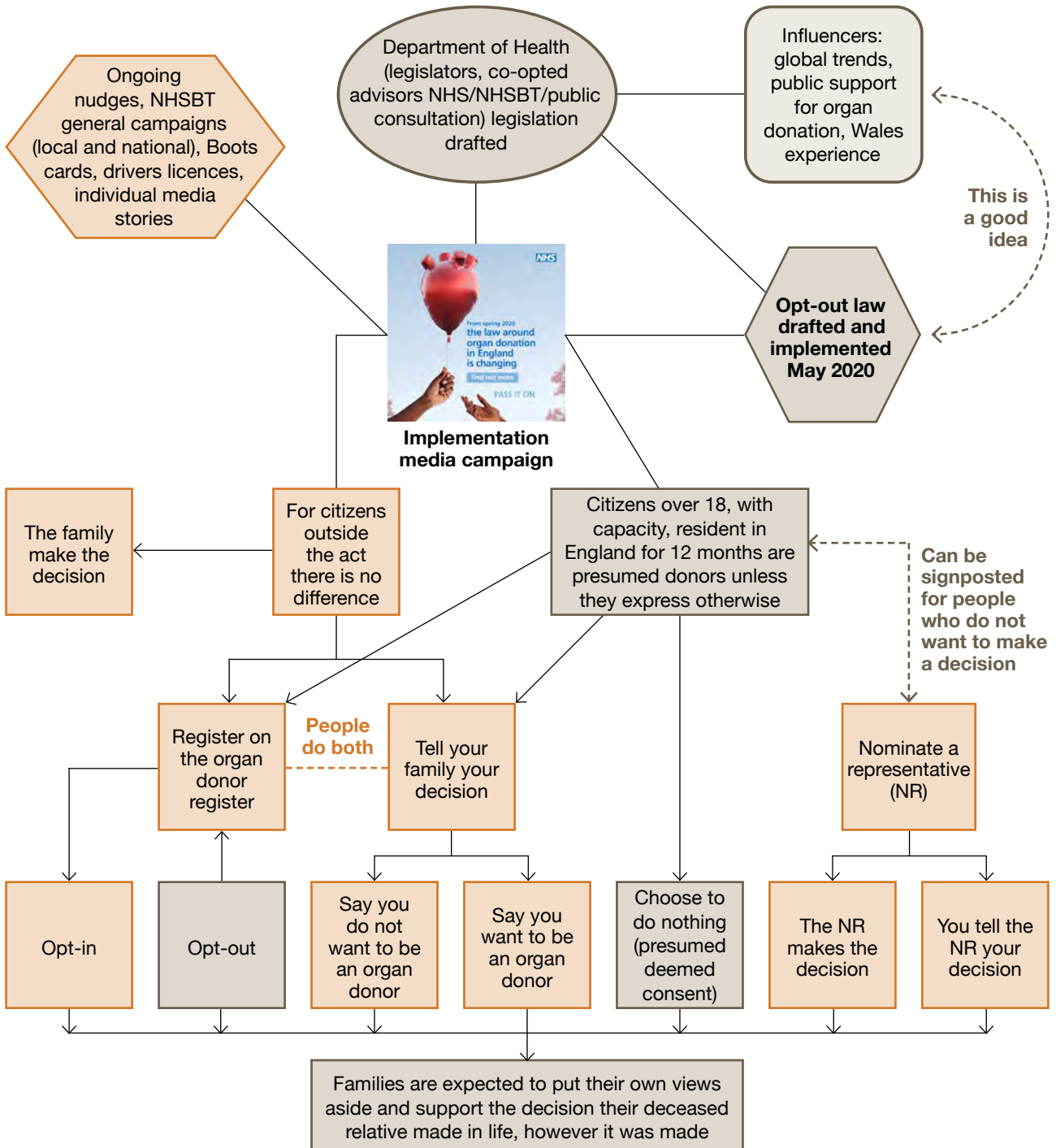
children	older people
desperate	obesity
heart breaking	fewer trauma incidents
tragedy	undemocratic
rare condition	mandatory donation
miracle	definition of death
hope	euthanasia
pride	organ transplant causing death
comfort	selling organs
memory	organ farming
hero	harvesting
culture	transplants stopped
taboo	fall in transplants
religion	COVID-19 pandemic
misinformation	role of healthcare workers
social media	lack of funding
reciprocity	serious incidents
trust	breakthrough
racism	experimental
autonomy	animal organs
individual rights	unnatural
control	science fiction
authoritarian	Frankenstein
dystopian	playing god
HIV	contamination
drug users	COVID-19

3.4: Thematic map illustration




Appendix 4: Supplementary files – Chapter 6

Supplementary file 1: An overview of the implementation of the ‘soft’ opt-out into the previous opt-in system in England




Supplementary file 2: Interface of UK Organ Donor Register




Register to donate
Choose this option if you would like to donate some or all of your organs and tissue.

DONATE
Register a decision to donate




Register not to donate
Choose this option to record a decision not to donate your organs and tissue.

DO NOT DONATE
Register a decision not to donate (opt out)



Amend your registration
Choose this option to update your existing registration or donation preferences.

AMEND
Amend your registration



Withdraw your registration
Choose this option to remove your existing registration from the register. This will leave no recorded organ donation decision for you.

WITHDRAW
Withdraw your registration

More options

Don't want to make a decision yourself?

If you don't want to make an organ donation decision yourself, or if you have specific instructions, you can choose someone to make that decision for you.

» [Nominate a representative](#)

Check your registration

To see if you have already recorded a decision on the NHS Organ Donor Register or to check that your information and preferences in the register are up to date please get in touch.

» [Contact us](#)

Organ donation law where you live

Organ donation law varies across different countries in the United Kingdom. Find out about the law where you are.

» [See the law where you are](#)

Talk to your loved ones

Whatever your decision, it's really important that you let those closest to you know.

» [Find out why](#)

www.organdonation.nhs.uk/register-your-decision/donate

Additional information

Ethnicity

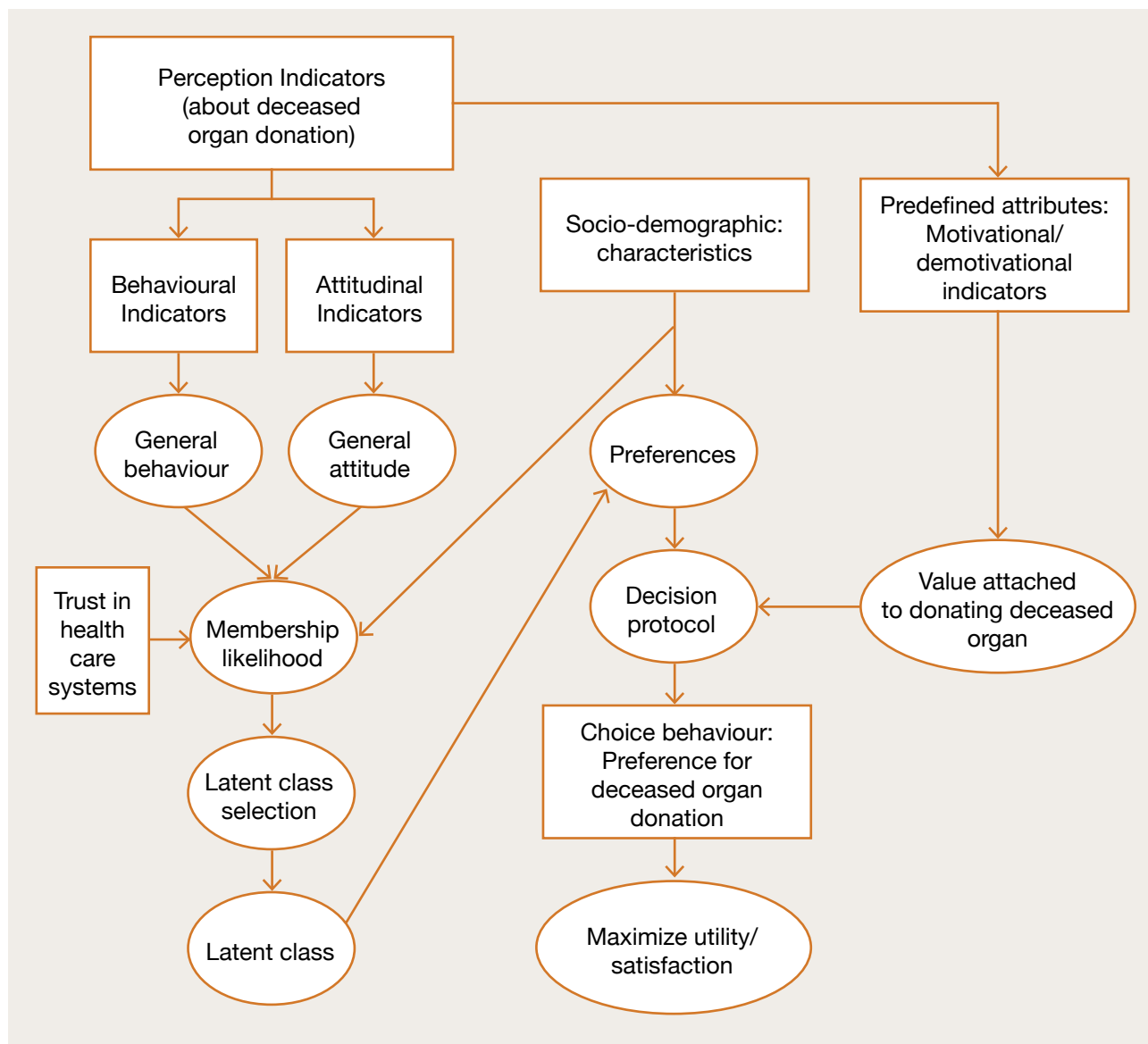
- ✓ Please select
- Asian or Asian British - Indian
- Asian or Asian British - Pakistani
- Asian or Asian British - Bangladeshi
- Asian or Asian British - Chinese
- Asian or Asian British - Other
- Gypsy or Irish Traveller
- Arab
- Black or Black British - Caribbean
- Black or Black British - African
- Black or Black British - Other
- Other
- White - British, English, Northern Irish, Scottish or Welsh
- White - Irish
- White - Other
- Mixed - White and Black Caribbean
- Mixed - White and Black African
- Mixed - White and Asian
- Mixed - Other

