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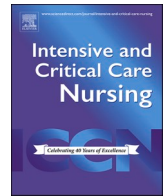
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Research Article

Potential donor family behaviours, experiences and decisions following implementation of the Organ Donation (Deemed Consent) Act 2019 in England: A qualitative study

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ABSTRACT

Background: In May 2020, England implemented “deemed consent” legislation, to make it easier for individuals to donate their organs and convey their decision when alive. Families are supposed to support the decision but can still override it if they disagree. We aimed to learn more about this changed role when families were approached about organ donation.

Methods: A qualitative study using semi-structured interviews with families, feedback from nurses, comparisons with audit data, and public involvement. We used framework analysis with a health systems perspective and utilitarian theory to explore if the law worked.

Findings: 103 participants were interviewed representing 83 potential donation cases. In 31/83 (37%) cases donation was fully supported, in 41/83 (49%) cases families supported retrieval of some organs, tissues and procedures, and in 11/83 (13%) cases families declined completely. Themes explaining why the law was not (yet) working included: Understanding and agreeing the family’s role, confusion about deemed consent, not supporting the deceased expressed decisions, organ donation as too much of a harm, the different experiences of donation pathways, transition from end-of-life to organ donation discussions, experiences of ‘consent’, paperwork and processes. Families frequently questioned if their relative wanted to have a surgery rather than supporting the person who died to save lives.

Conclusion: Families use the unique experience of their relative dying in intensive care to create alternate narratives whereby the outcome satisfies their own utility and not necessarily those of the potential donor. New public ongoing media campaigns crafted to be more supportive of organ donation as a benefit to transplant recipients could help families overcome the many difficulties they encounter at the bedside.

Implications for clinical practice: The soft opt-out policy has not empowered nurses to help families at their most vulnerable to increase their support for and consent to deceased organ donation.

Background

While there are multiple factors that can affect the availability of organs for transplant, the refusal of family members to consent to deceased organ donation is generally considered one of the main barriers to saving and improving more lives [1]. To address this issue, law makers in some countries have introduced opt-out systems of consent to deceased organ donation. Opt-out systems vary considerably but the underlying principle is the same: switching the default position of

citizens (who meet specific inclusion criteria) from opting-in to having the option to opt-out of organ donation during their life time [2]. Importantly, in theory, the role of the family also changes. While families remain essential by providing information about their relative who died and, thereby, the suitability of their organs for transplant, they are no longer the decision-maker regarding whether organ donation proceeds or not. The law requires them to support the assumed rational decision the deceased made during their lifetime, whilst in soft-opt out systems also allowing a caveat for family members to override their

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relative's decision [3]. Despite mixed evidence as to their effect, over time political support for opt-out systems has increased and more countries are implementing them [4,5]. Spain remains the world leader having an opt-out system for over 40 years. Apart from Germany most European countries have switched to versions of opt-out, other notable exceptions include Australia and the U.S which remain opt-in [6,7].

In May 2020, at the height of the COVID-19 pandemic, England, a devolved country in the United Kingdom (UK) implemented a nurse-led 'soft' opt-out system of consent to deceased organ donation [8]. The Act was designed with utilitarian principles to make it easier for individuals to donate their organs so that more people in need of replacement organs could benefit from transplants. Under the new system, all citizens over 18, with mental capacity, who had (voluntarily) resided in England for over 12 months and died in England met the criteria for the new Organ Donation (Deemed Consent) Act 2019. However, despite the fact that

families are no longer the decision makers, the Act is 'soft' as families are still given powers to override or veto the individuals autonomous decisions made in life. In addition, rather than entirely replacing the older opt-in system, the Act was implemented into the existing opt-in system, adding a new deemed consent pathway (Fig. 1). Specialist Nurses in Organ Donation (SNODs) and Specialist Requesters (SRs) who are SNODs considered to be highly skilled at gaining consent, lead the process.

