Max and Keira's Legacy: Evaluating the 2019 Deemed Consent Act's Impact on Specialist Nurse Education

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Abstract

Background:

Organ donation represents a rare yet vital opportunity to save and improve lives. In the UK, only around 1% of deaths occur in circumstances that permit organ donation, and three people die each day while waiting for a transplant. Despite this ongoing need, consent rates have declined. In response, the Organ Donation (Deemed Consent) Act 2019 (ODDC Act 2019) introduced an 'opt-out' system, whereby adults are considered willing to donate unless they have formally recorded a decision not to. However, emerging evidence indicates that legislation alone cannot address the complex, multifactorial influences on consent.

The ODDC Act is intentionally 'soft', meaning families are always consulted. In practice, grieving and unprepared families may struggle to uphold their relative's wishes where no prior discussion has taken place, or no clear evidence of intent exists. Although Specialist Nurses in Organ Donation (Specialist Nurses) received a comprehensive, tri-modular national training programme to support implementation, the rollout coincided with the COVID-19 pandemic (2020–2022). During this period, public education initiatives, including the 'Pass It On' campaign, were paused, limiting public awareness and understanding of deemed consent.

This thesis evaluates the development, delivery, and effectiveness of the Specialist Nurse training programme between 2020 and 2023. Using a multi-phased, mixed-methods complex systems evaluation, the research evaluates how the Opt-out Education Programme (OOEP) functioned and supported Specialist Nurses in implementing the Organ Donation (Deemed Consent) Act (2019), and generates system-level insights into the strengths and limitations of the UK organ donation system under deemed consent.

Methods:

Nine interconnected workstreams were undertaken, incorporating desk-based and field-based enquiry to evaluate organisational readiness and real-world implementation. Desk-based Workstreams 1.1 and 1.2 included a national Training Needs Analysis survey (n = 117), exploring preferred learning formats and baseline legislative understanding, alongside a series of Operational Survey Temperature Checks assessing emerging confidence and preparedness ahead of implementation. Workstream 1.3 analysed post-course evaluations from the three national training modules: Module 1 (n = 298), Module 2 (n = 248), and Module 3 (n = 215), focusing on perceived clarity, relevance, and usefulness.

Workstream 1.4 involved a critical friend pilot with seven expert Specialist Nurses, including a donor family representative, to review training design and clinical relevance.

Field-based Workstream 2.1 evaluated a three-hour online training session with eight participants, comparing virtual and classroom delivery while piloting the observational tool. Workstream 2.2 then moved into clinical practice, conducting real-time observations of Specialist Nurses undertaking family approaches under deemed consent. An observational framework aligned with Bloom's Taxonomy was used to assess how Specialist Nurses remembered, understood, applied, analysed, evaluated, and creatively adapted communication strategies in response to family needs. Workstream 2.3 comprised structured post-approach debriefs using Rolfe et al.'s (2001) 'What? So What? Now What?' reflective model to elucidate decision making and identify areas for refinement. Workstream 2.4 involved semi-structured interviews with 24 Specialist Nurses, exploring knowledge, confidence, attitudes, and operational interpretation across varied contexts. Finally, Workstream 2.5 surveyed the Specialist Nurse workforce in England, enabling national-level comparison with in-depth regional findings.

Findings and Conclusions:

The introduction of deemed consent during the COVID-19 pandemic limited public understanding of the law and coincided with declining consent rates and reduced public trust in the NHS, negatively affecting Specialist Nurses' confidence in invoking the legislation. Nonetheless, observational findings demonstrate that families are more likely to support donation when Specialist Nurses provide clear, empathetic, and meaningful explanations, outlining the donation pathway, addressing concerns sensitively, and emphasising the comfort, reassurance, and legacy donation can offer. Such conversations can positively influence families who initially feel uncertain or inclined to refuse.

A key theoretical contribution of this research is the inductive identification of *phronesis*, practical wisdom, as central to effective practice under deemed consent. Observational and interview data revealed that successful family approaches required more than procedural knowledge; they depended on moral, relational, and contextual judgement enacted in real time. These insights informed the development of a Phronesis-Based Assessment Framework, grounded in Bloom's Taxonomy, to evaluate both cognitive and wisdom-based dimensions of practice. The framework maps performance across six levels: remembering legislative criteria; understanding safeguards; applying tailored explanations; analysing and structuring donation conversations; evaluating legislative nuances; and creating new narratives when deemed consent is inappropriate or ineffective.

By integrating knowledge, ethical reasoning, contextual awareness, and compassionate communication, the framework demonstrates that legislation alone cannot improve donation outcomes. Rather, skilled and well-supported Specialist Nurses, exercising *phronesis* in practice, play a vital role in enabling informed family decision making under deemed consent.

Acknowledgements

I offer my heartfelt gratitude to Max and Keira, whose extraordinary gift made the opt-out law possible. I am deeply thankful to the potential donors and their families who, in the midst of sudden and devastating loss, allowed me to observe such sensitive and intimate conversations. I am equally grateful to the Specialist Nurses and Requesters whose compassion, professionalism, and expertise highlight the importance of this privileged and highly specialised role. Without the generosity of all these individuals, this research would not have been possible. I hope that what I have witnessed and learned will contribute meaningful knowledge to the field, offering comfort and support to families facing similar tragedies, and ultimately helping to save and transform lives.

My sincere thanks go to my supervisor, Professor Ben Kotzee, for his unwavering support, wisdom, and encouragement throughout this journey, and to Dr Ruth Wareham for her invaluable guidance. I am also grateful to my examiners, Professor Greenway and Dr Bailey, for their thoughtful questions, helpful feedback during the viva, and subsequent written recommendations, which strengthened this thesis. I am deeply grateful to Olive McGowan, Chief Nurse, for her belief in me and her continued support, particularly at moments of self-doubt. I would also like to thank colleagues past and present, Louise Hubner, Helen Bentley, Susan Lee, Jenny Hughes, Gordon Turpie, and Sam Halcrow, as well as the wider Professional Development and Legislation Change team and other collaborators, for their insight and generosity. My thanks also go to Sasha Cooke for her patient support with formatting, and to Jane Gray, Knowledge and Library Services Manager, for assistance with the literature search.

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Finally, I wish to thank those closest to me, with a heartfelt thank you to my wonderful husband for his kind and caring words of encouragement, and to our beautiful girls, Eva and Orla, who continue to inspire me every day. To my parents, Margaret and John, who predeceased me and instilled in me the Irish values of humour, humility, and tenacity, I remain forever grateful. To my brother, Kevin, whose quiet influence endures, I hope this reflects the pride you always had in me. And to my best friend, Martina, thank you for your constant encouragement. Throughout this PhD journey, I have drawn strength from an Irish proverb: *"Más cam nó díreach an ród, 's é an bóthar mór an t-aicearra."* Whether the road is straight or winding, sometimes the longer path is the one that brings you home!

Preface

This research has been motivated by over 20 years' experience working for NHS Blood and Transplant (NHSBT). Serving as a Donor Liaison Nurse (2001-2004), Specialist Nurse-Organ Donation (2004-2010), Specialist Nurse seconded to write policy and procedures for organ donation under the European Organ Donation Directive (2010-2011), Education and Service Development Manager (2011-2013), Secondment - Education and Governance Workstream Lead for opt-out (2019-2021) and Head of Education and Professional Development (2013–2019 & 2021 to the present day), my professional life has been devoted to advancing the cause of organ donation and transplantation.

Today, as one of the two Heads of Education and Professional Development, my main responsibility entails working closely with the NHSBT team to provide education and training to 300 Specialist Nurses specialising in organ donation and organ request procedures across the UK. These 300 Specialist Nurses are composed of two groups. Specialist Nurses-Organ Donation (SNODs), of whom there are 211, cover the entire donation pathway and Specialist Requesters (SRs), of whom there are 62, predominantly focus on requesting organ donation. In this thesis I will collectively refer to both roles as Specialist Nurses, until specific distinctions are necessary, when discussing the participant observations.

As a former Specialist Nurse, I've had the privilege of connecting with many donor families during what can only be described as intensely emotional and distressing moments in their lives. My role involved empowering families to support organ donation, which has driven my passion to explore the motivations behind their selfless support for organ and tissue donation. I am committed to understanding how we can best educate, train, and support Specialist Nurses to empower families in making informed and enduring donation decisions, ultimately contributing to saving and improving even more lives.

The idea for this thesis was formed in 2018, after completing my Master's degree, I collaborated with my supervisor to publish a paper titled 'Factors Influencing Families' Decisions Regarding Organ Donation' (Miller and Breakwell, 2018). This research not only contributed to my professional development but also allowed me to present at seminars and conferences, informing the education and training of Specialist Nurses. My growing interest in organ donation education and consent motivated me to explore and observe real-time experiences and interactions among Specialist Nurses, doctors, and nurses in the Intensive Care Unit (ICU) as they support potential donor families. This PhD inquiry, with a focus on education, was made possible thanks to a 75% funding grant from NHSBT. Originally designed as an EdD project, the interdependent nature of the research task led to the assessment of a complex system.

This multi-phased, mixed-methods complex systems evaluation addresses the persistent societal challenge of sustaining public support for organ donation, a challenge that spans religion, culture, education, hospital infrastructure, and public awareness. Problems of this nature, including shifts in opt-out legislation, are widely conceptualised as *wicked problems*: issues characterised by interdependent variables, conflicting stakeholder values, and continually evolving circumstances, which make them resistant to straightforward or final solutions (Head, 2022). As Scott (2024) observes, wicked problems are inherently 'messy,' demanding approaches that acknowledge ambiguity, complexity, and the relational dynamics embedded within them. Such problems involve incomplete, shifting, and contested information, making simple or universally accepted definitions impossible. Addressing wicked problems therefore requires more than technical expertise; it demands a deep understanding of stakeholders and the systems in which they operate. Systems thinking provides a useful way to engage with this complexity by revealing the interconnections, tensions, and feedback loops that shape how such issues develop. This holistic perspective enables more adaptive, innovative strategies and supports sensitive, informed responses to the evolving realities of organ donation policy and practice.

Publications, Conference Presentation and Award Arising from this Thesis

The research journey has been a long one, involving collaborating with my supervisors, colleagues at NHSBT and in the broader organ donation community. Some of my work has been published in article format and I draw on some of these papers in my thesis although there is no simple reproduction of any of these papers. I would like to thank all my co-authors and journal editors.

Publications

Hubner, L., Miller, C., Roberts, C., Paterson ,S. (2020) 'Implementing a legislation change in organ and tissue donation in England', *British Journal of Nursing.*29 (3), pp. 168-169.

Miller, C., Hubner, L., Griffiths, A. (2020) 'Legislation change in organ and tissue donation: educating specialist staff', *British Journal of Nursing*, 29, pp. 318–320.

Miller C, Hubner L, Roberts C, Paterson, S. (2020) 'Evaluation of staff training on legislation change in organ and tissue donation', *British Journal of Nursing*, 29, pp. 974–977.

Miller, C., Hubner, L., Cotter, B. (2021) 'Consolidating education on organ and tissue donation legislation changes', *British Journal of Nursing*, 29, pp. 1282–1285.

Miller, C., Hubner, L., Paterson, S, Cotter, B., Walton, P., Bentley, H., Roberts, Claire. (2021) 'Embedding changes in legislation for organ and tissue donation across England and Jersey', *British Journal of Nursing*. 30, pp. 310–312.

Miller, C., and Kotzee, B. (2026, accepted for publication) 'From Opt-Out to Action: Evaluating Specialist Nurse Organ Donation Training', *British Journal of Nursing*.

Rees, K., McLaughlin, L., Paredes-Zapata, D., Miller, C., Mays, N and Jane Noyes (2024) 'Qualitative Content and Discourse Analysis comparing the current consent systems for deceased organ donation in Spain and England', *Transplant International*, (37):12533 doi:10.3389/ti.2024.12533.

Walton, P., Miller, C., Maycock., S, Nocol, K. (2020) 'Deemed consent to organ donation: what critical care nurses need to know', *British Journal of Nursing*, 29, pp. 910–912. doi:10.12968/bjon.2020.29.15.910.

Conference Presentations

Miller, C. (2025, accepted for oral presentation) *Beyond Legislation: Evaluating Specialist Nurse Training and the Human Dimensions of England's Opt-Out Organ Donation Law*. Paper presented at the International Society for Organ Donation and Procurement (ISODP) Conference, **Japan**, 5th December 2025.