Religion

- ✓ Please select
- No religion
- Christian - Protestant
- Christian - Catholic
- Christian - Other
- Buddhist
- Hindu
- Jewish
- Muslim
- Sikh
- Other
- Not stated

www.organdonation.nhs.uk/register-your-decision

Supplementary file 3: Analytical and interpretive framework for preferences towards deceased organ donation, latent class membership and population subgroups



Factors in rectangles represent the variables that inform individual’s decision-making process about donating deceased organs that are observed by researchers, and those in ellipses are latent/unobservable by researchers. All these factors affect the value/satisfaction an individual attaches to becoming a deceased organ donor. General perceptions about deceased organ donation affect the general behaviour, attitude and the probability of individuals belonging to a specific deceased organ donor subgroup. The heterogeneous deceased donor subgroups are assumed to be formed, among others, by individual differing perceptions, behaviour, and attitudes towards deceased organ donation. The socio-demographic characteristics of individuals such as age, (health) educational level, ethnicity, religion, and life experiences are assumed to also affect the probability of an individual belonging to a given deceased donor subgroup.

The membership likelihood function provides the foundation for the formation of heterogeneous deceased donor subgroups. Though unobserved and statistically determined, it indicates the probability of individuals belonging to a given deceased donor subgroup.

Supplementary table 1: Sample distribution of respondents of the attitudinal tracker survey data per wave

Wave	Excluded sample	Sample used
Wave 1	12	1,488
Wave 2	13	1,484
Wave 3	4	997
Wave 4	10	1,489
Wave 5	10	1,590
Wave 6	37	1,821
Wave 7	35	1,767
Wave 8	21	1,775
Wave 9	17	1,781
Wave 10	29	2037
Wave 11	23	2,145
Wave 12	43	2,151

Source: NHSBT Organ Donation Attitudinal Tracker survey data (2015-2022).

Supplementary table 2: Sample Distribution of respondents of the Law Change data per survey wave

Wave	Sample
Wave 1	1,261
Wave 2	1,262
Wave 3	1,278
Wave 4	1,277
Wave 5	1,299
Wave 6	1,280
Wave 7	1,231
Wave 8	1,274
Wave 9	1,278
Wave 10	1,275
Wave 11	1,005
Wave 12	1,270
Wave 13	1,233
Wave14	1,277
Wave 15	1,282
Wave 16	1,229
Wave 17	2,502
Wave 18	1,273
Wave 19	1,282
Wave 20	1,277
Wave 21	1,280
Wave 22	1,275
Wave 23	1,274
Wave 24	1,280
Wave 25	1,269
Wave 26	1,276
Wave 27	1,272
Wave 28	1,275
Wave 29	1,270
Wave 30	2,551
Wave 31	2,513
Wave 32	2,556

Source: NHSBT complementary survey to monitor the awareness of the law change (35 waves (2018-2022))

Supplementary file 4: FORM I. Topic Guide/public interviews

Evaluation of the Organ Donation (Deemed Consent) Act, 2019

Organ Donation Conversations – Member of the public interview topic guide

Interviewees to include the general public including people who: support organ donation, do not support organ donation, support the changes in law, do not support the changes in law, people not associated with any organisations who promote organ donation as routine practice (e.g. health charities) people from BAME, minority and underrepresented groups and faith groups.

Introductions

- Researcher and overview of project
- Check time available for interview
- Consent
- Ensure participant knows we are there to listen to them and their views, there are no right or wrong answers or judgements.

General views on organ donation

Unpack personal views on organ donation (sample questions):

- Where did your views come from?
- Have you changed your views on organ donation?
- Have you any prior experiences of organ donation?
- Are you registered on the ODR?

Views and behaviours on the changes to consent for organ donation

Unpack views on the changes to consent to organ donation and any changes in behaviour (sample questions):

- How do you feel about the changes to consent for organ donation?
- Why do you think they changed the law?
- When and where did you first hear about them?
- Can you explain to me what the changes are?
- What difference would you like to see the changes make?
- What did you do when you heard about the changes e.g. register on the ODR talk about it, find out more etc? **If registered on the ODR find out if they indicated their religion. If had a conversion unpack how this conversation went, when and with whom etc.**
- Did anybody else in your family, friends, colleagues do anything?
- Anything else you would like to say about the changes to consent for organ donation?

Media campaign

- Unpack influence of the media campaign, understanding of key messages and any recommendations for future campaigns (sample questions). *Show interviewee samples of the implementation media campaign. Are you specifically aware of the BAME campaign? (Please give examples).*
- Do you remember seeing any of these materials?
- What do you think about it?
- What did you do when you first saw it?
- What recommendations would you make for future campaigns?
- *'Engaging with BAME and other minority and underrepresented groups is a priority for the various organisations involved in organ donation to make it easier for people to make their organ donation decision while they are alive, and therefore easier for the family after we die as they know what we wanted to happen'* what would you recommend to better engage with these groups to achieve this?
- *The Opt-Out figure is not high (around 3%) yet around 80% of these are from BAME and faith backgrounds we do not understand why that is happening. What do think about this, does it surprise you, why do you think this is the case?*

Impact of COVID-19

'The changes in law were passed in 2019. Government and various organisations involved in organ donation were part way through an advertising campaign when the COVID-19 pandemic started. The remainder of the planned advertising was cancelled.' Unpack interviewees views on any influences of COVID-19 on implementation of the change in law and in the future (sample questions):

- Do you think the COVID-19 pandemic influenced the implementation of the changes in law?
- Do you think the COVID-19 pandemic has influenced peoples' views and behaviours on organ donation?
- Do you think the COVID-19 pandemic will have any influence on the numbers of people who consent to organ donation in the future?

The BAME population has been disproportionately affected by COVID-19.

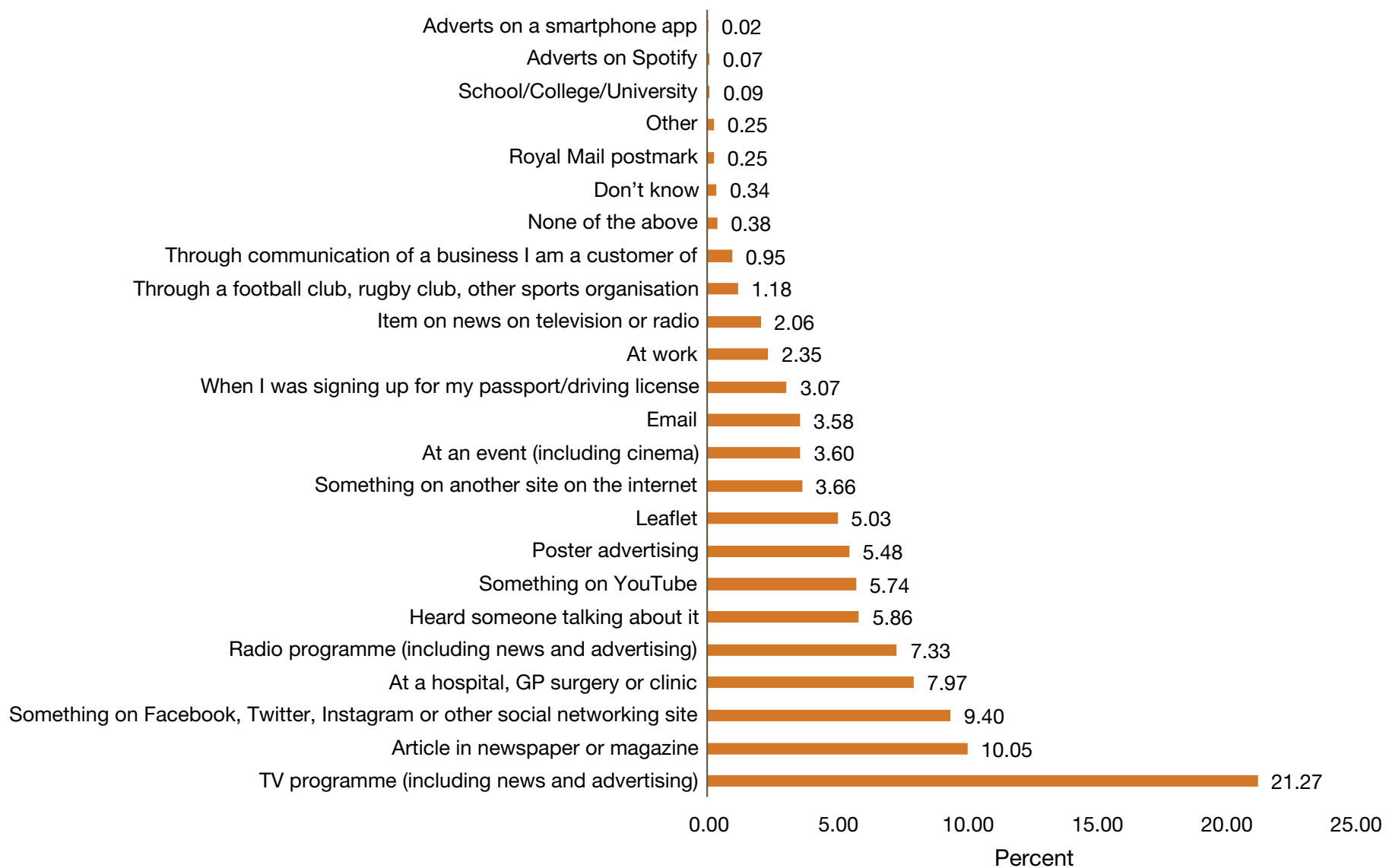
Do you think this will (or has had) any impacts on the attitude of BAME population to organ donation (unpack positive and negative impacts).