This qualitative study was part of a wider mixed-method evaluation investigating the implementation of the law change [9]. Here we turn to the experiences, behaviour and decisions of family members of potential donors, close friends and nominated representatives (who were involved in the decision-making process). Family members are (in theory) most affected by the legislation changes as their role has changed. They are no longer the decision makers with regard to deceased organ donation. It

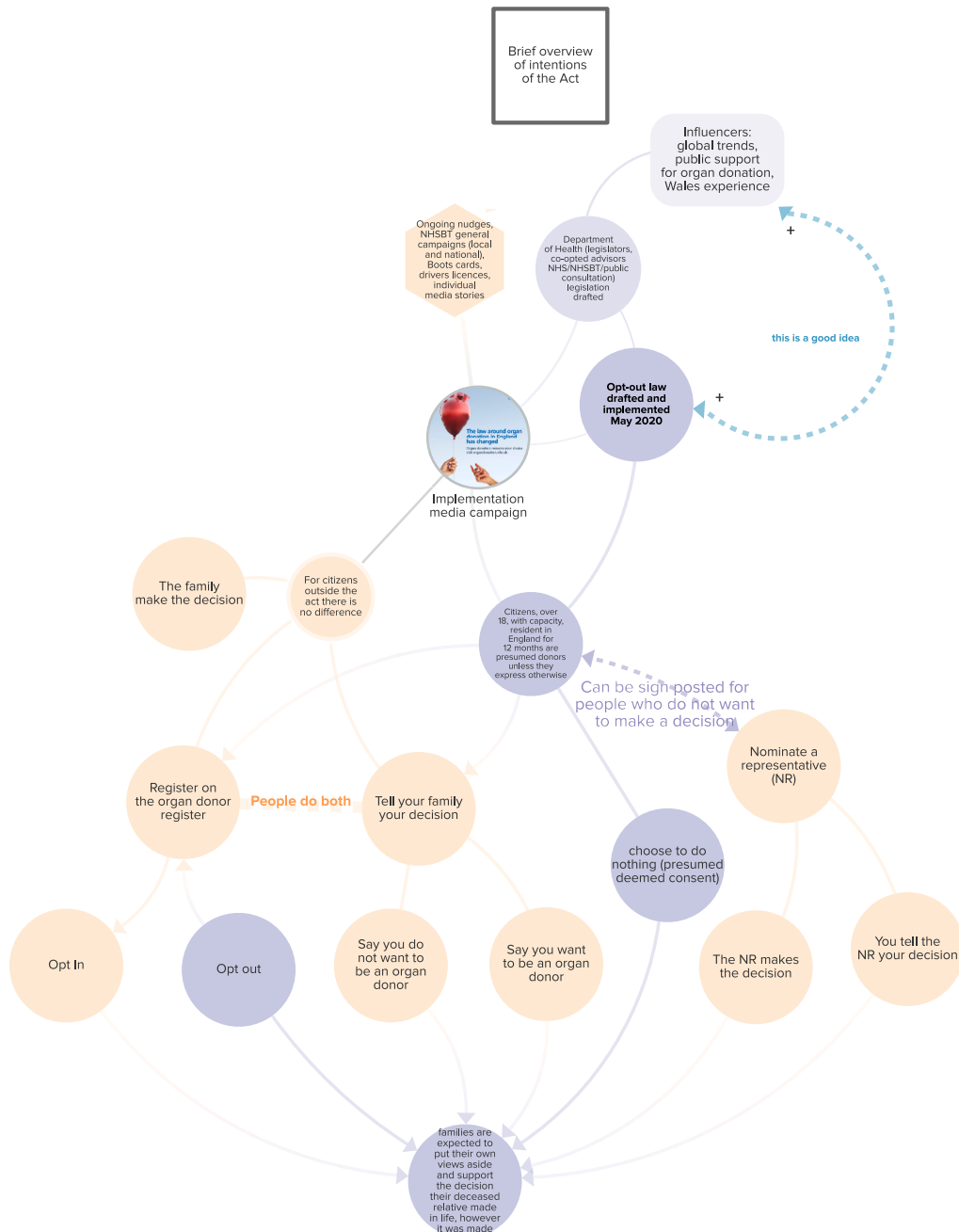


Fig. 1. Implementation of the Act into the existing system in England.

was therefore critical to learn directly from the experiences of family members to see if the intentions of law were being realised in practice. Despite multiple studies investigating the experiences, behaviours and rationale of families who support organ donation when their relative dies, there is limited primary qualitative research aiming to learn more from families who decline or override the organ donation decision especially when the decision is no longer theirs to make [10]. This study aimed to address this gap.