Miller, C (2025, accepted for oral presentation) *Deemed Consent Training for Specialist Nurses: Time to Evaluate and Elevate!* Paper presented at the British Transplantation Society Annual Congress 12th to 14th March 2025, **Brighton** - United Kingdom

Miller, C (2023) (2025, accepted for oral presentation) *Stories from around the Commonwealth: How we approach families about organ donation*. Paper presented at the British Transplantation Society and NHSBT Joint Congress 1st to 3rd March 2023 **Edinburgh** - United Kingdom.

Awards

Learning leader of the Year Gold Award 2021 – Learning Performance Institute

In 2021, I received the Learning Leader of the Year Gold Award for my leadership in educating Specialist Nurses about securing consent for organ donation under the new Organ Donation Deemed Consent Act (2019). The nomination came from the dedicated Opt-Out Legislation Change Team (LCT), whom I was privileged to work with in 2019. Despite COVID-19 challenges, we successfully transitioned from face-to-face to digital training delivery, meeting the 20th of May deadline for the law change. The Learning Performance Institute awards hold significant prestige in the field of education and training and Claudia Winkelman presented the award on 18th February 2021.

The 2021 UK Awards for Excellence in Organ and Tissue Donation and Transplantation

In addition, I received a Highly Commended Award for Excellence in Education - British Transplantation Society and NHSBT Joint Congress 2021.

Declaration

This thesis is submitted for the Degree of Doctor of Philosophy (PhD) in Education at the University of Birmingham. I declare that the work described herein is my own, except where clearly acknowledged and stated otherwise. I certify that I have not submitted any of the material in this thesis for a degree qualification at this or any other University.

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Glossary of Acronyms and Abbreviations

BACCN	British Association of Critical Care Nurses
BBN	Breaking Bad News
BMA	British Medical Association
CLOD	Clinical Lead – Organ Donation
COMBi	Competence Opportunity Motivation to Change Behaviour – Theory
DBD	Donation following Brain Death
DCD	Donation following Circulatory Death
DHSC	Department of Health and Social Care
DDR	Dead Donor Rule The dead donor rule is standardly formulated as the rule that 'donors must be determined to be dead before their organs are recovered'.
EOLC	End of Life Care
ED	Emergency Department (or Accident and Emergency)
Forum Theatre	The engagement of spectators influencing and engaging with the performance as both spectators and actors, termed 'spect-actors', with the power to stop and change the performance.
HoE	Head of Education and Professional Development
HCRW	Health and Care Research Wales
HRA	Health Research Authority
HTA	Human Tissue Authority
HTA Cop F	Human Tissue Authority Code of Practice F (Part two: Deceased organ and tissue donation)
LTEM	Learning Transfer Evaluation Model
ICU/ITU	Intensive Care Unit/Intensive Therapy Unit

IRAS	Integrated Research Application System
KPI	Key Performance Indicators
LTEM	Learning Transfer Evaluation Model
LCT	Legislation Change Team
ME	Minority Ethnic
NHS	National Health Service
NHS REC	National Health Service Research Ethic Committee
NHSBT	National Health Service Blood and Transplant
NIHR	National Institute of Health Research
NOK	Next of Kin
ODR	Organ Donor Register
ODTF	The Organ Donation Taskforce
OOEP	Opt-Out Education Programme
ODDC Act 2019	Organ Donation Deemed Consent Act (2019)
OTDT	Organ and Tissue Donation and Transplantation
PDA	Potential Donor Audit
PDS	Professional Development Specialist
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
SR	Specialist Requester (for organ donation)
UK	United Kingdom

Chapter 1. Introduction

The shortage of donor organs worldwide results in needless deaths while individuals wait for life-saving transplants. In the UK, thousands of people anxiously await a telephone call informing them of a transplantable organ match. Tragically, many die during this waiting period. The stark reality is that only one percent of the population who die, do so in circumstances where donation is possible, typically in an Intensive Care Unit (ICU) while ventilated.

The ethical complexities of organ donation and consent are undeniable. The consenting to remove an organ from a deceased loved one to save another's life is arguably one of the most challenging decisions a person or their family could face at the end of life. Opt-in donor consent systems require individuals actively to express their preferences for being a deceased organ donor after their death (Etheredge, 2021). This is typically achieved by the individual explicitly consenting to join the Organ Donor Register (ODR). The primary advantage of the opt-in system is its *transparency*; donors are fully aware of their participation and can make *informed* decisions. A key limitation of opt-in systems is their lower participation rate, as many people avoid taking the required action, often because doing so involves contemplating their own death. As a result, fewer individuals register, leading to reduced donation opportunities and, consequently, fewer transplants (Lytle, 2021).

Opt-out, also known as deemed, presumed or assumed consent donor systems, presume all individuals residing in a country to be willing deceased organ donors unless they specifically opt-out of doing so or raise an objection (Etheredge, 2021). These systems are designed to boost participation rates by automatically including individuals. This approach results in higher engagement, increased donations, and ultimately, more transplants. Opt-out systems can streamline and simplify processes. However, there are disadvantages to an opt-out system. The presumption of consent assumes consent without explicit confirmation. Opt-out systems therefore raise the ethical question: 'how can we be sure that someone would have consented if they were aware?' Some scholars argue that opt-out systems risk undermining genuine consent and may be perceived as coercive (MacKay, 2015). In addition to these ethical worries, the practical implementation of an opt-out system is not as straightforward as it seems. Efforts to implement the Welsh deemed consent system in 2015 depended heavily on creating a social context in which organ donation was perceived as a normal and expected behaviour. As Noyes et al, (2017) noted, public communication needed to encourage people to act as intended under the legislation, either, *formally record their decision, appoint a representative, discuss their wishes with family, or do nothing and therefore be considered to have consented*. In practice, however, families often struggle to interpret deemed consent when no prior discussion or recorded decision exists. This uncertainty can make it difficult for them to set aside their own views and support donation on behalf of the deceased, a challenge highlighted by Noyes et al, (2019).

Specialist Nurses play a vital role in supporting families to honour their loved ones' wishes, providing positive information about the benefits of organ donation. Despite these efforts, some family members still struggle with their own emotions and views regarding donation (McLaughlin et al, 2024).

Regrettably, some later experience grief compounded by intrusive thoughts related to end-of-life decisions for others (Shiozaki et al, 2008). Striking the right balance is challenging, resulting in some countries implementing hybrid systems or variations. Regardless of the system in place, public awareness, including transparent communication about donation processes and the ability to opt out are vital. Regular evaluation and adjustment of donation systems is paramount, to ensure that they remain ethical and effective. Ultimately, the goal is to maximise donations while respecting individual autonomy and ethical principles. The donation decision is one of the most difficult decisions any dying person, or their family, can make. The time around death is highly emotionally charged. Donation is a big decision to make when families are shocked, distressed and cognitively ill-equipped due to grief, to think straight. Relatives, faced with the grief of losing a loved one, must navigate a decision-making process related to organ donation. This process involves balancing their own beliefs and attitudes with the evoked wishes of the deceased (López et al, 2018). Healthcare professionals' (HCP's) interactions and behaviour also play a role in shaping family members' feelings and decisions during this challenging time. The family interview to ascertain the deceased's wishes regarding organ donation is not only a legal necessity but also the point at which most potential donors are lost (Frutos et al, 2005). Families often find it difficult to know what to do; torn between what is the right thing to do in the eyes of the law or of society and what feels right to them personally. It is not surprising that the shortage of organs for transplantation partly stems from family members' refusal to consent to donation during such a difficult and traumatic time. Opt-out legislation aims to release the burden of decision making from the family and can take different forms, such as *soft* or *hard* opt-out policies. However, despite having such legislation in place, families in most countries are still consulted, and their preferences often take precedence over the deceased individual's wishes (Costa-Font et al, 2021).

1.1. Enactment of the Organ Donation (Deemed Consent) Act 2019

In England, in response to these challenges, the Organ Donation (Deemed Consent) Act was passed in 2019. This follows the implementation of similar legislation in Wales in 2015. The ODDC Act 2019 was implemented in May 2020; however, as will be amply illustrated in this thesis, the implementation effort was hampered by the COVID-19 pandemic, which disrupted public awareness campaigns and saw Specialist Nurses moved from their organ donation responsibilities and deployed to Intensive Care Units (ICU's) to assist during the crisis. While the merits of a deemed consent system have been debated for many years, the catalyst behind the introduction of the ODDC Act (2019) was the case of two nine-year old children, Max Johnson and Keira Ball. Keira, who tragically lost her life, donated her heart to Max, and their story inspired the subsequent opt-out law named after them both. (Dr Rachel Clarke has published a book in 2024, entitled '*The Story of a Heart*' in their memory).

The ODDC Act 2019 originated in the House of Commons during the 2017-2019 session, making amendments to the Human Tissue Act (2004) regarding consent for activities related to transplantation. The legislation was introduced in Parliament as a private member's bill in the House of Commons by Geoffrey Robinson (then Labour MP for Coventry North-West) and was taken through the House of Lords by Lord Hunt of King's Heath – Birmingham (Labour). It received cross-party support. The Bill allowed for consent to be deemed given by a potential adult organ donor before their death, unless they had expressly stated otherwise, or an exception. In 2019 NHS Blood and Transplant (NHSBT), the National UK organisation responsible for managing blood, plasma and platelet donation, and organ, stem cell and tissue donation and transplantation; set up a programme board to implement the ODDC Act 2019 (Fig.1). The portfolio of projects and workstreams were structured into five projects under NHSBT management; Information and Communications Technology, Communications, Operations, Scotland and Tissues and Commissioning depicted below. In my capacity of Workstream Lead for Education and Governance, (Fig.2) together with one Team Manager and five Professional Development Specialists (PDSs), we formed the Legislation Change Team (LCT). Together we were responsible for devising and implementing an effective education and training program to support Specialist Nurses in applying the legislation in clinical practice. This initiative also aimed to meet the Department of Health and Social Care's (DHSC) target of ensuring that 100% of Specialist Nurses on the on-call rota were adequately trained.