Sample probes and prompts

- You mentioned...can you tell me more about...?
- That's interesting, can you tell me more about...?
- Why do you think that is?
- How has that been for you?
- What do you think about....?
- Why/why not?
- Can you tell me a bit more about that?
- Anything else you would like to say about that?

List of religions as listed on the organ donor register								
Purposeful sample framework	Christian – Protestant	Christian – Catholic	Christian – Other	Buddhist	Muslim	Sikh	Hindu	Jewish
Ethnicity as list on the ODR								
Asian or Asian British – Indian								
Asian or Asian British – Pakistani								
Asian or Asian British – Bangladeshi								
Asian or Asian British – Chinese								
Asian or Asian British – Other								
Gypsy or Irish Traveller								
Arab								
Black or Black British – Caribbean								
Black or Black British – African								
Black or Black British – Other								
Other								
White – British, English, Northern Irish, Scottish, or Welsh								
White – Irish								
White – Other								
Mixed – White and Black Caribbean								
Mixed – White and Black African								
Mixed – White and Asian								
Mixed – Other								
Other considerations Do they support organ donation/law change? Did they know about the changes? RED priority group								

Supplementary file 5: Sources of information about general organ donation publicity



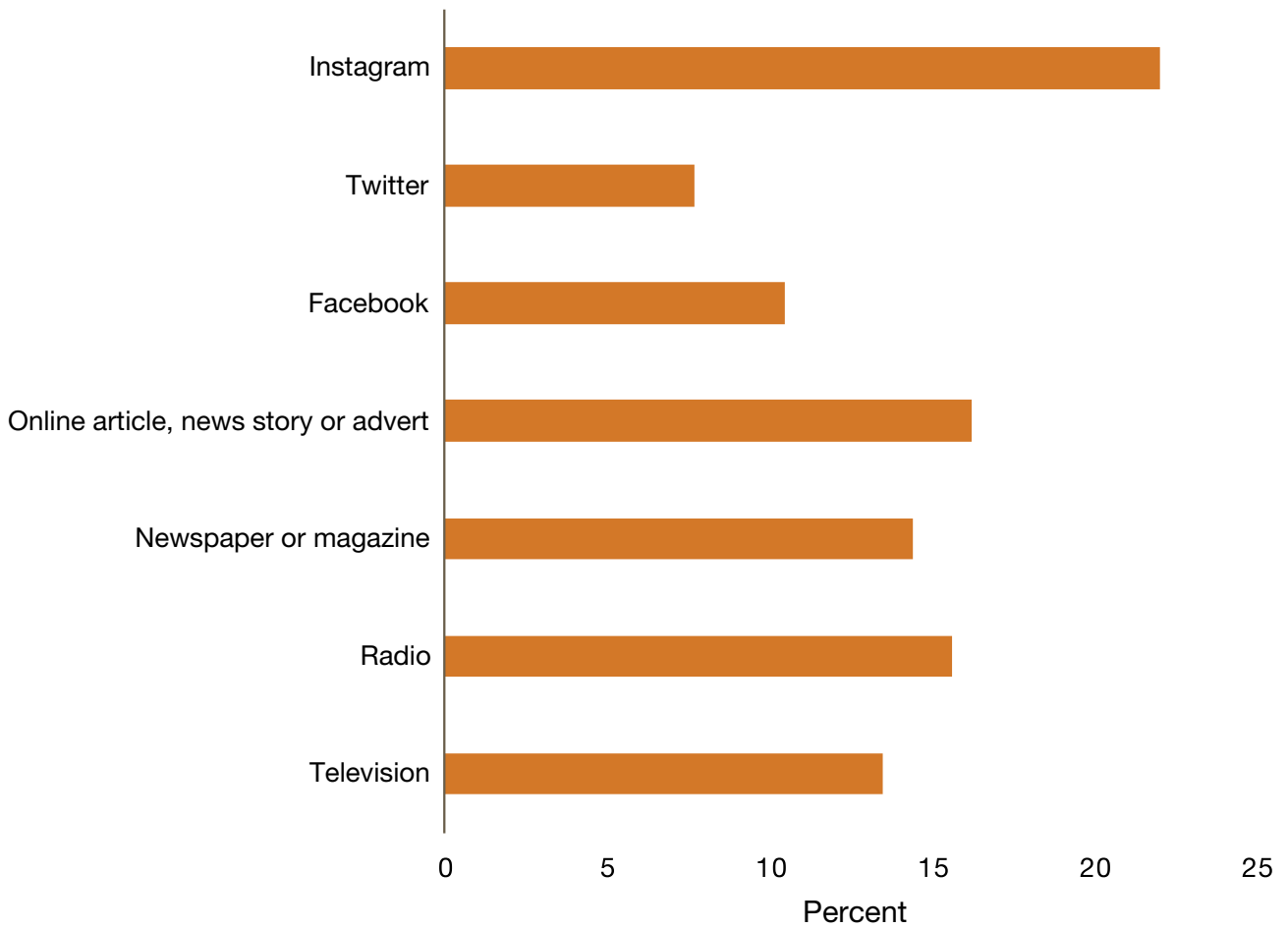
Source: NHSBT Organ Donation Attitudinal Tracker survey data (2015-2022).

Supplementary table 3: Public awareness of the law change

Wave	Yes	No	Don't know
Wave 1	52.8	39.1	8.1
Wave 2	55.3	37.5	7.1
Wave 3	36.3	55.1	8.6
Wave 4	38.4	53.4	8.2
Wave 5	58.4	35.7	5.9
Wave 6	59.2	34.2	6.6
Wave 7	51.1	40.8	8.1
Wave 8	55.7	37.1	7.2
Wave 9	53.8	38.6	7.6
Wave 10	55.2	39.3	5.5
Wave 11	64.6	31.2	4.2
Wave 12	59.5	34.7	5.7
Wave 13	60.7	34.7	4.6
Wave14	55.6	37.0	7.4
Wave 15	69.1	26.2	4.7
Wave 16	67.6	27.5	5.0
Wave 18	65.8	27.6	6.6
Wave 19	59.1	33.3	7.6
Wave 20	64.7	28.5	6.8
Wave 21	58.7	33.0	8.3
Wave 22	62.8	30.2	7.0
Wave 23	58.3	35.1	6.6
Wave 24	58.9	34.0	7.1
Wave 25	60.4	31.8	7.8
Wave 26	61.1	31.9	7.0
Wave 27	61.8	29.8	8.4
Wave 28	64.4	29.0	6.6
Wave 29	64.3	29.2	6.5
Wave 30	64.2	28.5	7.4
Wave 32	56.4	37.2	6.5
Wave 34	61.1	31.9	7.0
Wave 35	61.8	29.8	8.4
All	58.3	34.7	7.0

Source: NHSBT complementary survey to monitor the awareness of the law change (35 waves – 2018-2022), average sample 1,420 with 5% ethnic minority per survey).

Supplementary file 6: Sources of information about the law change



Source: NHSBT complementary survey to monitor the awareness of the law change (35 waves – 2018-2022).

Supplementary table 4: Test results for optimal number of population segments/ subgroups by survey wave

Classes	Log-likelihood	Number of parameters	AIC	CAIC	BIC
Wave 1					
2	-2474.163	3	4954.326	4973.241	4970.241
3	-2468.451	5	4946.902	4978.428	4973.428
4	-2467.544	7	4949.089	4993.225	4986.225
5	-2467.472	9	4952.944	5009.691	5000.691
6	-2467.467	11	4956.933	5026.29	5015.29
Wave 2					
2	-2474.163	3	4954.326	4973.241	4970.241
3	-2468.451	5	4946.902	4978.428	4973.428
4	-2467.544	7	4949.089	4993.225	4986.225
5	-2467.472	9	4952.944	5009.691	5000.691
6	-2467.467	11	4956.933	5026.29	5015.29
Wave 3					
2	-1636.86	3	3279.721	3297.435	3294.435
3	-1636.759	5	3283.519	3313.042	3308.042
4	-1636.499	7	3286.999	3328.332	3321.332
5	-1636.395	9	3290.79	3343.933	3334.933
6	-1634.864	11	3291.727	3356.68	3345.68
Wave 4					
2	-2452.222	3	4910.443	4929.361	4926.361
3	-2450.434	5	4910.869	4942.398	4937.398
4	-2450.308	7	4914.615	4958.756	4951.756
5	-2450.185	9	4918.37	4975.123	4966.123
6	-2450.17	11	4922.34	4991.704	4980.704
Wave 5					
2	-2585.149	3	5176.299	5195.413	5192.413
3	-2544.57	5	5099.14	5130.998	5125.998
4	-2544.522	7	5103.044	5147.644	5140.644
5	-2544.523	9	5107.047	5164.39	5155.39
6	-2544.516	11	5111.031	5181.117	5170.117
Wave 6					
2	-2966.223	3	5938.447	5957.968	5954.968
3	-2950.774	5	5911.548	5944.084	5939.084
4	-2950.736	7	5915.471	5961.021	5954.021
5	-2950.721	9	5919.442	5978.007	5969.007
6	-2950.692	11	5923.383	5994.962	5983.962