Methods

We conducted a theory informed and theory-testing qualitative Framework Analysis of semi-structured interviews with potential donor family members and close friends who were involved in the organ donation decision-making process at end of life. Interview data were supplemented by anonymised feedback from SNODs or SRs on cases where organ donation was declined. Qualitative Framework Analysis was chosen because of its suitability for addressing applied policy questions and evaluations [11]. The study is reported using the Consolidated Criteria for Reporting Qualitative Studies (COREQ) [12].

Theoretical perspectives

We conceptualised the Act as a highly complex intervention that was implemented into a complex and dynamic health care system at the point of an equally complex aspect of human behaviour – acute bereavement (Supplemental File 1).

Utilitarianism is a consequentialist ethical theory relevant to the law change and organ donation [13], which asserts that actions should only be judged on the basis of their results, irrespective of the motives driving the decisions that lead to the results. Although the principles underpinning the Act were designed to favour transplant recipients through more individuals wanting to help those needing donated organs, utilitarianism does not differentiate who or what should benefit, only that overall happiness (utility) should be maximised. The core principles of utilitarianism applied to deceased organ donation from the perspective of the donor family is outlined in Fig. 2. Morris and Holt hypothesised that family members would not act in line with utilitarian ethics underpinning the legislation to increase the benefits to transplant

recipients, but would 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 [14]. The study tested this hypothesis.

Data collection

Interviews

Recruitment opened in September 2021, and closed in July 2023 (22 months) in England across two NHSBT regions (London and North West). All family members, close friends and nominated representatives (>16 years) where the person who died was a potential organ donor were eligible for inclusion. Excluded criteria were people who lacked mental capacity to consent to the study, and people under 16. Interviews were offered initially virtually (Teams, Zoom, telephone) due to COVID-19 and then a face-to-face option was added. Interviews were undertaken by an experienced female researcher with a PhD (LM); two interviews were undertaken by another experienced female researcher with a midwifery qualification (LW). A topic guide and interview protocol were adapted from a previous study [3] and shared with the advisory group and selected key stakeholders (e.g. National Health Service Blood and Transplant (NHSBT)) staff involved in implementing the Act) for their input, and can be found in the protocol [9]. Detailed fieldnotes were recorded, participants were interviewed once and audio-recorded. Transcripts were not returned to participants. Interviews lasted 55-130mins with one-six family members (and sometimes included close friends) who were involved in deceased organ donation decision-making.

SNOD/SR feedback

We requested that SNODs/SRs respond anonymously to four questions (Supplemental File 2) in a free text box on their iPads for those cases where the family did not support organ donation and did not consent to interview.

Data analysis

We used the Framework method by creating an a priori coding index and analysed data by charting, mapping and interpreting to develop