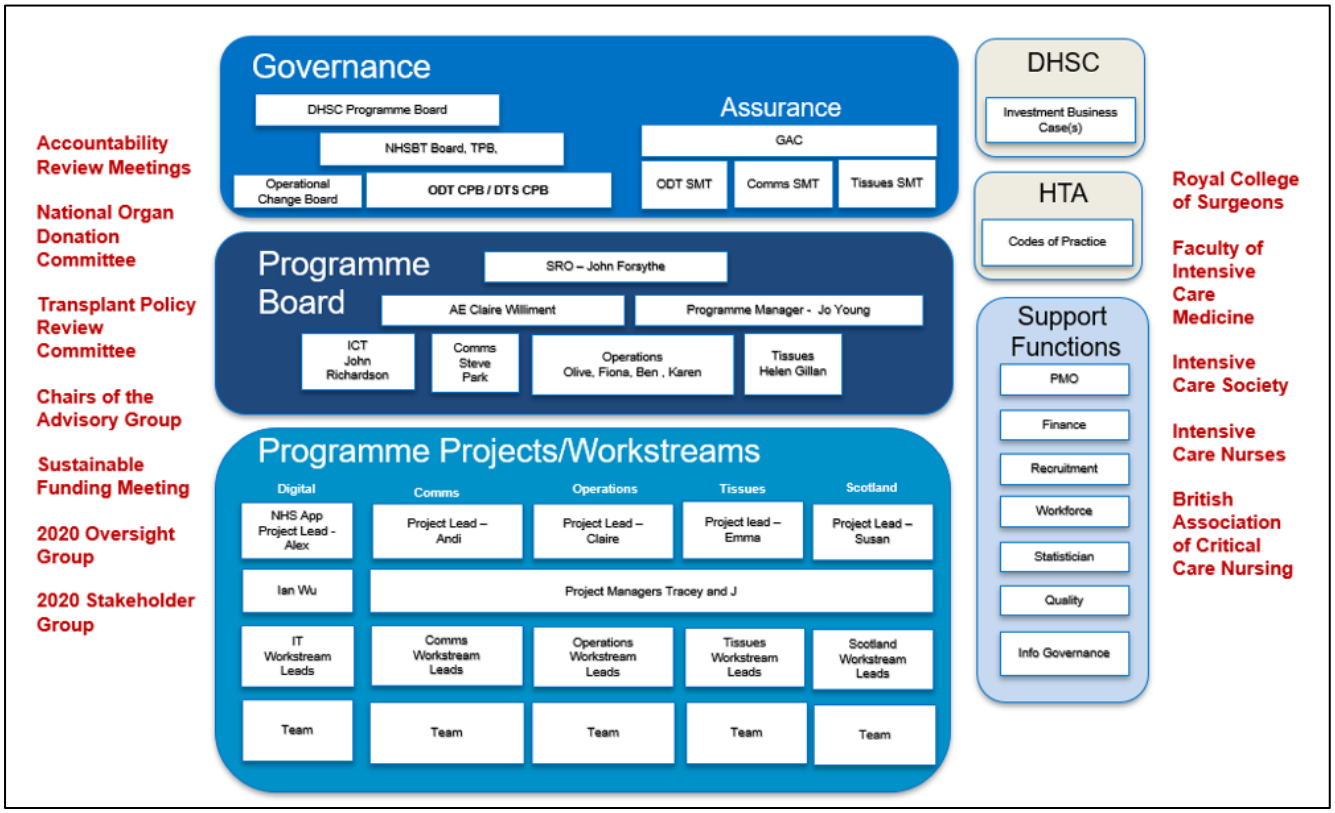

Figure 1 - NHSBT's agreed Programme Model for implementing opt-out system

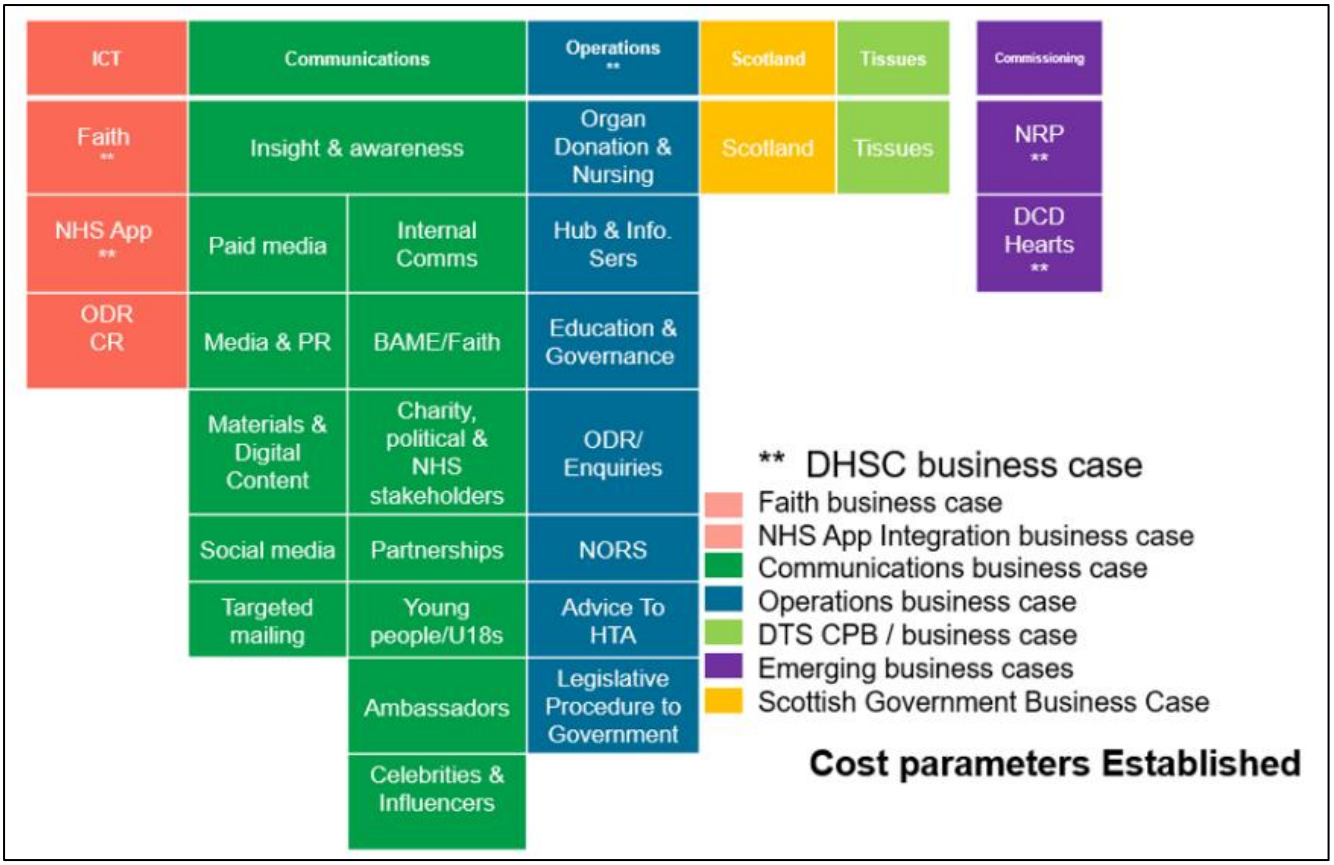

Figure 2 - NHSBT's Portfolio of Projects/Workstreams to Implement the Opt-Out System in England

In preparation for the change in legislation, a bespoke three-part Opt-Out Education Programme (OOEP) was developed and tested by the LCT. The modules were designed based on Malcolm Knowles adult learning theory (andragogy) (Knowles, 1988) and Benjamin Bloom's Taxonomy (1956). The first module was an exploration of the theoretical aspects of the law change, followed by module two's practical exercises involving donation conversations with professional actors. These exercises empowered Specialist Nurses to practice the deemed approach conversation in a secure environment. The third and final module seamlessly integrated both theory and practice, equipping the Specialist Nurses for the implementation of the new legislation. Drawing lessons from other countries, such as Spain, the NHSBT team recognised that legislation alone will not provide a 'magic' solution to the organ donation crisis. Factors like public awareness, infrastructure, education, and training would all play important roles. Embedding the law change would require more than a one-off approach; it would involve a cultural shift, a change of hearts and minds, and not just a simple mandate that everyone must follow.

Importantly, the ODDC Act (2019) was implemented against a backdrop of massive uncertainty. There is limited evidence regarding effective education and training strategies for implementing an opt out system (Walton et al, 2023). Specifically, there is, until today, a lack of evidence on how Specialist Nurses can positively influence the organ donation decision. It is unclear whether the family members response to the deemed approach is predetermined as either a 'yes' or a 'no', or whether factors such as the information provided, and the compassion shown play a role in shaping the final decision.

Faced with these outlined challenges, starting in 2019 (prior to the law change) this thesis research was designed to answer some of these questions. However, to understand *deemed consent*, it is important understand what makes consent valid.

1.2. Valid (Proper) Consent

To determine if consent is valid, we must consider various forms of consent and their implications. Beauchamp and Childress (2001) describe tacit or implicit consent as silent or passive by default. However, Price (2012) argues that presumed consent is invalid because silence is not typically accepted as consent in legal contexts. Other authors agree that implied consent in this context is consent by default (Lamb, 1990; Ellis, 1998; Hill, 1999) and warn that it may violate individual autonomy, making people feel like 'state-owned commodities' (Gillon, 1985; Wilks, 1998). Presumed consent can also undermine family authority (Cherry, 2019). Promoting organ donation through an opt-out system could damage public trust if organs are perceived as taken rather than given (Wright, 2008; DoH, 2008). This could be seen as the government prioritising its agenda over the family's, increasing distrust (Price, 2002). An opt-out system assumes consent unless individuals explicitly opt out, but not all who fail to opt out would consent to organ use. Beauchamp and Childress (2001) suggest that explicit or implicit consent may not be necessary. David Eastlund's concept of 'normative consent' (Nuffield Council on Bioethics, 2011) suggests that if refusing organ donation is morally wrong, explicit consent might not be necessary. This supports an opt-out system where everyone is considered a donor unless they belong to a safeguarded group or those who do not want to donate their organs. These reasons could be personal, religious, cultural, or ethical. The Mental Capacity Act (2005) allows patients to make advance directives, giving their wishes legal status and preventing family intervention. However, few people create advance directives, so family involvement remains key to maintain public confidence. Negative media coverage, such as the 1992 corneal donation scandal in France, highlights the importance of valid consent. Scandals at Bristol Royal Infirmary and Alder Hey in 2000 further emphasised the need for explicit authorisation for organ and tissue donation (English and Sommerville, 2003; Kennedy, (2016)).

Specialist Nurses in the UK are trained in advanced communication techniques to discuss organ donation with families, avoiding assumptions and using supportive language. It is important to explain the opt-out system and affirm that family support is required for donation to proceed. A common misconception is that of routine salvaging (Durkeminier and Sanders, 1968), whereby myths exist that the organs would be taken regardless of family support under the new law. Organ donation is a precious gift that can save or enhance lives, with a single donor potentially saving up to nine lives. Consent is the fundamental ethical and legal principle in organ donation. The Human Tissue Act (2004) regulates activities involving human tissue, arising from concerns about unauthorised organ retention. Explicit consent involves affirmative actions, while implicit consent occurs when inaction signifies agreement.

Deemed consent, presumes consent unless evidence refutes it. Informed consent ensures transparency, but can be challenging for Specialist Nurses and families, emphasising the family's role in decision-making (Raza and Neuberger, 2022). As we already saw above, organ donation opportunities are rare, with only 1% of deaths in the UK occurring in circumstances suitable for donation (Journey through Intensive Care and the Gift of Organ Donation, 2019). Organs must be retrieved shortly after death and be in a transplantable condition. Due to these constraints, every potential donor is precious.

1.3. Background to organ donation

Advances in organ donation over the years, has meant that in the UK organ retrieval is possible from three sources; neurologic deaths, controlled circulatory deaths, and live donors for kidneys and partial livers. Each of the routes for organ donation are detailed below. Donation after Brainstem Death (DBD) is possible from patients whose death has been confirmed using neurological criteria (also known as brain-stem death or brain death). Neurological criteria for the diagnosis and confirmation of death applies in circumstances where brain injury is suspected to have caused irreversible loss of the capacity for consciousness and irreversible loss of the capacity for respiration before terminal apnoea has resulted in hypoxic cardiac arrest and circulatory standstill (Academy of Medical Royal Colleges, 2025). This diagnosis is only possible in patients who are on mechanical ventilation. Donation after Circulatory Death (DCD), formerly known as Donation after *Cardiac* Death (DCD) or Non-Heart Beating Donation (NHBD), involves the retrieval of organs for transplantation from patients after the Withdrawal of Life-Sustaining Treatment (WoLST). The death of these patients is diagnosed and confirmed based on cardio-respiratory criteria (Academy of Medical Royal Colleges, 2025).

The most donated organ by a person in life, is a kidney, because a healthy person can lead a normal life with only one functioning kidney and, therefore, they are able to donate the other to help someone in need of a kidney transplant. Part of a liver can also be transplanted from a living donor to help someone in need of a liver transplant. Despite the numerous methods available for organ donation, a significant shortage persists. The reasons for this shortage will be examined in turn in the following discussions. Statistics from NHS Blood and Transplant (NHSBT) Activity Report (2023-2024), depicted in the graph below (Fig.3), show 1, 510 donors enabled 3,713 lives to be saved or improved by transplantation. NHSBT’s latest statistical report, shows the number of people on the waiting list for a transplant has reached an all-time high of 7,484 as of the end of March 2024. The red circle marks the impact of COVID 19, which caused a drop in both donors and transplants in 2020.

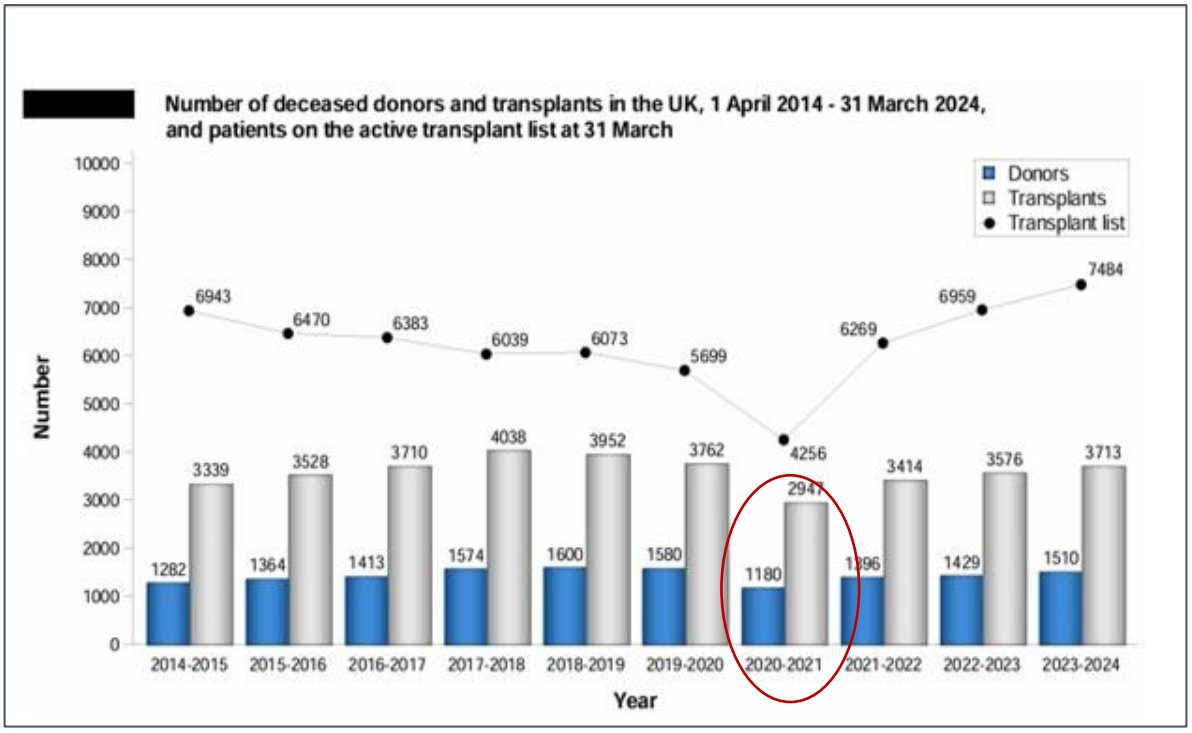

Figure 3 - Number of deceased donors and transplants in the UK, 1st April 2014-31st March 2024, and patients on the active transplant list on the 31st of March 2024.