Classes	Log-likelihood	Number of parameters	AIC	CAIC	BIC
Wave 7					
2	-2885.521	3	5777.042	5796.473	5793.473
3	-2885.388	5	5780.776	5813.161	5808.161
4	-2885.353	7	5784.707	5830.046	5823.046
5	-2885.343	9	5788.685	5846.978	5837.978
6	-2885.338	11	5792.676	5863.924	5852.924
Wave 8					
2	-2452.222	3	4910.443	4929.361	4926.361
3	-2450.434	5	4910.869	4942.398	4937.398
4	-2450.308	7	4914.615	4958.756	4951.756
5	-2450.185	9	4918.37	4975.123	4966.123
6	-2450.17	11	4922.34	4991.704	4980.704
Wave 9					
2	-2885.521	3	5777.042	5796.473	5793.473
3	-2885.388	5	5780.776	5813.161	5808.161
4	-2885.353	7	5784.707	5830.046	5823.046
5	-2885.343	9	5788.685	5846.978	5837.978
6	-2885.338	11	5792.676	5863.924	5852.924
Wave 11					
2	-2885.521	3	5777.042	5796.473	5793.473
3	-2885.388	5	5780.776	5813.161	5808.161
4	-2885.353	7	5784.707	5830.046	5823.046
5	-2885.343	9	5788.685	5846.978	5837.978
6	-2885.338	11	5792.676	5863.924	5852.924
Wave 12					
2	-2452.222	3	4910.443	4929.361	4926.361
3	-2450.434	5	4910.869	4942.398	4937.398
4	-2450.308	7	4914.615	4958.756	4951.756
5	-2450.185	9	4918.37	4975.123	4966.123
6	-2450.17	11	4922.34	4991.704	4980.704

Source: NHSBT Organ Donation Attitudinal Tracker survey data (2015-2022).

Supplementary table 5: Characteristics of respondents belonging to the four subgroups of deceased organ donation(row percentage)

Characteristics	Sample (n=2180)	Supportive donors	Sensitive donors	Ambivalent donors	Non donors
Share of subgroups in population		0.238	0.215	0.456	0.091
Average Age (years)***	2180	52	42	40	39
Willingness to donate***					
I would definitely donate all of my organs if possible	752	76.6	0.9	21.5	0.9
I would definitely donate some of my organs if possible	317	0.6	4.1	91.8	3.5
I would consider donating all of my organs	283	0.0	16.6	71.7	11.7
I would consider donating some of my organs	272	0.0	18.4	65.8	15.8
I don't know if I would donate my organs	408	0.0	63.0	18.4	18.6
I definitely wouldn't donate my organs	148	0.0	64.2	17.6	18.2
Support of organ donation***					
I strongly support organ donation in principle	899	57.0	1.2	39.3	2.6
I support organ donation in principle	690	9.6	6.5	76.4	7.5
I neither support nor oppose organ donation in principle	366	0.0	71.6	6.0	22.4
I oppose organ donation in principle	61	0.0	65.6	14.8	19.7
I strongly oppose organ donation in principle	72	0.0	56.9	31.9	11.1
No response	92	0.0	76.1	2.2	21.7
Aware of OD publicity***					
Yes	905	28.2	19.0	49.5	3.3
No	1177	26.3	22.9	38.1	12.8
Don't know	98	14.3	28.6	40.8	16.3
Awareness of organ donor register***					
Yes	1746	30.9	19.1	45.7	4.4
No	330	7.9	30.9	32.4	28.8
Don't Know	104	11.5	32.7	30.8	25.0
Registered decision on organ donor register***					
Yes, I have registered my decision	793	48.3	12.4	37.0	2.4
No, I don't think so	877	13.5	24.7	53.3	8.6
Not sure/don't know	203	25.1	26.6	42.9	5.4
No response	307	8.5	32.6	29.0	30.0

Characteristics	Sample (n=2180)	Supportive donors	Sensitive donors	Ambivalent donors	Non donors
Whether spoken to anyone about organ donation ***					
Yes	1032	40.4	12.5	43.1	4.0
No	1066	13.7	29.4	43.3	13.7
Don't know	82	18.3	32.9	36.6	12.2
Specific discussion about whether or not to donate organ with close family or partner***					
Yes – have told them about my decision around organ donation	766	50.0	9.7	38.6	1.7
No – have not told them about my decision around organ donation	218	9.2	20.2	58.7	11.9
Don't know	48	29.2	22.9	43.8	4.2
No response	1148	14.0	29.6	42.8	13.6
OD decisions told close family or partner***					
I told them that I want my organs to be donated	663	57.6	2.7	38.8	0.9
I told them that I do not want my organs to be donated	96	0.0	54.2	38.5	7.3
Don't know	7	14.3	57.1	28.6	0.0
Specifically told close family or partner that you want them to support your registered decision***i					
I told them that I want my organs to be donated	628	83.8	77.1	82.7	84.6
I told them that I do not want my organs to be donated	101	12.6	20.0	12.6	15.4
Don't know	30	3.7	2.9	4.8	0.0
Sex					
Male	979	50.4	28.1	42.3	81.2
Female	1198	49.5	71.9	57.6	18.3
Other	3	0.2	0.0	0.1	0.5
Region***					
North West England	292	34.3	12.0	35.6	18.2
North East England	115	48.7	7.0	39.1	5.2
Yorkshire and the Hum	186	37.1	12.4	33.9	16.7
West Midlands	239	26.8	27.2	33.1	13.0
East Midlands	197	33.0	14.7	32.5	19.8
East Anglia	182	23.1	20.9	55.5	0.6
London	481	3.3	33.7	60.5	2.5
South East England (excluding London)	310	32.6	20.0	40.3	7.1
South West England	178	36.5	26.4	36.0	1.1
Ethnic origin***					
Other	573	4.5	32.8	42.9	19.7
White	1607	34.4	17.5	42.9	5.2

Characteristics	Sample (n=2180)	Supportive donors	Sensitive donors	Ambivalent donors	Non donors
Faith base***					
Christianity	1007	25.8	16.5	46.7	11.0
Islam	213	0.0	55.4	31.9	12.7
Hinduism	70	12.9	14.3	54.3	18.6
Sikhism	30	16.7	26.7	43.3	13.3
Buddhism	15	33.3	33.3	33.3	0.0
Judaism	15	26.7	26.7	46.7	0.0
Other	41	34.2	26.8	31.7	7.3
Prefer not to say	789	35.6	18.6	40.8	4.9

Note:

*** Pearson's Chi-square test showing significant difference among subgroup at 1% level ($p < 0.01$);

i Sample was restricted to those who have registered a decision on the organ donor register.

Source: NHSBT Organ Donation Attitudinal Tracker survey data (2015-2022).

Supplementary table 6: Characteristics of interviewees

Category	General public (n=30)
Gender	
Male	11
Female	19
Ethnicity	
Black African/American	6
Asian	16
White	8
Religion	
Christian	6
Muslim	18
Other (Jewish, Sikh, Hindu, no religion)	6
Awareness of the law change	
Yes	24
No	6
Supportive of the change	
Yes	27
No	3
Decision on organ donor register	
Opted-in	6
Opted out	10
Uncertain	14

Source: Qualitative interview data

Appendix 5: Supplementary files – Chapter 8

Supplemental table 1: Summary demographics

Family members demographics 103 participants (n=2180)		N= (%)	Deceased demographics 83 cases		N= (%)
Age range			Age range		
18-35	13 (13%)		18-35	9 (11%)	
36-50	28 (27%)		36-50	15 (18%)	
51-70	52 (50%)		51-70	52 (63%)	
>71	10 (10%)		>71	7 (8%)	
Gender			Gender		
Male	29 (28%)		Male	48 (58%)	
Female	74 (72%)		Female	35 (42%)	
Relationship to deceased			Type of death		
1. spouse or partner;	36 (35%)		Sudden Brain injury	40 (48%)	
2. parent or child;	44 (43%)		Cardiac related	16 (19%)	
3. brother or sister;	11 (11%)		Accident	10 (12%)	
4. grandparent or grandchild;	2 (2%)		Suicide	7 (8%)	
5. niece or nephew	1 (1%)		Other (unsure, infection, awaiting confirmation, in hospital injury, alcohol related, multiple issues, rare disease, murder)	10 (12%)	
6. other (e.g. sister in law, step daughter, brother in law, aunt, cousin)	6 (6%)				
7. friend of longstanding	(3%)		Donation via* (based on families recollection of events)		
			DBD	34 (41%)	
			DCD	49 (59%)	
Ethnicity			Ethnicity		
White	83 (81%)		White	65 (78%)	
Asian	6 (6%)		Asian	6 (7%)	
Black	4 (4%)		Black	4 (5%)	
Mixed race	10 (10%)		Mixed race	8 (10%)	
Religion			Religion		
Not religious	72 (70%)		Not religious	62 (75%)	
Church of England	8 (8%)		Church of England	3 (4%)	
Catholic	6 (6%)		Christian	7 (8%)	
Christian	7 (7%)		Other (e.g. Muslim, Hindu Sikh, humanist, pagan, born again Christian)	11 (13%)	
Other (e.g. Muslim, Hindu, Sikh)	6 (6%)				
Spiritual (e.g. no specific religion, practice, personal beliefs unwilling to share)	4 (4%)		Deceased Decision pathway		
			OPT-IN ODR	39 (47%)	
			Verbally Expressed	17 (20%)	
			Deemed Consent	24 (29%)	
Deprivation*					
Levels 1-5 10%-50% least deprived	34 (33%)				
Levels 6 & 7 40 & 50% most deprived	14 (14%)				
Level 8 30% most deprived	10 (10%)				
Level 9 20% most deprived	16 (16%)				
Level 10 10% most deprived	9 (9%)				
*Non England residents scores were added using similar deprivation templates and available information.					
Number of people present for organ donation conversation *approx. number of people involved for some parts of the organ donation consent processes with SNODs/SRs		N=245*			