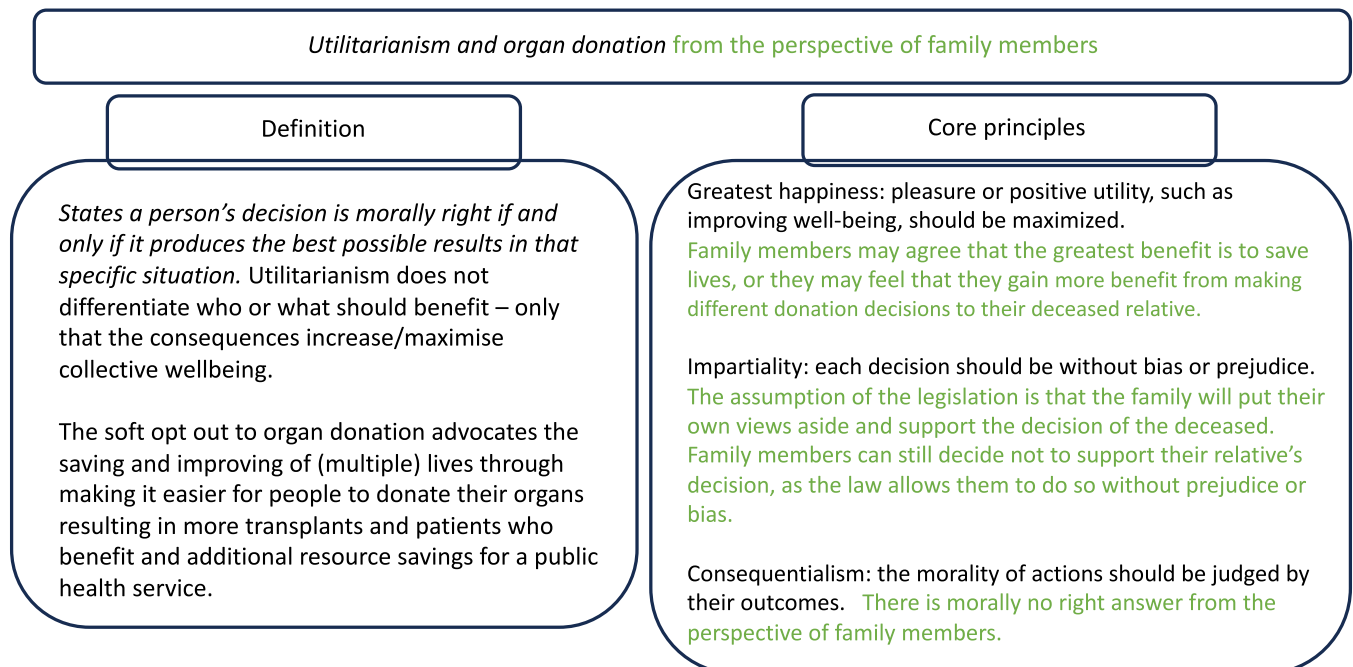


Fig. 2. Utilitarianism and organ donation from the perspective of family members.

themes viewed through Utilitarianism and using the complex health system model [11]. Codes included, for example, personal motivations to donate or not, views on the law and any difference it made, the deceased decision, what the family did in response, family dynamics, consent conversation, tipping points, comfort and care, views on media campaigns or other nudges (e.g. driving licence renewal). Interviews were transcribed verbatim, uploaded to NVivo 12 and coded by three female researchers (AJ, LM, SJ). The SNOD/SR free text responses were also uploaded to NVivo and coded.

Validity, reliability and rigour

Discussion of data meaning and emerging themes started as soon as data collection began. Emerging interpretations were shared at fortnightly team and separate analysis meetings via detailed fieldnotes, additional visual methods to map and chart data, supplemented by notes of possible patterns and explanations of reported behaviour. We used four well-established quality criteria (credibility, dependability, confirmability and transferability) [15]. Presenting findings to a multi-disciplinary advisory group, plus regular updates and engagement with NHSBT staff at a local and national level, provided additional feedback and markers of rigour.

Reflexivity

The research team included a mix of male, female and ethnically diverse academics and lay representatives with a mix of experience in nursing, 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 (LM, JN). Potential biases were acknowledged and addressed by inviting wider expert input to discuss emerging findings.

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. We adapted a framework for ethical decision-making used successfully in previous studies which focused on respect, compassion, options and choices, support and inclusion, and which incorporated a distress protocol [3,16].

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 organ donation from a minority ethnic perspective, as well as additional services involved in bereavement care and supporting potential donor families in England. We followed the National Institute for Health Research standards for patient and public involvement [17].

Findings

We received 148 forms and 136 had usable contact details of potential participants. We undertook 84 interviews with 103 people representing 83 potential organ donation cases (Table 1). Participants were predominately white 83/103 (81 %), female 74/103 (72 %), not religious 72/103 (70 %) and were predominantly a spouse/partner or a parent or child of the deceased 80/103 (78 %). Of the 83 cases, 31/83 (37 %) fully supported the organ donation, 41/83 (49 %) supported some organs, tissues and processes related to donation but not others, and 11/83 (13 %) refused any donation. Further details of the decision pathway are available in Table 2. We received additional information on a further 23 cases where family members declined organ donation via the SNOD/SR free text questions.

For context, it is important to note that there was an overall decline

Table 1
Summary demographics table.