To close the gap between availability and demand for organs more people need to agree to donate, and more organs need to be retrieved and transplanted successfully. NHS Blood and Transplant's 2030 'Meeting the Need' Strategy aims to improve the organ donation and transplantation service in the UK (NHS Blood and Transplant 2021). The strategy aims to make use of every opportunity for donation and transplant, and to increase the number of donors by implementing of opt out legislation. The shortage for donor organs for transplantation is a worldwide problem. Whilst organ donation saves lives, one of the main challenges is that demand far outstrips supply and people die needlessly, whilst waiting (Etheredge, 2021). This uncomfortable position makes it incumbent on countries to consider different ways to increase organ donation.

Previously, in England an opt-in system was in operation, where people opted-in to be an organ donor via the organ Donor register (ODR), their driver's license, passport or Boots Advantage Card. Since the effective implementation date of the ODDC Act (2019) on May 20th, 2020, all adults in England are now considered potential organ donors unless they choose to opt out or are in a safeguarded group. To protect vulnerable people, the law does not apply to children, only adults of the age of 18 and over, other safeguards and exclusion criteria applies to those who lack the capacity to understand the concept of opting out or those who are not ordinarily a resident in England or those who do not live in England on a voluntarily basis. Also, groups that are harder to reach with health messaging, such as newcomers to England, individuals in unstable living conditions, or those with lower educational levels, are at a higher risk of not knowing how to prevent their organs from being donated against their wishes. The ODDC Act (2019) heralds a new system of consent for organ and tissue donation in England, known as 'opt-out' or 'deemed consent'. It is the intention to increase the number of organs available to people in need of a transplant.

To help overcome this shortage and change the default position. People can make their decision known by opting out of the ODR or verbally expressing that they do not want to a donor to a family member or friend. Other options people have is to appoint or nominate a representative to decide on their behalf after death. Under the new opt-out legislation NHSBT's Specialist Nurses are responsible for conducting sensitive deemed consent conversations and securing consent for organ donation from potential donor families, in a completely new and unfamiliar way. Although the law has changed, families continue to be involved in discussions before organ and tissue donation goes ahead.

1.4. Specialist Nurse Education and Training Program for Opt-Out

In anticipation of implementing deemed consent, a comprehensive OOEP (Fig.4) was specifically designed for Specialist Nurses. The programme covered the following theoretical and practical content.

Theory and Regulation:

a) The theoretical aspects of the law change, including regulations and policies related to organ donation.
b) Specialist Nurses gained a solid understanding of the legal framework and their responsibilities.

Practical Training:

a) In a psychologically safe environment, nurses had the opportunity to practice conversations related to deemed consent.
b) Professional actors played a key role in simulating scenarios, allowing Specialist Nurses to refine their communication skills.

Consolidation Module:

a) The final part of the program brought together theory and practice
b) Participants synthesised their knowledge and learned how to apply it effectively in real-world situations.

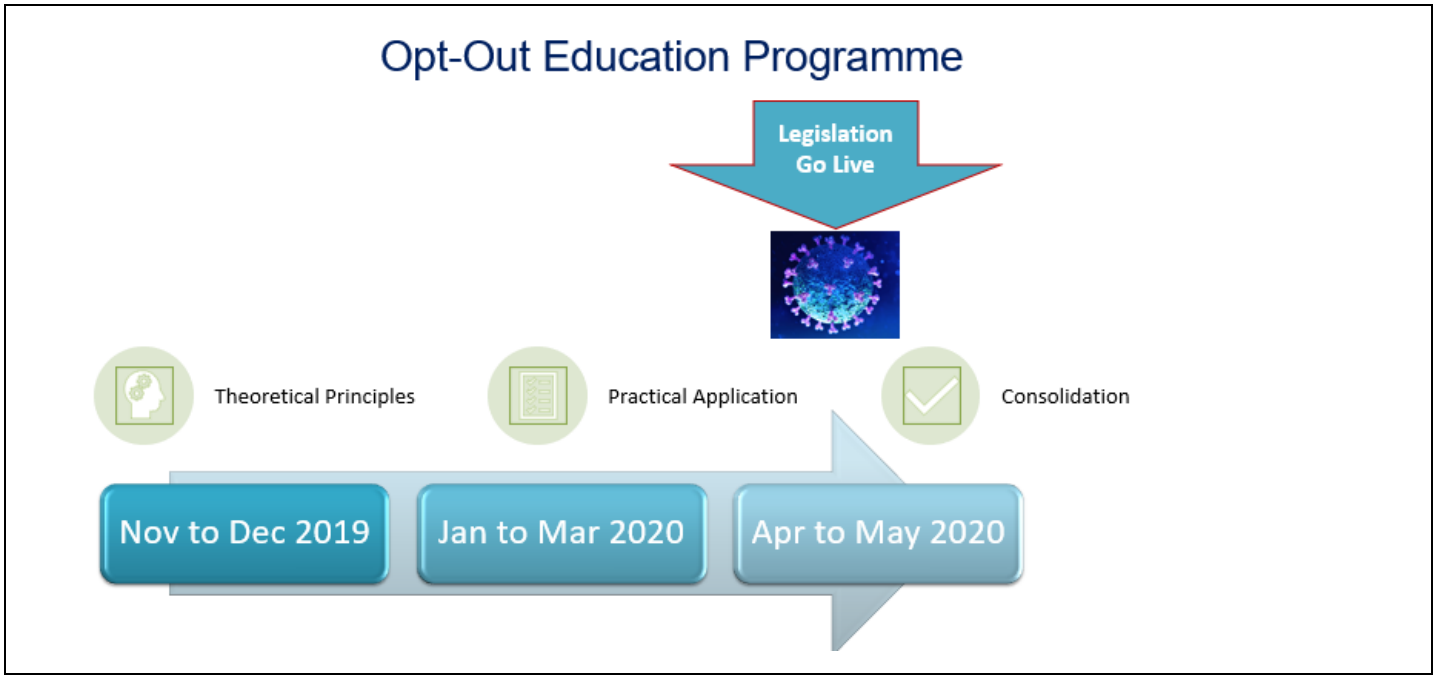

Figure 4 - Opt-Out Education Programme (OOEP)- Content and Timeline

As the Education and Governance Lead for the Legislation Change Team (LCT), I along with other LCT members (including former Specialist Nurses and educators), played a pivotal role in delivering this training. Our collective expertise ensured that Specialist Nurses were well-prepared for the implementation of the law change. The OOEP started in November 2019 and due to the impact of COVID-19 did not finish until July 15th, 2020. Despite the global pandemic, the Deemed Consent Law was enacted on the 20th of May 2020. During the House of Lords debate on 18th May 2020 (Draft Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 Volume 803: debated on Monday 18 May 2020). Lord Bethell, the Parliamentary Under-Secretary of State for Health and Social Care, acknowledged that deemed consent would not come into practice straight away due to COVID-19, and the need to ensure transplants go ahead when it is safe and training for returning Specialist Nurses has been completed.

1.5. The Role of this Thesis

For this thesis, a multi-phased mixed-methods complex systems evaluation of the OOEP, specifically designed for Specialist Nurses as part of NHSBT's wider legislation change programme, was conducted. The complex evaluation consisted of assessments of implementation, process, and impact of the education and training provided to the Specialist Nurses on the law change. The primary goal was to determine the effectiveness of the training provided to Specialist Nurses prior to (2019) during (2020) and immediately after (2020-ongoing embedding) the legislation change period. To achieve this, several research questions were posed, all aimed at addressing the broader overarching question; how did the Organ and Opt-out Education Programme (OOEP) function in practice, and how effectively did it support Specialist Nurses to implement the Organ Donation (Deemed Consent) Act (2019) within the UK organ donation system? The training began in advance of the legislation in 2019; to prepare the Specialist Nurses for the law change in May 2020.

100% of the Specialist Nurses participating on the on-call rota were trained as per the Department of Health and Social Care (DHSC) target and the evaluations for the OOEP showed that the training was well received. However, in order better to understand the effectiveness of the legislation change in the real world, research was conducted regarding the effectiveness of the training after the legislation change had taken effect, to observe how the training changed the Specialist Nurses practice. Observations in the 'real world' clinical context showed a mixed uptake of the legislation. In addition to observing the Specialist Nurses on ICU having sensitive deemed consent conversation, debriefs and semi-structured interviews were undertaken to gather further insight about the impact of the training and hear about the practicalities of implementing the law change from the Specialist Nurses perspective. A final workforce survey was also undertaken to see if the findings were transferable across the whole Specialist Nurse workforce covering England.

After the implementation of the law change, online debriefs and shared practice sessions were facilitated. While the aspects related to the implementation process in complex systems evaluation are valuable, it is equally important to assess whether there was an impact on donation rates. Undoubtedly, even if the Specialist Nurses were effectively trained and applied their training proficiently in the real world after the law change, the ultimate objective was not merely to educate the Specialist Nurses, but to positively influence organ donation rates. However, the impact of the legislative change on donation rates depends on various external factors beyond the legislation itself or the new training program. The subsequent global pandemic affected the training plan, rollout, and public awareness. The complex nature of the research problem required the study to be structured as a complex systems evaluation. It was not just an appraisal of training or its effectiveness; it also focused on the tangible impact of the training by examining how it changed the practices of Specialist Nurses after the law change. This assessment looked at changes in practice, not just training modifications. Additionally, the study examined the entire organ donation system, beyond just the training and practices of Specialist Nurses. As a result, the research, which initially commenced as a training evaluation, gradually transformed into a thorough complex systems evaluation with an emphasis on one practitioner group, the Specialist Nurses.

The thesis begins with a two-part literature search in Chapter Two. Firstly, it aims to highlight the causes of organ shortage. Secondly, it investigates the role of the opt-out system in educating the public and Healthcare Professionals (HCPs), by thoroughly reviewing the literature to examine the evidence backing the opt-out system. Chapter Three details the research methods used for the complex systems evaluation to gauge the impact of the legislation training programme designed for Specialist Nurses in support of the ODDC Act (2019). This includes program training evaluations, participant observation, semi-structured interviews, debriefs, and survey findings. Chapter Four highlights the research findings, followed by a discussion of their implications in Chapter Five. The thesis concludes in Chapter Six with recommendations for future practice. It is hoped that the research will be of relevance and significance in supporting Specialist Nurses as they navigate the practical implementation of the opt-out legislation.

By empowering families to honour their loved one to become an organ donor, the study contributes to saving and improving lives. Additionally, the research offers valuable recommendations on how to effectively apply the legislation.

Chapter 2. Literature Review

This two-part literature review firstly explores the causes of organ shortages, while the second part examines the role of the opt-out system in educating the public and Health Care Professionals (HCPs).

2.1. Literature Search

The purpose of this literature review is to set the scene for the research, by discussing what literature exists in relation to opt out systems, where the gaps might be and how this research might yield new knowledge in the area. The focus will therefore be on why there is an organ shortage, the benefits and disadvantages of an opt out system and the role of education in promoting donation. The literature review is divided into two parts. The first part examines the causes and consequences of the organ shortage, and the second part reviews the literature regarding the impact of presumed consent on organ donation rates and outcomes.