Supplemental table 2: Summary decision pathway and family behaviours

Deceased Decision pathway	N= (%)	Summary family behaviours in relation to deceased decision	
OPT-IN ODR	39/83, 47%	Fully supported – 21/39, 54% Partially supported – 16/39, 41% Overrode completely – 2/39, 5%	Additional contextual data provided by SNODs/SRs from a further 23 cases who refused organ donation.
Verbally Expressed	17/83, 20%	Fully supported – 5/17, 29% Partially supported – 12/17, 71% Overrode completely – 0	
Deemed Consent	24/83, 29%	Fully supported – 3/24, 13% Partially supported – 12/24, 50% Overrode completely – 9/24, 38%	
Family Consent	3/83, 4%	Said yes to everything – 2/3, 67% Said no to some things – 1/3, 33% Said no – 0	

Of the 11 cases where the family declined organ donation, 9/11 cases were from a white background, 2/11 were black or Asian. 8/11 had no specific religion, or religion did not influence the decision, 3/11 were religious (Muslim, spiritual, Christian) and of these religion was cited as a potential factor in the decision making of 2/11 cases.

Supplemental file 1: Logic model

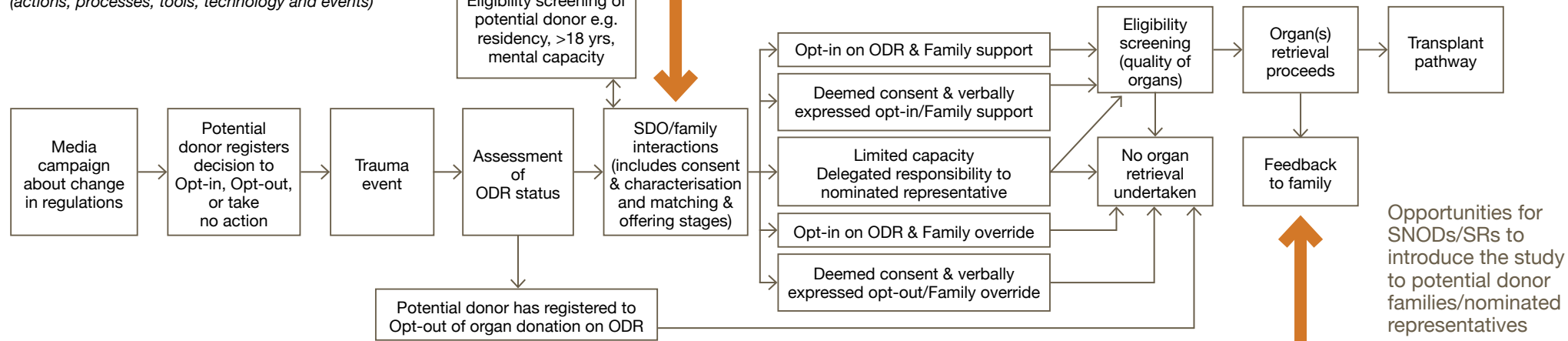
Inputs

(human, material, financial and other resources necessary for delivering the programme)

Staff capacity, hospital capacity, hospital infrastructure, finance, data, communications systems and networks

Activities

(actions, processes, tools, technology and events)



Outputs/ outcomes

(direct results of activities and consequential changes over time)

Change in number of people registered as Opting In
Change in number of people registered as Opting Out

Change in number of donated organs

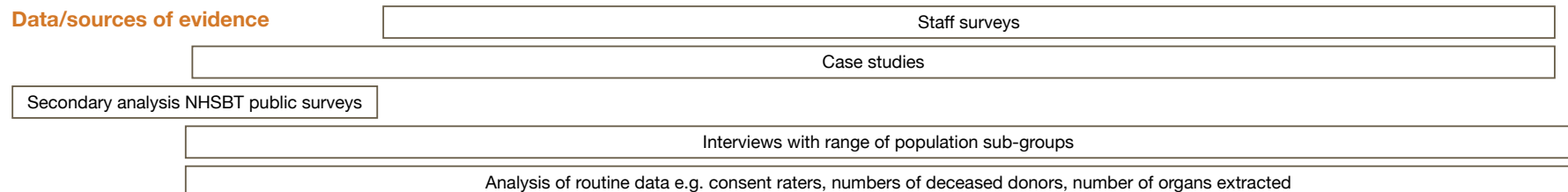
Change in number of successful organ transplant procedures

Moderators and contextual factors

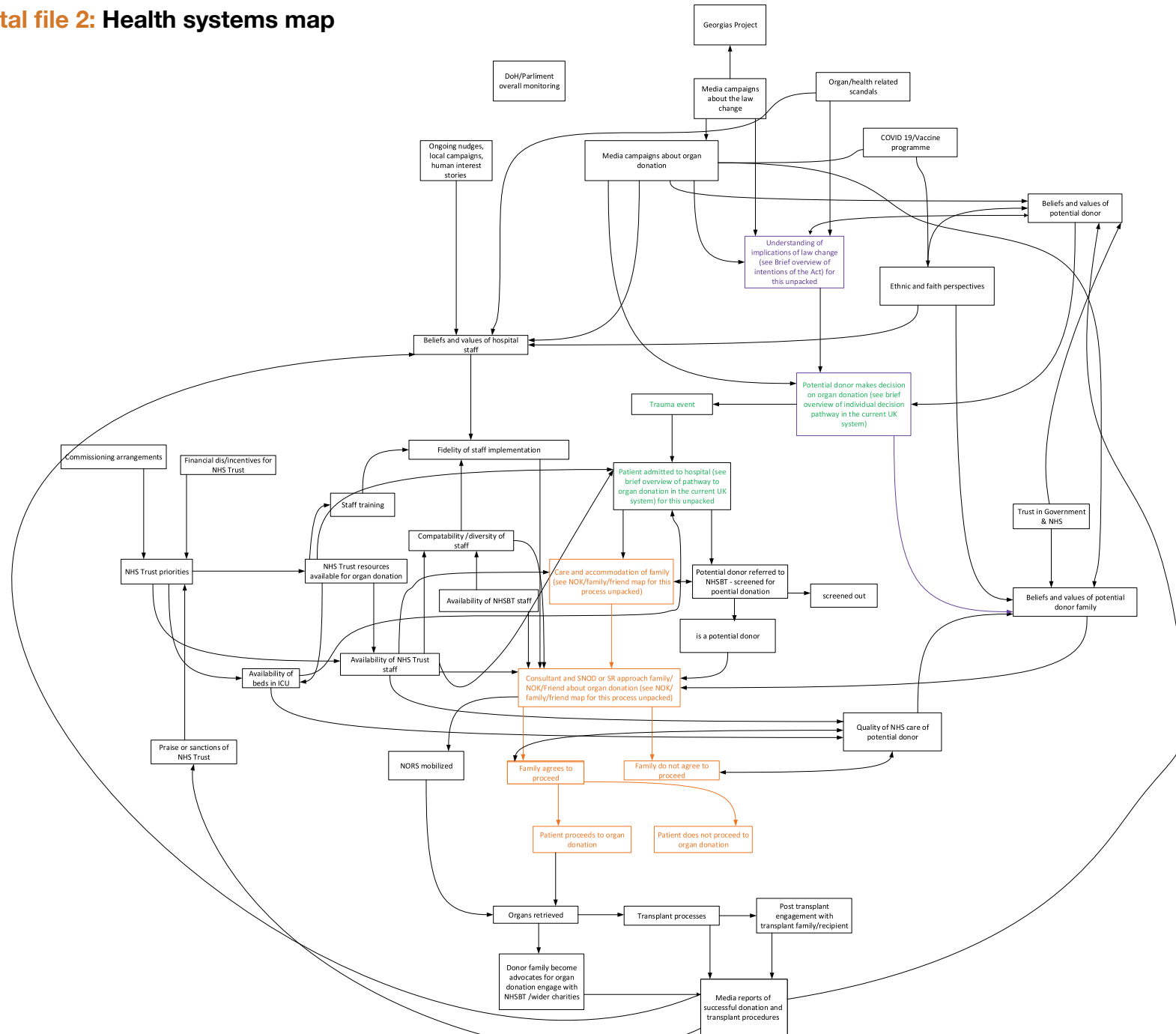
Political and social events that may influence effectiveness of media campaign
Ethics, attitudes, beliefs and perceptions of populations on organ donation
Frequency, location and nature of trauma events

Impact of population health on quality of organs

Data/sources of evidence




Supplemental file 2: Health systems map



Supplemental file 3: Consent to be contacted form

FORM C, Consent to contact re&reps/ IRAS no 297313 /Version 2 /02.07.22

Evaluation of the Organ Donation (Deemed Consent) Act, 2019



FORM C: Participant Consent to be Contacted by Research Team

PLEASE complete for EVERY case where:
deceased opted OUT (Verbal & ODR),
family said NO,
deceased/family member were from minority/ethnic and/or religious/faith background (any decision)

clear form

1. Were there any problems (e.g. pre-approach, family disagreements) you encountered that you think influenced the outcome of this case?