Family members demographics 103 participants		Deceased Demographics 83 cases	
Age range	N= (%)	Age range	N= (%)
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 %)
Sex		Sex	
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 %)	Donation via* *based on families recollection of events	
8. friend of longstanding.	3 (3 %)	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 %)	Deceased Decision pathway	
Spiritual (e.g. no specific religion, practice, personal beliefs unwilling to share)	4 (4 %)	OPT-IN ODR	39 (47 %)

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Table 1 (continued)

Family members demographics 103 participants		Deceased Demographics 83 cases	
Age range	N= (%)	Age range	N= (%)
Deprivation*		Verbally Expressed	17 (20 %)
Levels 1–5 10 %–50 % least deprived	34 (33 %)	Deemed Consent	24 (29 %)
Levels 6 & 7 40 % & 50 % most deprived	14 (14 %)	Family Consent	3 (4 %)
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	N=245*		
*approx. number of people involved for some parts of the organ donation consent processes with SNODs/SRs			

#Of the 136 forms received, we made initial telephone contact with 104 potential participants and undertook 84 interviews. 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.

in recorded consent rates in England from 67 % in 2019 before the law change to 61 % in 2023 [18]. Consent is considered to have been supported if one or more organ or tissue is donated out of a long list of potential options. (Supplemental File 3) We developed two high level themes: 1. family behaviour and decisions; and 2. family experiences of navigating and following organ donation systems and processes; plus 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. The themes are presented and explained below with illustrative quotes from participants mapped onto the themes in Table 3.

Family behaviours and decisions

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 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 participants had little to no memory of the initial media campaign when shown examples. Most people agreed with the sentiments of the follow-up media campaign with its message to ‘Leave them Certain’ but almost nobody had seen this campaign or anything to do with organ donation in recent media. Campaigns themselves were framed in a value-neutral way, informing rather than promoting organ donation. The implicit utilitarianism of the Act, which assumes that the best consequences for the donor will be brought about by donating organs was lost on family members. Most family members still thought that the decision was theirs to make. As Morris and Holt predicted [14], this resulted in tensions between family members and SNODs/SRs who were trying to balance honouring the decision of the deceased person with family members’

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.			

perceptions 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.

Overall confusion about deemed consent

Deemed consent should be applied when the potential donor has not expressed a decision during their lifetime. The deemed consent rate in England was 57 % in the period April 2022–March 2023 and far lower than the rate in other consent pathways. 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 supported the donation of some organs and tissues but not others, and 9 families overrode the 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 asked by the SNOD/SR in order for consent to be deemed.

Common misconceptions included deemed consent being associated with giving families more decision making powers, or conversely taking away potential donor and family member decision making powers, or that deemed consent would somehow undermine the excellent clinical care the family had received. 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 deemed consent would generate public opposition as it became better known and therefore might encourage people to opt out of organ donation, especially within the UK cultural context.

Table 3
Participant illustrative quotes mapped to themes and sub-themes.

3.1 Family behaviours and decisions	
3.1.1 Understanding and agreeing the family member role	<p>“...It just needs to be out there, families need to know this... [shown images of leave them certain media campaign]...I’ve never seen this, it is good but I’ve not seen it...where is this been shown... it needs to be out there much more” (043, verbally expressed, daughter, supported)</p> <p>“Organ donation is on my mind, obviously given what we have been through, but I have seen absolutely nothing, not a thing, you would think with social media as well...have you [asks partner] Partner: no nothing, and I work for a big company and nobody there has seen anything either I’m sure of it...maybe they could help get messages out there because families don’t know...” (011, deemed, Son, supported)</p>
3.1.2 Overall confusion about deemed consent	<p><i>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)</i></p> <p><i>“[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...there is really no way to distinguish between the two.” (018, Parent of adult child, ODR-In)</i></p>
3.1.2.1 Not supporting deemed consent	<p><i>“I suppose it was that we didn’t know whether she would or wouldn’t [want 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)</i></p> <p><i>“We didn’t discuss it (organ donation), 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, the</i></p>

Table 3 (continued)

3.1 Family behaviours and decisions	
	<p><i>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)</i></p> <p><i>“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)</i></p> <p><i>“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</i></p>

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Table 3 (continued)