2.1.1. Search Strategy - Phases one and two

In Aveyard's (2018) practical guide to undertaking a literature search in health and social care, the literature review process is described as a 'comprehensive study and interpretation of literature that relates to a particular topic'. Using the Population, Intervention, Comparator and Outcome (PICO) framework (Appendix 1), a research question was developed to help understand the effectiveness of the OOEP. PICO is a method of searching for evidence, commonly used within health and medicine. It helps break down the scenario and turn it into a question (National Institute for Health and Care Excellence (NICE), (2023). The PICO framework helped structure and focus the research question and effectively find the information needed.

The literature search strategy was conducted in two phases. Phase one (Appendix 2) focussing on the reason for the organ shortage and how opt-out aims to address the shortage, using the search terms 'organ donor' or 'organ donation'; 'opt-out' or 'presumed consent' or 'deemed consent'. Phase two of the search refined the impact of opt-out system in addressing the organ shortage and focussed in on the education aspects (Appendix 3). To help refine and focus upon the impact of education on implementing the opt out law change, additional search terms were added including: 'medical education' or 'nursing education' or 'professional education' or 'education' or 'training'. The search was initially conducted and stored on the Healthcare Databases Advanced Search (HDAS) system, which became obsolete after March 2022. Therefore, the search had to be repeated on the new NHS Knowledge and Library Hub platform, developed by Health Education England. The following databases were searched systematically for publications: EMBASE (pharmacological and biomedical literature), BNI (British Nursing Index), CINAHL (Cumulative Index to Nursing and Allied Health Literature), Medline (medical literature) and EMCARE (nursing and allied healthcare database) and PsycINFO (psychological literature).

2.1.2. Categories of papers found during phase one of the literature search

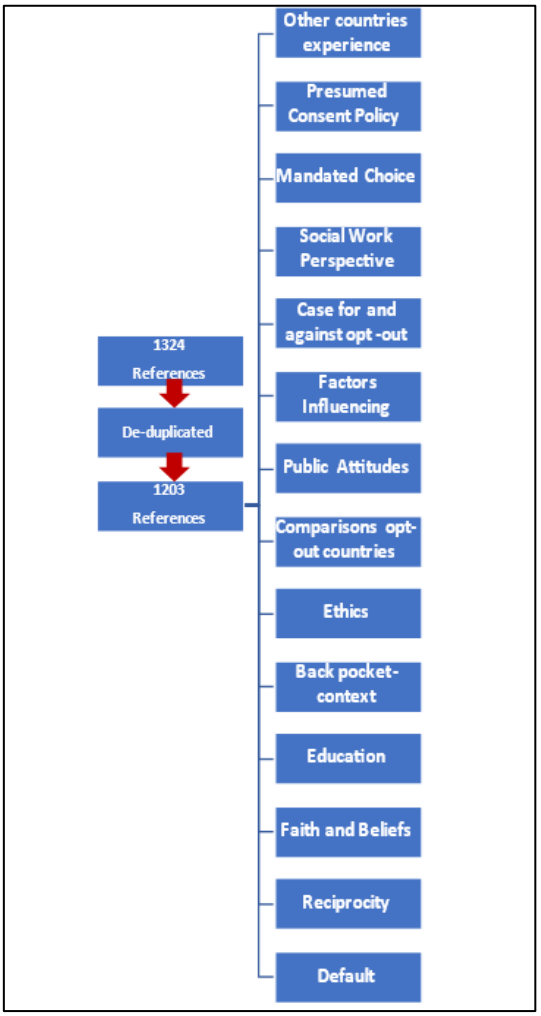

Figure 5 - Phase one of the literature search - impact of deemed consent legislation in addressing the shortage and a particular focus on education

No restrictions were given to the years searched, instead all databases were searched from the coverage start date for each database, to 27th February 2023, yielding 1,357 papers (EMBASE=335; BNI=104, CINAHL=262; MEDLINE=494 and EMCARE=162). After removing duplicates (n154), the search was further refined to 1,203 papers. This early search yielded many papers that were sifted into categories and reviewed to show themes and reasons for the organ shortage, and the impact of opt-out systems are in addressing the shortage. The categories are depicted in the table 1 below.

2.1.3. Education focussed literature search- opt out legislation

Phase two of the literature search involved refining phase one of the literature review and looking at the reasons for the organ shortage to re-focus the search on the education interventions for the law change. To enable an educationally focussed search, two further key words were added: ‘education’ and ‘training’, using the controlled thesaurus terms (where available) for the individual databases to include, nursing, medical and health care professional education.

The results narrowed the initial search down to 159 papers following a search of the databases and removal of duplicates (BNI 102 Psych Info 3 Medline 20 Emcare 14 Embase 126 and CINAHL 29). The papers were then grouped into different categories based on their topics. After discarding 13 papers that did not fit any category, the remaining papers were distributed as follows: education=15, tissue donation=6, nurse education=14, impact of presumed consent=6, transplantation focus=5, editorial/discussion=13, factors influencing consent=4, ethics=4, medical education=7, Health Care Professional Education=8, other countries experiences of opt-out=16, mandated choice=1, live donation=1 and schools education=1.

2.1.4. Inclusion and exclusion criteria

The inclusion and exclusion criteria applied to the literature searches are detailed in the table below.

Table 1 - Inclusion and exclusion criteria for the literature review

Inclusion	Exclusion
Empirical research	Anything other than opt-out related content including reference to education
Ethical aspects	Editorials/Commentary
Factors influencing consent	
Mandated choice as opposed to opt out	
Other Countries experiences	
Presumed consent policy versus opt in	
Comparison studies – opt in versus opt out	
Education – Health care professionals	
Public awareness	
Relevant discussion/opinion papers	

The published literature spans from 25 years, up to the present year. Both peer reviewed and non-peer reviewed (grey literature) papers were considered. This was partly due to the conflicting evidence base regarding the impact of opt out. Citations were downloaded to RefWorks. All 159 titles and abstracts were screened. Full text manuscripts of papers considered to be potentially relevant were obtained for all papers, where possible. The relevance of each paper was assessed according to the inclusion criteria detailed in the table 2.1.1 above. However, 13 discussion/opinion papers were included due to the relevance and depth of discussion. Websites of selected Government and Regulatory organisations were browsed for additional information. The reference lists of included studies were also checked for potentially relevant references.

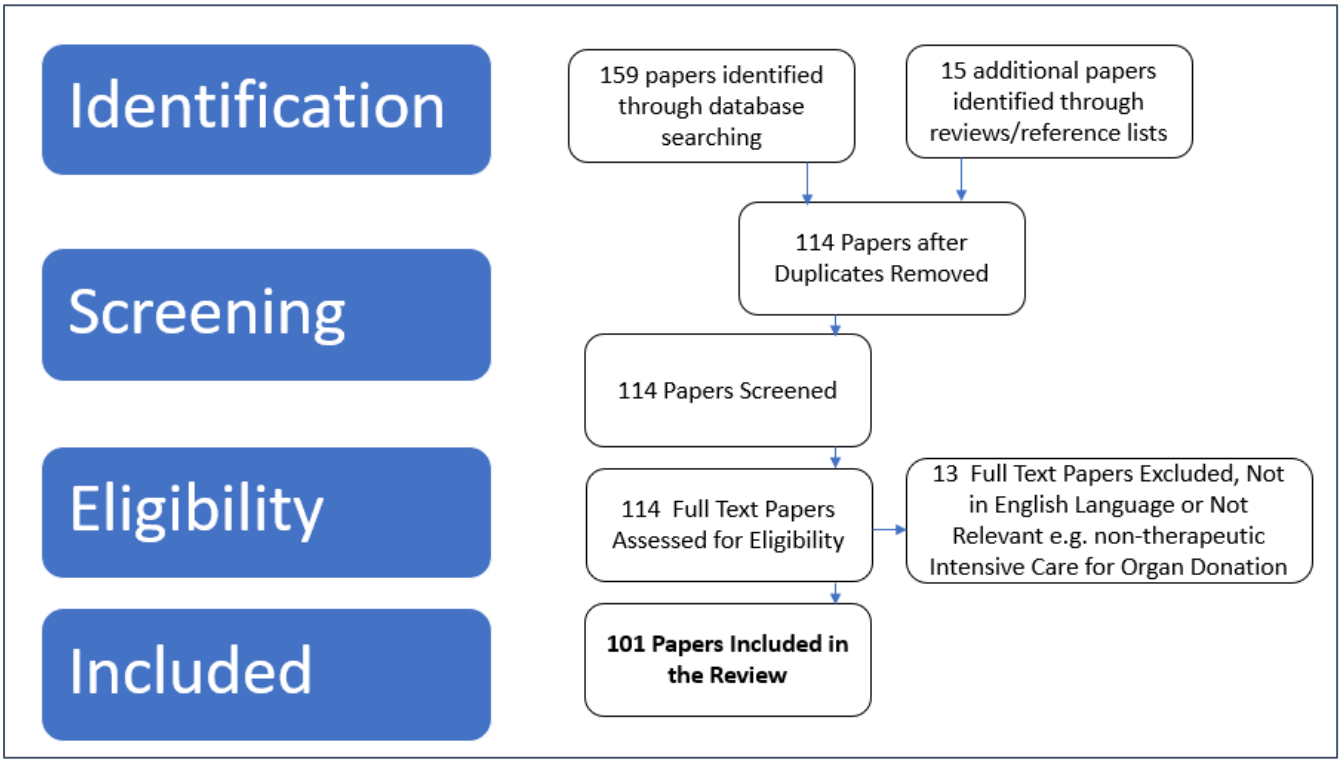

Figure 6 - Education focussed search strategy – opt-out legislation

After selecting the relevant papers for the study, a comprehensive analysis of the 101 chosen papers was conducted using thematic analysis. Each paper was meticulously read and re-read to fully engage with the text and ensure a deep understanding. Extensive notes were taken to document observations and insights, and significant themes were highlighted as they emerged. The analysis employed a combination of inductive thematic analysis (allowing themes to emerge from the data) and deductive thematic analysis (applying pre-conceived themes to the data). This dynamic hybrid approach, switching between inductive and deductive methods, ensured that the analysis was grounded in the actual content of the papers, with both methods mutually enhancing each other, providing a rich and nuanced understanding of the themes (Hatta et al, 2020; Proudfoot, 2023). In the following chapter, the themes that the literature presents concerning the reason for the organ shortage, legislation, education, and public awareness will be explored.

2.2. Reasons for the Organ Shortage

The shortage of organs for transplantation is a complex issue influenced by various factors, including the limited number of suitable donors, lack of awareness and education about organ donation, and family consent issues. Medical and ethical concerns, particularly regarding Donation after Circulatory Death (DCD), also play a role. Cultural and religious beliefs, mistrust in the medical system due to past scandals, and legal and policy barriers further complicate the situation. The main problems mentioned will be addressed individually below.

2.2.1. Lack of Suitable Donors

The characteristics of potential donors are changing. Increased longevity, obesity, higher rates of diabetes, and other comorbidities, along with fewer trauma-related deaths, have reduced the donor pool (NHS Blood and Transplant, 2019; Levit, 2015; Saidi and Kenari, 2014; Caplan, 2016). This means the profile of the donor pool has shifted from young, trauma related donors, to that of older donors with multiple co-morbidities (Cohen et al, 2005). Additionally, societal factors such as the willingness to donate, scepticism around brain death, cultural and religious beliefs, and healthcare professionals' attitudes towards organ donation also play significant roles (Baer, 1997; Ehrle, Shafer and Nelson, 1999; Nathan et al, 2003).

2.2.2. Religious and Cultural Objections

Objections to organ donation are often deeply rooted in religious beliefs. Islam, the world's second most practiced religion, has seen an increase in followers in Western countries due to recent migration trends (Ali, 2020). Studies indicate that Muslims in the Western world generally hold more negative attitudes toward organ donation and transplantation compared to individuals from other religious backgrounds (Ali, 2020). This reluctance can be attributed to various factors, including misunderstandings of religious rulings, opinions of religious leaders, limited information on organ donation, mistrust of the healthcare system, family opinions, quality of care, and concerns over body integrity (Ali, 2020; Webb et al, 2015). A study examining the perspectives of Christianity, Islam, and Judaism on cadaveric organ donation found that providing religious authority on the matter positively impacts families, aiding them in navigating difficult decisions (Bokek-Cohen et al, 2005). Pradeep et al, (2019) emphasised that addressing the organ donor shortage in South Asian communities requires overcoming deeply intertwined factors such as religion, culture, distrust in the medical system, and lack of awareness. Religion, faith, beliefs, and culture are among the biggest barriers to organ donation, due to complex personal beliefs, emotions, rituals, and practices. Spiritual beliefs and altruism significantly influence one's decision to donate (Yunus et al, 2018).