2. Where applicable, why do you think the family said no or felt unable to support the deceased decision?

3. Is there anything that you think would have changed the family's mind or influenced the outcome of this case?

4. Is there anything else you would like to share that would help us understand more about why family say no to organ donation?

5. If applicable, why did this family decide not to give consent to be contacted to share their very important views and experiences?

SNOD/SR confirm: (SNOD/SR Please INITIAL each box as appropriate)

1. You have spoken with the family about the study.

2. Family have been given a study information pack.

3. Family consent to the Specialist Nurse sharing contact details below with the University research team.

4. Family consent to the research team at LSHTM, contacting them, using the contact details below, to discuss the study and their potential contribution.

Participant contact details:

Name (Print):

Email address:

Address:

Contact telephone

Specialist nurse answer:
Was consent ascertained: Yes No

Any further information you would like to provide or think helpful to share about this case

Submit

Supplemental file 4: Sample framework for recruiting family members

Purposeful sample framework for recruiting family members, close friends and nominated representatives			
Approach all family members, close friends and nominated representatives where the person who died was a potential organ donor.			
In addition please place special emphasise to gain consent to contact for ALL CASES who match the following:			
Cases* where DECEASED:		Cases*where the FAMILY, CLOSE FRIEND, NEXT OF KIN, nominated representative:	
Opted-out via the organ donor register	0	Overrode the deceased decision on the organ donor register (opt-in/opt-out)	0
Opted-out via an expressed decision	0	Overrode the deceased expressed decision (opt-in/opt-out)	0
Nominated a representative	0	Supported/overrode the nominated representative	0
Fitted criteria to deem consent	0	Overrode the deemed consent	0
Was Black, Asian, Minority or from an ethic background (made any decision)	0	Were in disagreement (some supported/some did not) with the organ donation decision (however it was made) and overrode it.	0
		Were in disagreement (some supported/some did not) with the organ donation decision (however it was made) but in the end supported the deceased decision.	0
		Changed or influenced the deceased decision. E.g. an opt-in decision via the organ donor register turns into an expressed opt-out decision.	0
		All other cases where the family, next of kin or nominated representatives overrode, changed or influenced the deceased decision in anyway.	0
		Were Black, Asian, Minority or from an ethic back background (supported, overrode, disagreed, changed influenced the decision)	0

All cases which were classified as a 'missed referral' i.e. cases where the deceased was potentially eligible for organ donation but never spoke to a SNOD.			

All cases which were classified as 'less than ideal approaches' e.g. ED approach, late referrals, clinical mis communications or anything leading to an approach which was felt to miss the 'gold standard approach'			
* More than one criteria may apply to cases. The purpose of this sample framework is to learn about the potential impacts of the law change on people's behaviours. We can best do this by speaking to family members, close friends and nominated representatives who fit the criteria across this purposive sample framework. There is a special emphasis on 'opt-outs' and 'overrides' as these cases represents the biggest gaps in research. This study wants to fill this gap so that everybody (policy makers, NHS, NHSBT, other professionals, the public and potential donor families) can learn about the key influencers on (consent to) organ donation.			

Appendix 6: Chapter 9

Figure 1: Flow chart of the English process constructed from documents (18-20) and Stakeholder Engagement

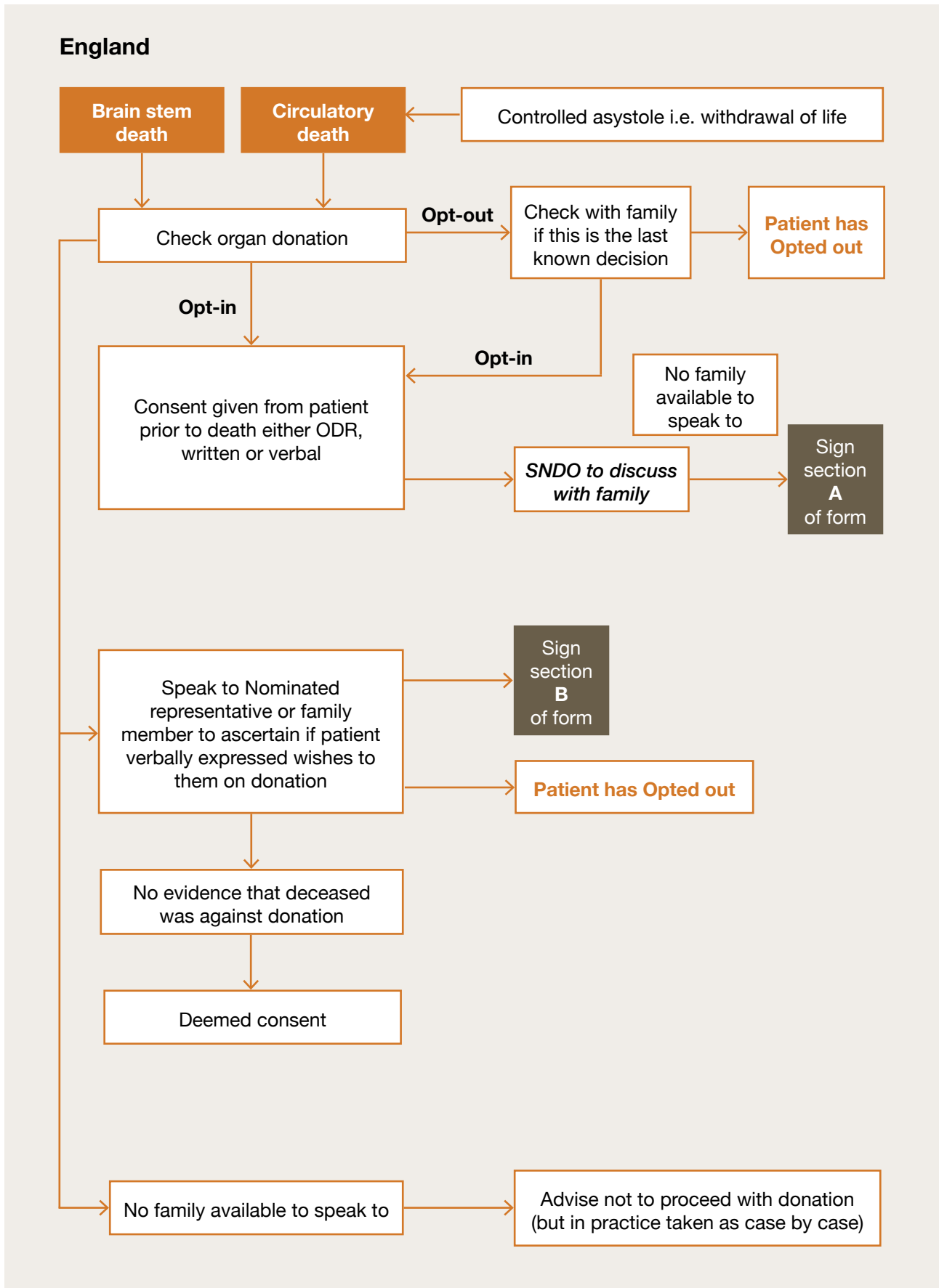


Figure 2: Flow chart of the Spanish process constructed from documents (14-17) and Stakeholder Engagement