3.1 Family behaviours and decisions	
	<p>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)</p> <p>"That's exactly what they asked me [did she express a view], I'll tell you the truth, 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)</p> <p>"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." You're actually very subtly putting pressure on because you're saying, "look you could literally help Joe Plug who is down the road!". That would be far more effective, than how it came to us" (026, Spouse, deemed consent, declined)</p>
3.1.2.2 (Ambivalent) support for deemed consent	<p>"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</p>

Table 3 (continued)

3.1 Family behaviours and decisions	
	<p>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, supported)</p>
3.1.3 Not supporting the deceased person's expressed decision	<p>"[Daughter]...I said that's not right, I remember we watched a show and he said no...[Wife]: no I wasn't there when he said that, I didn't know... if I didn't know what (daughter) said I probably would have said yes but (daughter) said no he didn't want it, that [the ODR] was wrong..." (074, wife and daughter, ODR-In, declined)</p>
3.1.4 Organ donation as too much of a harm	<p>The cumulative process and multiple factors influencing family members to refuse to support the decision to donate organs were:</p> <ul style="list-style-type: none"> – 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. 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 more organ things like liver, kidney, but not brain or eyes. But my brother had such a strong reaction to it, that then did change my view. I still didn't want her messed with, but my brother was like "absolutely not, I'm putting my foot down...and that's where we ended up 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. <p>"Weirdly I think the worst part or most emotional part was when they took her jewellery off her, that was horrible. It was</p>

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Table 3 (continued)

3.1 Family behaviours and decisions	
	<p>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)</p> <p>3.1.5 Supporting their relative’s expressed decision to be an organ donor</p> <p>“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 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)</p> <p>“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. (015, Husband, ODR-in)”</p>
3.2 Experiences of navigating and following organ donation systems and processes	
3.2.1 The different experiences of Donation via Brain Death (DBD) and Donation via Circulatory Death (DCD)	<p>“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)</p> <p>“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)</p> <p>“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)</p>
3.2.2 Experiences of the transition from end of life to organ donation discussions	<p>“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)</p> <p>“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... 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)</p> <p>“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</p>

Table 3 (continued)

3.1 Family behaviours and decisions	
	<p>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)</p> <p>“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)</p>
3.2.3 Experiences of consent and associated paperwork and processes	<p>“No. It’s 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)</p> <p>“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 [Islets i.e. in the pancreas] I don’t even know what these are, but yes we said yes” (077, sibling, deemed consent)</p> <p>“[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)</p> <p>“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 fuck is going on! Don’t get rid of those questions – they were the only good thing about it all.” (052, daughter, ODR-In)</p>
	(continued on next page)

Table 3 (continued)

3.1 Family behaviours and decisions
<p>"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)</p>
<p>"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)</p>
<p>"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)</p>
<p>"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,</p>

Table 3 (continued)

3.1 Family behaviours and decisions
<p>cannot remember, thinks said no to skin, eyes and research which might involve animals in the future).</p>
<p>"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)</p>
<p>"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)</p>

Not supporting deemed consent. Families struggled to view deemed consent as affirming that their relative would have supported organ donation. The quotes in Table 3 illustrate the uncertainty of deemed consent, which allowed family members to rehearse the value they themselves placed on organ donation (rather than the deceased person's valuation).

Morris and Holt also suggested that the opt-out system involving family members could allow 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 as illustrated in Table 3.

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.

Some families who declined organ donation via deemed consent had recommendations to make organ donation more personal (and thus more acceptable) by informing the family about who the organs would be 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 with their own values and preferences, and create a legitimate and defensible alternative narrative as to why the organ donation should not proceed.

(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 decisions without the deemed consent option. The utilitarian values implicit in the Act were only helpful for families in supporting deemed consent if the family supported organ donation, if 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.

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 2023. In our sample, we did not recruit any families that had overridden a verbally expressed decision, although as reported in an analysis of staff experiences, 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 [19].

In our sample, two families overrode an opt-in decision on the Organ Donor Register (ODR). The ODR registration created conflict and confusion in these families. 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 formally a long time ago, a passing remark (after the registered decision) without any substantial detail, and a (vague) memory of such remarks, 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 an outdated 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).