Ghorbani et al.'s (2011) retrospective telephone study in Iran, where an expert coordinator asked non-donor family members the reasons for their refusal, revealed that the main reason for refusing organ donation was due to misunderstandings around brain death. The study focused on 146 potential organ donor families who refused donation. Of the 81 families contacted, the main reason expressed for refusal was denial and rejection of brain-death criteria (44.4%). Other reasons included belief in a miracle (13.6%); fear about organ trade and unknown organ destination (9.9%); religious beliefs (8.6%); insecurity about the brain-death diagnosis (6.2%); unstable family mood (6.2%); unknown donor wishes about donation (4.9%); belief in body integrity after death (3.7%); and fear of objection by other family members (2.5%). Chaim and Duguet's (2018) study on Islamic bioethics highlighted a lack of public education and awareness of the medical procedures related to transplantation. While the Islamic religion does not prohibit organ donation (especially cadaveric), Muslims tend to support explicit consent over presumed consent.

Randhawa et al.'s, (2010) study, which interviewed 17 of the main United Kingdom faith and belief leaders about their views on opt-in and opt-out systems of organ donation, found that most faith and belief leaders support the opt-in system and favour retaining it over introducing an opt-out system. Despite recognising the shortcomings of the opt-in system, the majority felt there was potential to make improvements without changing legislation. Randhawa, (2013) acknowledged in his faith engagement and organ donation action plan that all faith leaders value the importance of organ donation as an issue that needs to be acknowledged and debated within their faith communities. Furthermore, there is a need for engagement at both national and local levels concerning the diagnosis and definition of death and organ donation. The NHSBT communications department observed spikes in opt-out activity in late November 2019, primarily among Black, Asian, and Minority Ethnic (BAME) populations. Misinformation circulating on WhatsApp and social media contributed to these spikes, including false claims about government ownership of bodies after death. Navigating these complex factors requires ongoing education, awareness, and respectful dialogue within communities.

The Annual Report on Ethnicity Differences in Organ Donation and Transplantation (2021/2022) by NHS Blood and Transplant (NHSBT) sheds light on disparities within the UK. The key findings include donor representation; people of Asian heritage constituted 3% of deceased donors but accounted for 15% of deceased donor transplants and 18% of the transplant waiting list. Similarly, individuals of Black heritage represented 2% of deceased donors but contributed to 9% of deceased donor transplants and 10% of the waiting list. To bridge this gap, it is important for more people of Black and Asian heritage to engage in discussions about organ donation. Encouraging support within the same ethnic communities can positively impact waiting lists (Sade and Boan, 2014). Unfortunately, family consent remains lower for potential donors from ethnic minority backgrounds. Last year, only 40% of ethnic minority donors received family consent, compared to 71% for white potential donors. Families refusing donation continues to be a significant factor contributing to the shortage of organs.

2.2.3. Public Awareness - The Role of the Family in Decision Making

Public awareness and education significantly influence the population’s willingness to donate organs, highlighting the importance of family involvement in these decisions. Family involvement can complicate matters, especially with deemed consent. The following discussion examines why family members may struggle to support organ donation. Before considering organ donation, family members must accept that their loved one is brain dead and that donation will follow the DBD pathway (Kentish-Barnes et al., 2019), or that further medical treatment is futile, in which case, donation follows the withdrawal of life-sustaining treatment and circulatory death. The main contributors to the scarcity of organs, besides the diagnosis of death, are the donation process itself, which depends on the personal choice and awareness of each potential donor. Personal choice, or the lack thereof, also affects and is influenced by the relatives of the deceased or dying patient, who must make a difficult decision in a complex social and institutional context (Mossialos et al, 2008).

Martínez et al. (2001) analysed the variables associated with families' decisions to give or refuse consent for organ donation. In their study of 68 cases of organ donation requests from families in 13 Spanish hospitals, the strongest factors influencing family decisions were the family's knowledge of the deceased's wishes regarding donation, family dynamics, perceived satisfaction with medical care, and the number of family members present during the donation request conversation. The study concluded that further informative and educational efforts are needed to promote a positive attitude towards donation among the general population and potential donor families. Shepherd, O'Carroll, and Ferguson (2014) also explored the family's role in organ donation decisions. Their systematic review identified four main themes influencing family consent rates for deceased organ donation: communication, trust, knowledge, and emotions. They concluded that improving communication between healthcare professionals and families, enhancing trust in the donation process, providing accurate and clear information about donation, and addressing emotional barriers could increase family consent rates.

Decisions about health issues are not always driven by rational or cognitive-based processes. This is especially true for the decision to donate organs. While hints about the decision-making process are discussed throughout the literature, non-cognitive factors have not been tested systematically. Structural equation modelling of data from 4,426 participants in six different geographic locations in the United States shows that cognitive-based factors, such as knowledge about donation, are less influential than non-cognitive variables like the desire to maintain bodily integrity, worries about signing a donor card 'jinxing' a person, and medical mistrust (Shepherd et al., 2023). Trust is essential for human interaction. Trust in the healthcare system and the professionals within it is fundamental to the success of organ donation and transplantation (Hansen et al., 2021). It is evident that people are more likely to donate where trust exists (Dabrock, Taupitz, and Reid, 2012; Diaz-Cobacho, 2021) than where there is distrust (Morgan, 2009; Schwettmann, 2015). A study mapping trust relationships in organ donation found that collaboration involving policymakers, healthcare institutions, healthcare professionals, donors, recipients, and families' fosters support and mutual trust (Martínez-López, 2023). Trust becomes particularly relevant in the face of irreducible uncertainty (Möllering, 2006; Lahno, 2001), such as when people lack information or are overwhelmed with information, limiting their ability to make decisions or act in specific situations.

2.2.4. Support for Donation

Shepherd, O'Carroll, and Ferguson (2014) found that family members are much more likely to support the donation of their loved one's organs if they have registered as donors themselves. Bilgel's (2012) study, which included data from 24 countries from 1993-2006, estimated that countries with presumed consent legislation have, on average, 13-18 per cent higher organ donation rates than countries with informed consent legislation, provided family consent is routinely sought and a combined registry is maintained, or neither practice is implemented.

Walker et al.'s (2013) systematic integrative literature review, originating from eight Western countries, highlighted factors influencing bereaved families' decisions to agree or decline the donation of their deceased relative's organs. They found that family members were more likely to consent to donation when their relative had expressed a wish to donate. Conversely, family members declined donation when they lacked knowledge or awareness of the deceased person's donation wishes, or if a signed donor card was absent. The review provides valuable insights into increasing consent rates through family-centred care interventions that reflect the needs of the bereaved.

Other studies concur that family members are more likely to consent to donation if their relative had expressed a wish to be an organ donor (Roza et al, 2010; Exley, White, & Martin, 2002; Haddow, 2004; Jacoby & Jaccard, 2010; Rodrigue et al, 2006; Siminoff et al, 2001; Sque et al, 2005; Stouder et al, 2009). Furthermore, studies suggest that irrespective of the type of consent system and the identified role of the family as per legislation, in practice, the family takes an active role in the donation decision-making process (Boyarsky et al, 2012; Rosenblum et al, 2012). Indeed, McLaughlin et al, (2024) found that families often use their unique experiences of their relative dying in intensive care to create alternative narratives. These narratives tend to satisfy the families' needs and perspectives, rather than necessarily reflecting the donor's wishes. Families often ignored the deemed legislation, creating alternative narratives to override the presumed decision to donate. This led to the desire to save lives, usually endorsed by the living, completely disappearing from the decision-making process.

2.2.5. Sudden and Unexpected Loss

Participants in Sque et al.'s (2018) study involving 31 bereaved donor family participants provided rich data on their donation decision-making experiences through retrospective, qualitative interviews, highlighting how *temporality* (timing and context) influences donation decisions, offering important insights for future education, policy, practice, and research. Decision-making for potential donor families often occurs in the context of a sudden and unexpected critical illness or event. Family members in the study shared their stories of facing the rapid and unforeseen loss of their loved ones, who became potential organ donors. Many felt shocked and unprepared by the swift progression to a brain death diagnosis.

One participant described their experience:

> '...this was happening all too quickly…and I think that was part of the grieving process in that; wait a minute. Hang on a second. She's not dead and we're whipping bits out of her'. (Sque, et al, 2018. P.3).

Another family member shared:

> 'I had about a minute…where I sensed something was wrong…But that's all. There was no warning' (Sque, et al, 2018. P.4).

The timing and sensitivity of the organ donation approach are fundamental in helping family members make morally comfortable decisions. Physicians and nurses also face these sensitivities, and their dual roles as *caregivers and organ brokers* can sometimes lead to moral conflicts (St Ledger et al, 2019).

2.2.6. Fear of Bodily Mutilation

The desire to be buried whole and a fear of bodily mutilation are longstanding barriers to organ and tissue donation (Verble and Worth, 1999; DeJong et al, 1998; Sque et al, 2007). In Sque et al's, (2018) study, many participants emphasized the importance of protecting the deceased person's body, expressing concerns about violation, mutilation, or damage. They wished to preserve their loved one's appearance, dignity, and integrity. This desire to be buried whole was also highlighted by Canadian transplant experts in Baer's (1997) paper, where fears about premature termination of life support due to consent for donation were noted. Many people, believing in an afterlife, want their loved ones buried intact. Some fear mutilation or loss of identity upon receiving another person's organs (Sque et al, 2007). 'Ick' factors, which are basic disgust responses to the idea of organ and tissue donation or transplantation, are common. Concerns about having one's body 'mutilated' or 'defiled' after death are prevalent (Kopfman et al, 1998; Skumanich & Kintsfather, 1996; O'Carroll et al, 2011). Sque et all's (2007) study contrasts the 'gift of life' with the 'sacrifice' narrative, showing how this impacts family decision-making. While families are generally aware of the benefits of organ transplantation, they may struggle to see beyond the procedure. Some people wish to spare their loved ones any further pain, even after death. Can and Hovardaoglu's (2017) study suggests similar influencing variables: the wishes of the deceased about donation, suspicions regarding brain death, the desire to protect the deceased's body, and family satisfaction with how medical personnel handle the donation request. McLaughlin's 2024 study found that families were more focused on whether their loved one wanted their organs retrieved rather (process) than on the potential to save lives (good news story). These studies indicates that both education of the public about maintaining a positive attitude towards organ donation and education of HCP's are key factors in decreasing the organ shortage.

2.2.7. Non-donation of Specific Organs and Tissue

While all participants in Bracher et al.'s (2021) study agreed to donation, personal beliefs, fears, and concerns led to the non-donation of specific organs and tissues, including the heart, skin, bone, and most often, the eyes. Participants wanted to ensure their donations were used exclusively for transplantation and not for research or experimentation. NHSBT evidence shows that although 85% of registered donors are willing to donate kidneys, pancreas, heart, lungs, liver, and corneas post-mortem, 15% selectively refuse to donate at least one of these, with 10.1% refusing to donate their eyes. A recent study by Long-Sutehall et al, (2023), examining eye donation within palliative and hospice care, found that almost half of the patients (46%) met the criteria for eye donation, but less than 4% of eligible cases were approached or referred for eye donation. This discrepancy highlights that eye donation practices in the UK are not universally implemented.

Despite patients' willingness to discuss eye donation at the end of life, several barriers exist, including limited opportunities and the capability to facilitate eye donation. Additionally, HCP's require specialised education and training related to eye donation to effectively engage patients and enable informed decisions. It's important to note that deemed consent legislation covers routine organs and tissues, including eyes. However, explicit consent from family members is required for specific purposes such as research or the donation of novel or rare organs like hands, upper limbs, or uterus. The evolving landscape of organ and tissue donation in England continues to emphasise the importance of informed consent and family involvement (Saidi and Kenari, 2014; Ackerman et al., 2019; Caplan, 2016). This necessitates that Specialist Nurses be well-versed in the legal and ethical aspects of organ donation to support patients and their families effectively.

2.2.8. Scepticism around brain death

Public understanding of death and the organ donation process remains clouded by ambiguity and mistrust. Concerns persist that organs might be removed prematurely, even before official declaration of a patient's death (English and Sommerville, 2003). These uncertainties also impact healthcare professionals (HCPs) who grapple with ethical and legal complexities related to organ donation. One critical aspect is brain death, which is often complex and misunderstood.