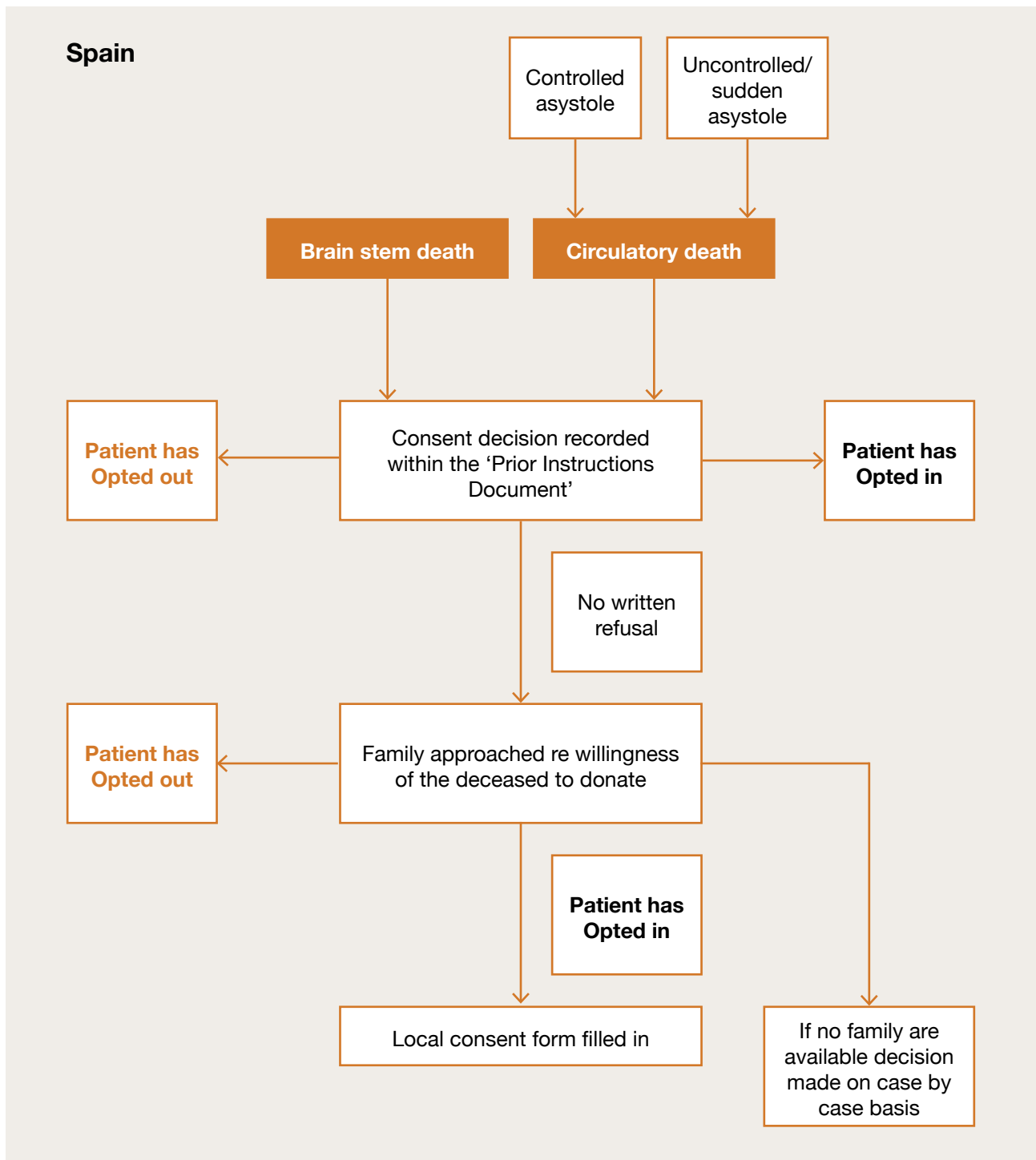


Table 1: Document list

Document	Description	Page length
From Spain ONT:		
Private Sector Donation [9]	Framework Protocol for organ and tissue donation in the private sector	93
Exchange SS1 2396 [10]	The basis of the Quality and Safety Framework Program for the procurement and transplantation of human organs and exchange with other countries	9
National Consensus Document 2012 [11]	Describes the situation in 2012 of asystole donation in Spain and other countries and provides a number of recommendations for the development of new these features and/or to improve the effectiveness of existing programs	205
Quality Improvement Programme [12]	This report shows the results of an evaluation of the current organ donation and transplant process (year 2019)	27
Royal Decree 1723-2012 [13]	Regulates the activities of obtaining, clinical use and territorial coordination of human organs intended for transplantation and establishes quality and safety requirements. (The first Legal document)	34
Barcelona University Hospital Consent Form	The current consent Form used for donation at the Barcelona University Hospital	1
Catalonia Regional Consent Form	The current consent form used for donation in the Catalonia region	1
Virgin Del Rocio University Hospital Consent form	The current consent form used for donation in the Virgin Del Rocio University Hospital	2 (page 1 consent, page 2 revoking of consent)
Emergency Professionals and the process of Donation [14]	Recommendations/Guidelines for Emergency Clinicians with respect to organ donation at presentation to hospital	27
From England NHSBT:		
Organ and/or Tissue Donation Manual (SOP5818/2) [15]	The standard operating procedures governing organ and tissue donation within the UK	33
Code F: Donation of Solid Organs and Tissue for Transplantation. Human Tissue Authority (HTA) [16]	Human tissue authority Codes of Practice	44
Consent Form for Organ and/or Tissue Donation [17]	The UK wide consent form for organ and tissue donation	7

Table 2: Comparisons between England and Spain

	England	Spain
Consent system	'Soft' opt-out, opt-in and family consent for organs and tissues. Scheduled purposes and research not covered by the Act.	'Hard' opt-out, opt-in and family consent based on the will of the deceased for scientific and therapeutic purposes
Eligibility criteria to apply opt-out system	Over 18, ordinarily (12 months prior to death) and voluntarily resident in England, dies in England, with full mental capacity.	Over 18, has full mental capacity and be in adequate health
Age of consent for adults	18	18
Organs and Tissues included in opt-out system in place	Only organs and tissues "routinely collected and used for life saving/ improvement treatments"	Includes both organs and tissues routinely collected for life saving / improvement treatments, scheduled purposes and research
Family made aware prior to admission to ICU to consider organ donation	No	Yes
Family spoken to regarding withdrawal of treatment in DCD death and tests for DBD	Yes	Yes
Organ Donor Register	Yes – but has no legal status	No ODR in Spain
Prior Instructions Document	No	Yes – and has legal status
Determine the last known decision of the deceased	Yes	Yes
Nominated representative	Yes	No
Family hierarchy	Yes	Yes
Key hierarchical family member identified and spoken to as a priority	No (it is in the guidance but rarely done in practice as a priority)	Yes
Witness to conversation between SNOD and relatives/TC and relatives	Yes	Yes
Mandatory/legal requirement that family member signs donation form	No	Yes
Leaflets given	Yes – content and context varies	No
Details of all organs and Tissues taken explained	Yes	Simply
Details of body appearance following donation described to the family	Yes	Yes
Family continued to be supported by TC or SNOD if consent declined	No	Yes
Family follow-up	If signed consent given	No
Family informed of those whom donation helped	If signed consent given	No-can receive a thankyou letter if they sign for this
Can be contacted by those receiving donation	If signed consent given	No

Table 3: Mechanisms which are bringing about the desired outcomes, or not, in relation to consent

Healthcare professionals	
<p>England Only SNODS/SRs are allowed to approach family members about organ donation. Anyone else is actively discouraged from mentioning organ donation. This is because it is thought that NHS staff may create a context where organ donation is not presented in an appropriate way leading to reduced opportunities to gain consent. During the family discussion the SNOD/SR guidance document suggests that SNODs should remain impartial but often the advice and legislation is open to interpretation, often misleading, with arguments for and against ways to act. Therefore interpretation of this depends on the individual SNOD/SR involved.</p> <hr/> <p>Spain Although TCs are encouraged to speak to families about organ donation, other health professionals are able to offer encouragement for donation should it be mentioned earlier. (14) Organ donation is thought of by health professionals outside of ITU and thus a lot earlier in the care pathway of the patient, even extending to community and emergency services.</p>	<p>Although all ‘families are encouraged to support the decision their relative made in life’. In England 43% of families said no in 2022-23 whereas around 10% of families still refuse in Spain (outcome). The Spanish system therefore contains more factors that create supportive contexts that bring about higher consent rates (mechanisms).</p> <p>Having a more unified and bespoke approach for the TCs and this being reflected in a wider culture of support appears to be a factor that creates a mechanism for achieving higher consent rates (outcome).</p> <p>In the Spanish system, the potential for organ donation can create a context that subsequently influences the decision as to which hospital the patient is brought, enabling discussions to occur about admittance to ICU purely for donation, rather than recovery (mechanism). By empowering those outside of ITU to consider organ donation, creates a context which helps highlight potential donors to the TC and potentially aid conversations to patients prior to their death (mechanism).</p>
System configuration	
<p>England ITU beds remain a scarce and precious resource to treat patients who are alive. There are no specialist organ donation centres in England. Every acute hospital is able to offer/honour organ donation on site as it is the organ retrieval team and SNOD/SRs who travel to the hospital.</p> <hr/> <p>Spain Patients in Spain can be admitted to ITU purely for the purpose of donation. Spain has specialist organ donation hospitals which have designated TCs.</p>	<p>The lack of ability to admit potential organ donors to ITU purely for organ donation reflects unequal End of Life care policies between England and Spain (comparative context) and could help explain the differences in consent rates (outcomes) but also potentially indicates a discrepancy in priorities between countries (contexts and mechanism) that also impacts negatively on consent rates (outcome).</p> <p>In Spain organ donation is more visible and acceptable – due to capacity to host more potential organ donors without adding strain or worry to the ITU service. This creates a context and mechanism that makes organ donation easier. The NHS would however need to increase ITU capacity to adopt this approach to create a similar context and mechanism leading to better consent outcomes.</p> <p>In both countries it is specialist teams that provide the care (context), but in England the more complex process can take hours to days (context). This means that the family may have to wait a length of time before being able to speak to the SNOD/SR and go through the longer processes (mechanism) and this can often influence their decision to decline donation (outcome).</p> <p>The length of time can also give families more time to revoke consent (mechanism leading to outcome) if it is given and they may decline consent straight away feeling that their loved one has already suffered enough or to be able to start making funeral arrangements (mechanism and outcome).</p>

Faith and beliefs

England

Throughout the English guidelines faith/beliefs are mentioned frequently and there are documents dedicated to this. There is also the option of recording this when someone registers a decision on the organ donor register.

Spain

Although faith and beliefs are important they are rarely specifically mentioned in the documents or given a huge amount of coverage.

While there are detailed guidance on faith/beliefs (context) the guidance in the documents for healthcare professionals and options on the ODR are not translating into practice – vast inequalities remain in organ donation in the UK (outcome).