The verbally expressed pathway created more problems for families. There were more opportunities for families to disagree when there was no ODR decision. They were more prone to question the relative who recalled the decision and to put that relative under pressure. Some even claimed that the deceased was unaware of the implications of what they were saying at the time. This created a context to challenge the validity of the expressed consent, and then turn it into a legitimate expressed 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 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.

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 with relatives, or did nothing, thereby opening up the deemed consent pathway. In reality, family members were in 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 felt 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 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 and these are expanded with quotes in Table 3.

In the following sub-themes, we move on to 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. Overall, the factors reported by families as influences on their decisions to agree to deceased organ donation are summarised in Table 3 and match well with previous studies [20–22].

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, families fully supported their relative's verbally expressed decision in 5 cases and 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, in 16 cases the family said "yes" to some organs, tissues and processes but not others. Although it has no legal status, the 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.

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.

Experiences of navigating and following organ donation systems and processes

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

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 organ retrieval.

In all of the sub-themes reported below, we also found 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.

The different experiences of donation via brain death (DBD) and donation via circulatory death (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. This often involved cases where there was perceived delays in withdrawing treatment and progressing to funeral arrangements, often combined with no guarantees of a successful organ retrieval. If family members saw other family members in (increasing) distress this (often in combination with the aforementioned) tended to lead to a rejection of the utilitarian benefit to transplant recipients and a shift towards what was best for the family.

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.

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.

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 their relative and the family being cared for to, 'they want something'. Some family members became very suspicious very quickly, about what had happened previously and what lay ahead, which they (as yet) knew nothing about. At the same time, families frequently described the topic of organ donation coming too late, getting confused with end-of-life discussions, and thus becoming too much to bear on top of preceding events and decisions.

Experiences of consent and associated paperwork and processes

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

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. 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.

As a result, 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. These are summarised in [Supplemental File 3](#). 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 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. 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, as 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.

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.

Valuing SNODs and SRs

All family members commented that the care and support received from the SNODs/SRs was outstanding. This included families who eventually refused organ donation. Families noticed an increase in support once the SNOD/SR arrived. Most felt that they would not have been able to get through the long process without the SNODs/SRs. After-care 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 refusal was 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 because anything would have changed or influenced their behaviour regarding organ donation.

Perspectives of the SNODs and SRs as to why families said no

The SNOD/SR free text responses regarding another 23 cases (who either declined an interview or were not able to be asked) indicated that families were declining organ donation based on several factors. These included the length of time and processes involved in retrieval, family disagreements (often in the aftermath of the suddenness of the death), in chaotic (family) circumstances, and religious beliefs. However the SNODs/SRs often noted that religious objections could be 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 to enable family members to support organ donation. Some stated that the law was too soft and 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

This is the first large-scale and rigorously conducted theory-informed and theory-testing qualitative study with families approached about organ donation following implementation of the soft opt-out system in England. Overall, the legislation was intended to make it easier for people to donate their organs to benefit transplant recipients (the utilitarian principle of helping transplant recipients). In doing so, the 'soft' opt-out legislation 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 an overly long and complex nurse-led process that tries to reconcile these two competing perspectives but satisfies neither. This study also presents the first test of the utilitarian principles underpinning the Act in a real world setting. Findings support the hypotheses of Morris and Holt, thereby suggesting that a new theoretical approach is required to change the behaviours of family members to one that supports the donation decision made by their relative during their lifetime. This study fills important gaps in previous understanding as to why and how families come to decline or not fully support deceased organ donation by agreeing to some organs and tissues but not others. Consent rates have gone down since the implementation of the Act during the pandemic. While it is perhaps too early to tell whether they will recover, the findings presented here do not provide clear grounds for optimism.

Families did not base their decisions on what was assumed would happen in the legislation. Many families did something completely different, and slowly created alternate narrative(s) to unpick the deceased's decision or implied decision made in life, to the point where the goal to save lives (so easy for the living to endorse as a matter of principle) disappeared completely from bereaved families' decision-making

considerations and subsequent behaviour. Family members were frequently unpicking the decisions of the deceased and subtly imposing their own values, judgements and preferences on the process to challenge and overturn the consent given in life by the deceased person. Families who declined donation generally became increasingly ambivalent and then negative about organ donation during the very long and complex process [23]. This was especially the case when families did not know what their relative would have wanted, which created a specific barrier to seeing the benefits of organ donation for potential recipients [24]. 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 [25]. As a result, many families struggled to comprehend the processes involved in organ donation. They most frequently asked themselves if their relative would have wanted organ retrieval, and not whether the person who died wanted to save lives (in line with the utilitarian principle underpinning the Act) [14].