Families of potential donors may struggle to fully comprehend the explanations provided by medical staff. Doubts may arise about whether their loved one is truly dead or eligible for organ donation. Coping with loss, some families cling to a faint hope of recovery. However, when death is definitively confirmed, this hope shatters, and they confront the painful reality (Santos et al, 2014). The hospital experience compounds these challenges for grieving families. Coupled with the possibility of organ donation, it becomes an emotionally charged situation. Walker et al.'s (2013) study participants expressed concerns related to the quality of care and communication, shedding light on why some family members choose not to donate. Similarly, DeJong et al.'s (1998) study highlighted issues surrounding patient and family care, the donation request.

2.2.9. Challenges and Ethical Complexities in Donation After Circulatory Death (DCD)

Donation after circulatory death (DCD) presents a unique set of clinical, ethical and emotional challenges for families and healthcare professionals. Earlier work by Morris et al. (1992) showed that families of paediatric patients were more willing to consent to organ donation than those of adults, yet subsequent research revealed significant professional uncertainty. Joffe et al, (2007) found that many paediatricians lacked confidence that DCD donors were truly dead, highlighting ongoing debates surrounding the concept of irreversibility in DCD. Ethical tensions further emerge because DCD care pathways inherently shift the focus of treatment benefit from the dying patient to the future transplant recipient, a shift which can provoke discomfort and moral conflict among clinicians (Orøy et al, 2015; Bastami et al, 2013). Bastami et al, (2013) also identified deep-rooted societal and professional anxieties, including fears of hastening death, conflicts of interest and discomfort with the blurring of boundaries during prognostic discussions.

This blurring intensifies when Health Care Professionals (HCPs) perceive that care is increasingly orientated towards the needs of potential recipients rather than the dying patient, contributing to moral unease (Bastami et al., 2013; Coleman and Bonner, 2014). Standardised DCD protocols and clear, transparent guidelines have therefore been recommended to support ethical practice and maintain public trust (Bastami et al., 2013; Coleman and Bonner, 2014), alongside public education aimed at strengthening understanding and acceptance of DCD (Cantarovich, 2004; Wright, 2007).

These ethical concerns are further magnified by evidence that families of potential DCD donors are substantially more likely to override consent compared with families approached for donation after brainstem death (DBD). Morgan et al, (2018) found that the likelihood of families overriding a registered donation decision was 2.7 times higher in DCD cases, with 34% of DCD related overrides linked to the perceived length and emotional burden of the DCD process compared with only 11% in DBD. Their study also demonstrated that lack of Specialist Nurse for Organ Donation (SNOD) involvement further tripled the odds of an override, highlighting how procedural clarity, skilled communication and pathway efficiency are essential to supporting families during decision making. Taken together, the literature illustrates that the complexities inherent to The challenges of DCD, including clinical, ethical and practical issues, combine with changeable system factors to influence whether families honour first person consent, highlighting the need for both improved processes and better education. Donation after circulatory death (DCD) presents unique challenges for families. Morris et al, (1992) found that families of paediatric patients were more willing to consent to donation compared to families of adult patients. However, a survey by Joffe et al. (2007) revealed that many paediatricians were not confident that DCD donors were truly dead, highlighting the need for further debate on the concept of irreversibility in DCD. The ethical distinction in DCD care, where treatments benefit the transplant recipient rather than the patient, can cause concern and conflict among healthcare providers (Orøy et al., 2015; Bastami et al., 2013). Bastami et al. (2013) also identified deep-rooted concerns about DCD among both medical personnel and the public, including fears of active participation in killing the patient and potential conflicts of interest. Blurring of the boundaries during clarifications of the prognosis of death, the ambiguity in care being increased, and the HCPs concern gradually shifting from the patient towards their organs and patients in need of life-sustaining transplants, causes concern and conflict for some HCP's (Bastami etal's, 2013; Coleman and Bonner, 2014). Standardised DCD protocols and clear guidelines are recommended to address these issues and maintain trust in the transplantation system (Bastami et al., 2013; Coleman and Bonner, 2014). Education and public awareness campaigns are crucial to improving understanding and acceptance of DCD, ultimately fostering positive attitudes towards organ donation (Cantarovich, 2004; Wright, 2007).

2.3. The impact of the organ shortage

The shortage of organs has profound consequences. Organ transplantation is a highly successful treatment for end-stage organ failure, transforming tens of thousands of lives annually. However, many patients die each year while waiting for a transplant.

The disparity between the number of people needing transplants and the available donors is a significant challenge. Organ transplantation is one of medicine's great success stories, as a curative treatment for end-stage organ failure (Shanmugarajah et al, 2014). Organ transplants transform tens of thousands of lives each year (Organ Donation Taskforce, 2008) and yet, tragically, hundreds of people die each year in the UK whilst waiting for a transplant. There are many more people worldwide waiting for an organ transplant, than there are organ donors (Beyar, 2011). The organ shortage has serious consequences for patients, families, and society. Patients who need an organ transplant face a long and uncertain wait, with a risk of dying before receiving a suitable organ. The shortage of organs available for transplant remains the most challenging issue within the field of transplantation.

2.4. Finding a solution to the organ shortage

There are various mechanisms, some controversial, that can potentially be used to expand the donor pool (Caplan, 2016). Some believe that the current neurological criteria for death, such as brain death, are too restrictive. There is a call to expand donor criteria to include cases like the 'persistent vegetative state' or situations where a potential donor is soon to die (referred to as 'death by donation') Sade and Boan, (2014). However, altering the criteria for neurological death is risky. Public support for donation hinges on the assurance that patients are declared dead before organ removal, known as the Dead Donor Rule (DDR). The DDR is a key ethical guideline in organ transplantation, ensuring that organ removal does not result in the donor's death. (Nair-Collins, Green and Sutin 2015). While there is some public support for organ donation even in scenarios that might violate the DDR, allowing donors who choose their own way to die or shifting the criteria for brain death could create public fears and mistrust in the organ donation system (Nair-Collins; Schweikart, (2019)).

A less controversial approach involves enacting legislation and policies that seek permission to preserve organs for donation when death occurs due to an out-of-hospital cardiac arrest. On this approach, when first responders are on the scene of an unexpected cardiac arrest, they could seek permission to preserve organs following cardiac death (Wall et al, 2014). This step avoids approaching shocked and emotionally distressed families immediately for organ donation. The request for organ donation is made at a later point, when the family has had time to process the situation and consider their decision. This approach, known as 'Uncontrolled Donation after Circulatory Death' (uDCD) has the potential to significantly widen the donor pool. Considering that only 1% of the 600,000 deaths occur in intensive care units (where donation is possible), uDCD could make many more donors available. Balancing ethical considerations and practical opportunities remains vital in ongoing efforts to save lives through organ donation.

2.5. Systems of Organ Donation

Another way of addressing the organ shortage is through engineering of the legal system of organ-donation. One particularly important intervention is the introduction in some countries of 'opt-out' systems of organ donation, aiming to increase rates of organ donors, by presuming people are willing to donate after death, unless they have explicitly objected (Williams et al, 2022). In such systems, behavioural nudges create organ donation as the default and rely on people's tendency to stick with the status quo or choose default options, (Johnson and Goldstein, 2003; Mackay and Robonson, 2016). While sharing a default in favour of donation, opt-out systems differ in several key respects, such as the role and importance assigned to the family members of potential donors and their preferences, and exclusions or safeguards which often specify the demographic groups, organs and tissues that remain, outside the scope of the opt-out system (Williams et al, 2022). Below I described the main possible systems of organ donation.

2.5.1. Opt-in

Under 'opt in' systems, an express consent policy requires individuals to explicitly declare their willingness to become donors (Sterri et al, 2022).

2.5.2. Opt-out

In contrast, under 'opt-out' policies, no one is presumed willing to donate unless they have made an explicit decision to be a deceased donor (Etheredge, 2021). Opt-out systems presume individuals residing in a country or state as willing deceased organ donors, unless they specifically opt-out (Etheredge, 2021). The opt-out system is also sometimes known as a *presumed* or *deemed* consent system. Opting-out requires individuals to state their objection to being a deceased organ donor, whilst alive on the opt-out register for example. Within opt-out systems, two further refined types of system are possible.

2.5.3. Hard opt-out

The principle behind a *hard* opt-out system of organ donation, is that organs are removed after death, if the individual has not opted out; in a hard opt-out system, the family is given no role in deciding whether the organs are removed for donation or not. It is this system that leads to the frequently heard objection that the state is taking over the person's body after death, and there are major ethical concerns (Etheredge, 2021). Hard opt-out systems assume that everyone in a country or state agrees to donate their organs after death, unless they explicitly state otherwise (Etheredge, 2021). This is also called *presumed consent.* People opt-out by expressing their objection to organ donation while they are alive, and register it in a national database (Etheredge, 2021). Examples of countries operating a hard opt-out system are Singapore and Austria. In Singapore, donation proceeds unless it is known that the deceased objected before death, and the views of relatives are not actively sought (Sipes, 1991).

The Singapore study found that kidney donation increased from 4.7 to 31.3 per million population in the three-year period after a change in legislation (Rithalia, et al, 2009). Similarly, Austria operates a hard opt-out system and, in Austria there was evidence of an increase of 4.6 to 10.1 donors per million population per year, in the four years after the introduction of presumed consent. The largest increase in Austria was 27.2 donors per million population (pmp) in the five years after the introduction of infrastructure changes e.g., employing full-time transplant coordinators. In Austria the presumed consent law operates the harshest form of presumed consent, by relegating those who decline to donate at the bottom of the transplant waiting list, should they ever need an organ transplant (Rithalia et al, 2009). It is interesting that Brazil introduced presumed consent legislation in 1997, whereby the family were not consulted for donation to proceed; where absence of a documented objection from the deceased exists on their identity card or driver's license (Csillag, 1998). However, the law in Brazil was abolished just 20 months after its introduction, demonstrating that a *hard* opt-out system, regardless of its effect on donor numbers, was too unpopular to be maintained; and secondly, similarly to Spain and arguably Wales, a legislative change alone does not make a difference (Csillag, 1998).

2.5.4. Soft opt-out

A soft opt-out system, which replaced the previous opt-in approach in England, presumes that all potential donors are willing to donate unless they have explicitly registered their objection. Despite this presumption, the family members are still consulted to confirm the deceased's wishes, retaining the power to veto the donation (Senanayake, et al, 2022). Spain's transplant success is often attributed to its 'opt-out' policy, but the system is more nuanced. Spanish experts do not consider Spain an 'opt-out' country, as there is no opt-out register and families are always consulted for donation authorisation. These factors challenge the core principles of opt-out donation, reducing its perceived impact. Moreover, it deserves to be noted that, in Spain, it took a decade after the 'opt-out' policy's introduction for deceased donor numbers to rise, due to several hospital-level initiatives. Furthermore, the rise was not affected by an opt-out policy alone. The Spanish government established a national transplant network and invested in training hospital staff to identify potential donors early. A network of specially trained transplant coordinators approaches families for donations. Efforts to promote donation after circulatory death and use expanded criteria allografts have also increased organ utilisation. These initiatives are believed to have had a greater impact on donation rates than the opt-out system itself.

2.5.5. Reciprocity Focussed Systems

Austria operates a strict hard opt-out system, in which individuals who decline to be organ donors are placed at the lowest priority on the transplant waiting list should they ever require an organ (Rithalia et al., 2009).
Chile, a middle-income country, uses a soft opt-out system, people are presumed to be donors unless they have formally opted out. However, because families are still consulted before donation proceeds, the system is classified as soft rather than a fully hard opt-out model.

Chile has also adopted reciprocity policies, similar to Israel and Singapore, giving transplant priority to registered donors (Zúñiga-Fajuri, 2015). A review of Chile's donor registries from January 2000 to December 2011 by Domínguez and Rojas (2013) found that the introduction of presumed consent did not improve donation rates and may have reduced them. Donation rates dropped from 8.31 donors per million population (2000–2009) to 5.95 (2010–2011), a 29% decline. Family refusal rates increased to 50.4% in 2011. By the end of 2011, 2,520 citizens, representing 37% of those renewing identity cards or driving licences, had registered as non-donors. Surveys conducted by Corporación del Trasplante and IPSOS between 2002 and 2007 found that 75% of Chileans expressed willingness to donate their organs. Despite this, the introduction of the new law has encountered resistance, largely due to public mistrust in the healthcare system. Because families in Chile retain a central role in authorising donation, the practical application of the law remains complex. As seen in other countries, individuals are generally more willing to donate their own organs than to consent to donation on behalf of a deceased relative (Mossialos et al, 2008). Domínguez and Rojas (2013) argue that reframing the wording of the question asked during national identification renewals could help harness status quo bias, encouraging more people to remain registered donors by default. In Israel, the persistent shortage of organs led to the introduction of the 2008 Organ Transplant Law, which prioritises individuals who have signed a donor card or have a close family member who has donated. This reciprocity-based approach has often been described as a 'don't give, don't get' policy (Berzon, 2018).