The organ donor register

England

The organ donor register enables people to record a decision about organ donation prior to death. It enables people to choose which organs and tissues they would like to donate or not. However, there are many avenues to recording a decision, the forms are not universal and they do not reflect what the family is asked after death. Therefore, despite people making these decisions the family will still be approached and questioned to ensure that the decisions made by the potential donor have not changed.

In England the HTA states that although ‘consent has been obtained, it is not mandatory that organ donation proceeds’ especially if ‘the family do not support it’. The SNOD/SRs are left to determine each situation on their own best judgements as the current guidelines are not clear.

Ironically if the nominated representative can’t be contacted in time, consent can be deemed yet if no family are available and there is nothing recorded on the ODR it is advised that consent does not go ahead.

Spain

The patient will be required to get a form from their GP which has to be signed by a witness. This decision is then shared on their health record. Due to the increased effort in Spain to register an opt-out decision which is witnessed, this may explain why there are higher numbers of organ donation but also that families are more likely to discuss the decision with their relatives or friends and have more trust in the system that it is an integral part of end of life care.

In practice an opt-in decision is always discussed with the family, and the guidance advises that even opt-out decisions should be discussed to ensure this was the last known decision.

In England, although the organ donor register gives the opportunity for people to record a decision prior to death it does not have any legal status (context). This means that family members can easily override their relative’s decision to donate their organs made in life (unintended mechanism) resulting in lowered consent rates than anticipated (outcome).

In England, the consent process for the bereaved family is more burdensome (context), potentially contributing to revoking of consent or reluctance to give consent (mechanism and outcome). It can also be a surprise to the family that a decision has been recorded by the potential donor as a decision can be made effortlessly when applying for a boots advantage card or drivers licences for example but these are kept separate and independent from medical notes (context and mechanism). This could help explain why the numbers of people opting-in to donation have increased somewhat, but overall consent to deceased organ donation has not (outcome).

In England, deemed consent is not properly or always understood by family members yet as a positive decision that supports organ donation and perhaps why families are continuing to override the deemed consent.

Opportunities to say no

England

There are further opportunities for consent to be declined as highlighted in figure 1. The potential donor can opt-out/in via the ODR or by expressing it verbally to family and friends. The nominated representative may also decline donation. By further checking if an opt-in decision on the ODR was the final decision offers a further opportunity. If the family disagree with the potential donors decision in life, sometimes donation does not occur out of fear of upsetting the family and risk to what messages would be interpreted by the wider public. The family are frequently reminded that they can decline at any point until the retrieval has commenced, *'Withdrawal of consent should be discussed at the outset when consent is being sought.'* This is also a regulatory requirement written into the procedural documents before deemed consent was introduced This suggests that no is the default answer expected, which is the opposite of a deemed consent system.

Spain

Consent to donation can be declined either by writing in the prior instructions document or declared to the family who can then continue to decline on the potential donors behalf after their death. In Spain the TC will strive to understand the reasons why donation is declined, and they are encouraged to give the family time to ensure this is the final decision before accepting it.

Despite a law which switched the default to one where organ donation is presumed, documents and guidance appear to support the opposite in the England (context). Tailoring this part of the process to the family and being allowed to speak more simply about the organs, tissues and processes may make this process easier and shorter. Therefore easier to say yes, and easier for everyone involved to go through (mechanism) and give their consent to organ donation (outcome).

The family and language

England

When families are approached, they are asked what the potential donor's last decision would have been and whether the deceased expressed any thoughts on becoming a donor. The current policy suggests that the family are approached according to the highest qualifying relationship. This does not always happen in practice as the SNOD/SR tries to navigate the family dynamics while at the same time tries to gain evidence to support a *'final decision on donation'* that can be from any family member.

Spain

The family are asked what would have been the willingness of the deceased to donate their organs and the key family member is identified.

In both countries the family are made aware that donation can be declined (if no decision has already been made by the deceased). In both cases the decision is respected and the TC/SNOD seeks to understand why.

However, in Spain the TC gives the family time to further think about their decision before accepting it as the final decision. The TC can also bring up ethical arguments for organ donation and also use the argument that it is likely that they will need an organ in their lifetime, which could influence the family decision and use arguments for courage, generosity and proximity e.g. *'you are likely to need an organ at some point in your life'*.

Rhetorically, this language possibly evokes feelings and thoughts of being brave and confident in testing times (context and mechanism). In England, the language appears to be less emotive by asking about the last known decision of the potential donor, which may not be as impactful as the rhetorical language typically used and encouraged in Spain.

Willingness itself evokes feelings or thoughts about the inclination or desire to help others if it is needed (context and mechanism). It appears to be almost a leading question. Nonetheless family dynamics can often be difficult to grasp and work with, particularly at times of acute grief. Families are complex and not all respond in the same ways to simple linguistic interventions and again this mechanism does not always work in practice (outcome).

Consent forms	
<p>England The 7 pages consist of yes/no tick box answers for a list of organ, tissues and processes involved in donation. For every donation (even for opt-in decisions on the ODR) the family will go through the same process. This is done to conform with the Human Tissue Act 2004, although the forms have no legal status and are not mandatory to sign.</p>	<p>The length and detail of the consent process and form (context) could become overwhelming for a family and dissuade them from supporting (mechanism) the current donation (outcome) or what they perceive might be involved in the future in terms of retrieval (mechanism). The consent form may also leave SNODs/SRs feeling vulnerable given it is not mandatory for the authoriser to sign especially if there has been some conflict on the final decision between the family (context and mechanism), and the SNOD/SR more likely to stand down (outcome). The SNOD/SR may also be more likely to accept a decline in consent (outcome) given the mixed messages in the legislation and guidance, and if the family are divided, or especially traumatised, or the donor is borderline given the additional time and burden of the consent and retrieval processes (mechanism).</p>
<p>Spain Consent forms are created by local hospitals using the ONT template. They are short (one/two pages) and it is mandatory for the authorising family member to sign. Some forms have space for the family to write which organs they believe donor would or would not wish to donate; in others this decision is written within the medical notes instead. The form has legal status.</p>	

Figure 3: Summary of changes to Organ and Tissue Donation Consent Manual

SOP5818/6 – Organ and Tissue Donation Consent Manual



Blood and Transplant
Copy No:
Effective date: 24/05/2023

1. Summary of changes

Please add changes in purple and record here.

- Addition of the requirement to ascertain from the family how the potential donor would like their ethnicity and religion recorded, using the recommended Office of National Statistics categories (Pages 10, 11 & 20)
- Inclusion of deemed consent legislation for Guernsey and Northern Ireland (Pages 4, 15 & 34)
- Copy of the consent form FRM4281 to be given to the family upon request (Page 22)

Appendix 7: Published papers (abstracts and links)

Title: A machine-learning approach to estimating public intentions to become a living kidney donor in England: Evidence from repeated cross-sectional survey data.

Authors: Boadu Paul, McLaughlin Leah, Al-Haboubi Mustafa, Bostock Jennifer, Noyes Jane, O'Neill Stephen, Mays Nicholas

(2023) *Frontiers in Public Health*. DOI=10.3389/fpubh.2022.1052338

Abstract

Background: Living kidney organ donors offer a cost-effective alternative to deceased organ donation. They enable patients with life-threatening conditions to receive grafts that would otherwise not be available, thereby creating space for other patients waiting for organs and contributing to reducing overall waiting times for organs. There is an emerging consensus that an increase in living donation could contribute even more than deceased donation to reducing inequalities in organ donation between different population sub-groups in England. Increasing living donation is thus a priority for National Health Service Blood and Transplant (NHSBT) in the United Kingdom.

Methods: Using the random forest model, a machine learning (ML) approach, this study analysed eight waves of repeated cross-sectional survey data collected from 2017 to 2021 (n=14,278) as part of the organ donation attitudinal tracker survey commissioned by NHSBT in England to identify and help predict key factors that inform public intentions to become living donors.

Results: Overall, around 58.8% of the population would consider donating their kidney to a family member (50.5%), a friend (28%) or an unknown person (13.2%). The ML algorithm identified important factors that influence intentions to become a living kidney donor. They include, in reducing order of importance, support for organ donation, awareness of organ donation publicity campaigns, gender, age, occupation, religion, number of children in the household, and ethnic origin. Support for organ donation, awareness of public campaigns, and being younger were all positively associated with predicted propensity for living donation. The variable importance scores show that ethnic origin and religion were less important than the other variables in predicting living donor intention.

Conclusion: Factors influencing intentions to become a living donor are complex and highly individual in nature. Machine learning methods that allow for complex interactions between characteristics can be helpful in explaining these decisions. This work has identified important factors and subgroups that have higher propensity for living donation. Interventions should target both potential live donors and recipients. Research is needed to explore the extent to which these preferences are malleable to better understand what works and in which contexts to increase live organ donation.

The Policy Innovation and Evaluation Research Unit (PIRU) brings together leading health and social care expertise to improve evidence-based policy-making and its implementation across the National Health Service, social care and public health.

We strengthen early policy development by exploiting the best routine data and by subjecting initiatives to speedy, thorough evaluation. We also help to optimise policy implementation across the Department of Health and Social Care's responsibilities.

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PIRU is a collaboration between the London School of Hygiene & Tropical Medicine (LSHTM), the Care Policy & Evaluation Centre (CPEC, formerly PSSRU) at the London School of Economics and Political Science (LSE), and Imperial College London Business School.

The Unit is funded by the National Institute for Health Research (NIHR) Policy Research Programme.



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