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 family members and close friends to support organ donation [26]. 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 in the UK, having been replaced with messaging around talking about organ donation and the benefits to others, following the law change.

Families greatly valued the guidance, support and reassurance provided by SNODs/SRs throughout the difficult process [27]. Nonetheless, irrespective of whether the families said "yes" or "no", most found the process(es) exhausting and distressing. For families who supported deceased donation, they were enduring the overly long and complex process for the benefit of others. Nonetheless, irrespective of which clinical or consent pathway applied, for most, there remained a threshold beyond which the family were unwilling to go in terms of organ donation.

Findings also show that SNODs and SRs, although highly valued, have no new strategies or tools available to them under the new opt-out legislation to ensure that the donation decision of the deceased person made during their lifetime is honoured by their family members when they die [19,28]. The ODR only gives an indication of the person's in principle support for organ donation but has no legal status and potential organ donors are generally not nominating a representative outside of their family to convey their donation decision if they die.

In another workstream of this study looking at the attitudes of the public [2], we found that the broadly utilitarian social values underpinning the Act aligned well with many (but not all) of individual's in principle support for organ donation; 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 by donating their organs or tissues to a living person. This fits well with deemed (also called presumed consent); i.e. a form of implied consent which represents one fewer thing for people to have to do in a busy world. It can be seen as logical to introduce legislation which switches the default to align with these utilitarian values. However, these utilitarian principles fail to hold up in circumstances of the acutely bereaved having to support their relative's organ donation decision made in life.

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 (used in the early government publicity ahead of the law change) 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 for people to register organ donation decisions, more 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 should help families see the benefits to them of enabling the donation of organs and tissues which can save lives and improve treatments. Elsewhere we report the impact of implementation across the service which includes system wide recommendations with a view towards simplification [9].

Strengths and limitations

This study was very rigorously conducted and we were able to include a wide range of perspectives, including families who declined organ donation who have not been well represented in previous research. We were limited to recruiting family members through the SNODs/SRs at the bedside which meant that not all eligible participants were given opportunities to decide if they wanted to take part or not. We did not recruit any nominated representatives, but the ODR shows that only a handful of potential donors have nominated one.

Conclusion

Given the traumatic circumstances which often precede organ donation, the (very) soft opt-out policy in England was unlikely to empower SNODs/SRs to help families at their most vulnerable to any great degree to increase their support for and consent to deceased organ donation. 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 what their relative wanted happens. If families become more aware of their changed (but essential) role, this may create new narratives for families. These new narratives would ideally focus less on processes involved in organ donation and retrieval, and more about what family members are able to do to help those in need of an organ transplant by honouring their relative's decision made in life to donate.

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Ethical statement

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. We adapted a framework for ethical decision-making used successfully in previous studies which focused on respect, compassion, options and choices, support and inclusion, and which incorporated a distress protocol.

CRedit authorship contribution statement

Leah McLaughlin: Writing – original draft, Visualization, Validation, Resources, Project administration, Methodology, Investigation,

Funding acquisition, Formal analysis, Data curation, Conceptualization. **Nicholas Mays:** Writing – review & editing, Supervision, Funding acquisition, Formal analysis, Conceptualization. **Mustafa Al-Haboubi:** Writing – review & editing, Validation, Resources, Investigation, Formal analysis. **Lorraine Williams:** Writing – review & editing, Investigation, Formal analysis, Data curation. **Jennifer Bostock:** Writing – review & editing, Validation, Funding acquisition, Formal analysis. **Paul Boadu:** Writing – review & editing, Validation, Investigation, Formal analysis. **Jane Noyes:** Writing – review & editing, Validation, Supervision, Methodology, Investigation, Funding acquisition, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.iccn.2024.103816>.

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