2.5.6. Mandated Choice

Mandated choice, where people are legally obliged to choose to be a donor *or* not, whilst still alive, and have their decision recorded (Spital, 1995). Mandated choices are often made when applying for a driving licence or other official documentation. Mandated choice is implemented in New Zealand and several states in the United States. In New Zealand, there is no official donor register. Individuals indicate their wish to be an organ donor when applying for or renewing a driver's licence. If they choose to donate, 'donor' will be printed on their licence, but this is only an expression of interest. Despite the legislative framework in place, the potential donor's family also play an important role in the opt-out system. Legally, there are two different opt-out systems, one *soft* where the family can veto the presumed consent, and a *hard* system, where family members have no say in the matter. However, even in countries with *hard* opt out systems, Specialist Nurses often consult the family and let their decision take precedence over the presumed consent of the deceased (Rosenblum et al, 2012; Neades, 2009; Noyes et al, 2017). Figure 7 below from the World Health Organisation database, illustrates the global distribution of countries per type of consent for deceased organ donation systems.

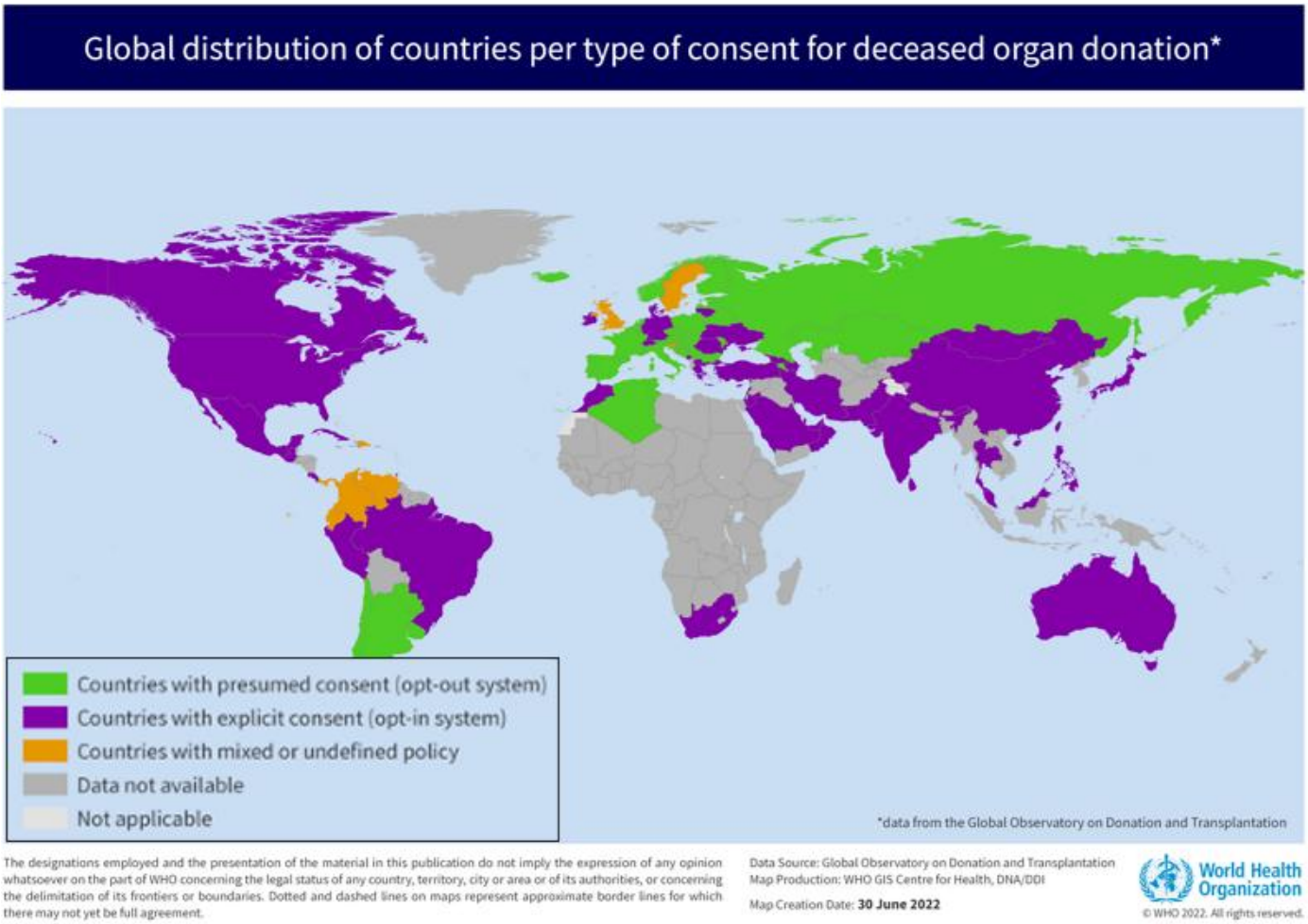

Figure 7 - Countries per model of consent-based comparisons for deceased organ donation systems

Looking globally to understand the difference between an ‘opt-in’ or ‘opt-out’ system, a study by Arshad et al, (2019) shows that there is no significant difference in the number of deceased donors or organ transplants between countries that have an 'opt-in' or 'opt-out' system, except for a lower number of living donors in opt-out countries. The cross-sectional study comparing organ donation and transplantation rates between opt-out versus opt-in countries was undertaken, focusing on 35 countries (17 countries classified as opt-out and 18 classified as opt-in). Organ donation and transplantation rates were adjusted for country specific socio-economic factors that could confuse organ donation/transplant activity rates and were measured over a 4-year period (2012–2016) investigating for any significant difference by measuring organ donation rates (living and deceased), kidney transplant activity, non-renal transplant activity, total solid organ transplantation activity.

To avoid the important bias of including Spain in the opt-in group, the authors made the analysis by including and then excluding Spain, in both cases, for which no significant differences were found. Besides lower living donor rates Arshad et all’s (2019) data does not demonstrate a significant difference in deceased donor rates or any form of solid organ transplantation activity between opt-out versus opt-in registration systems. Rather than fixating on registration systems, addressing other barriers to securing consent remains fundamental for increasing organ donation.

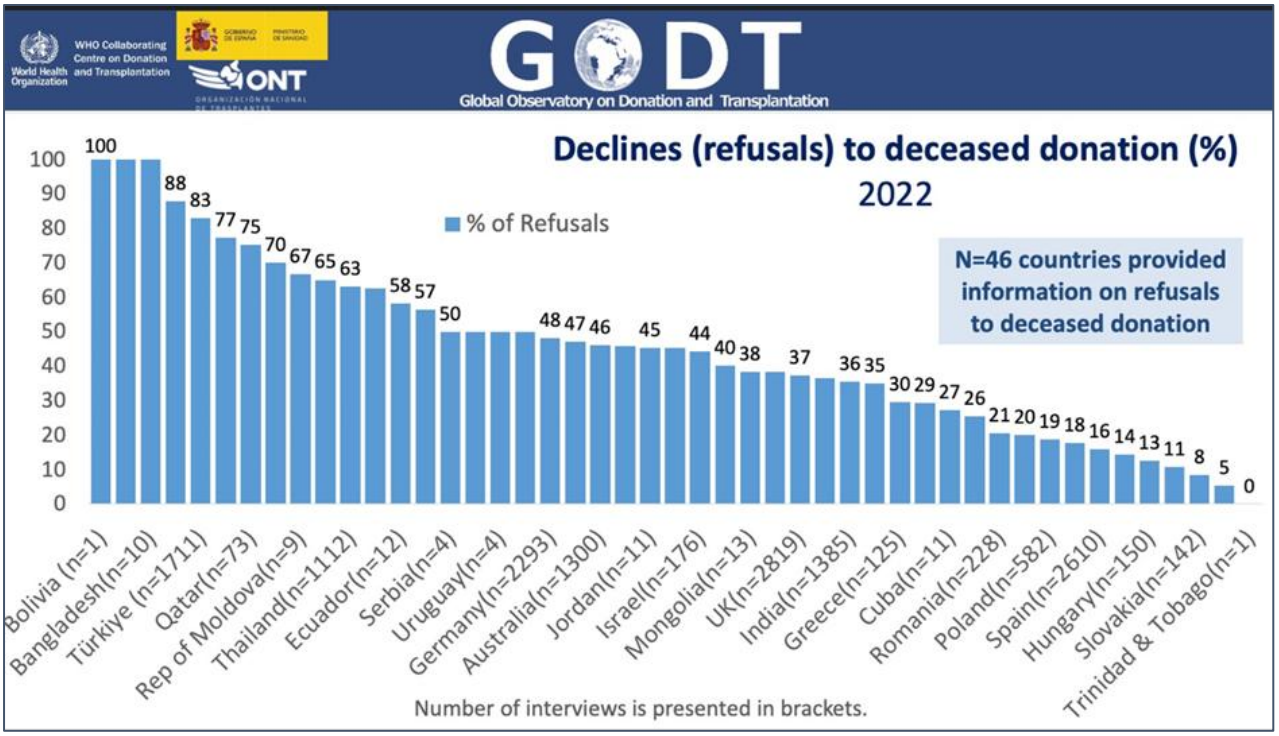

Figure 8 - Countries provided information on refusals to deceased donation (2022) Per Million Population Source Global Observatory on Donation and Transplantation https://www.transplant-observatory.org/

2.6. Comparisons between hard and soft opt-out

While legislation, particularly presumed consent laws, plays a role in encouraging organ donation, the decision to donate is often made either through wills or advanced directives before death, or posthumously by family members (Costa-Font, Rudisill, and Salcher-Konrad, 2021). This highlights the crucial role of family and the importance of prior discussions about donation. A significant factor in increasing organ donation is the family's power to veto, regardless of the legislation in place. The idea of shifting to an opt-out system is based on the notion that it can bridge the gap between people's willingness to donate and their actual behaviour. By removing the need for active consent, an opt-out system aims to boost organ donation rates. However, this approach raises ethical concerns, and the evidence supporting its effectiveness is still weak. There are notable differences between hard and soft opt-out systems, making comparisons difficult and findings from hard opt-out systems may not apply to soft opt-out legislation. Comparative studies also face limitations due to other changes that accompany opt-out legislation as part of a broader system. Rithalia et al. (2009) suggest that hard opt-out legislation can increase organ donation, but other factors also play a significant role. Presumed consent legislation, which allows organ donation unless explicitly refused, has been shown to increase organ donation rates in several studies. Abadie and Gay (2006) compared 22 countries from 1993 to 2002 and reported a 25-30 per cent increase in donation rates for presumed consent countries. Neto et al, (2007) examined 34 countries over five years and found a similar effect of 21-26 per cent. Healy et al, (2005) also confirmed that presumed consent countries had higher donation rates by 2.7 donors per million population, based on data from 17 countries from 1990 to 2002.

However, Yiling et al (2018) conducted three studies to examine how different organ donation legislative systems affect the perception of the donor's true wish. The participants were from America and Europe, and they were exposed to either a default opt-in, a default opt-out, a mandated choice, or a mandatory system. The participants had to act as a third party and estimate the likelihood that the deceased person who was registered as a donor, really wanted to donate his or her organs. The results indicate that the participants inferred a stronger preference to donate under the default opt-in and mandated choice systems than under the default opt-out and mandatory systems. This was true for both American and European participants. Similarly, in the UK, the more people who join the ODR and tell their families of their decision to be a donor, the more families will support that decision, and the more lives will be saved. This is because individuals who have proactively registered their decision to donate are more likely to have discussed their wishes with their families, leading to greater family support and higher consent rates at the time (Miller et al, 2019).Several studies have compared organ donation rates between countries with opt-out systems and those with informed consent systems (opt-in and opt-out). The findings suggest that opt-out countries tend to have higher donation rates (Abadie and Gay 2006; Horvat et al., 2010; Bendorf et al., 2013; Shepherd et al., 2014; Ugur, 2015; Neto et al., 2007; Healy et al., 2005; Gimbel et al., 2003; Rithalia et al., 2009).

However, these studies often overlook other influential factors, such as cultural, social, legal, and institutional differences. A different perspective emerges from studies challenging the assumption that opt-out systems unilaterally lead to higher donation rates (Coppen et a., 2008; Bilgel, 2012; Boyarsky et al, 2012; Arshad et al, 2019; Matesanz and Dominguez, 2013; Vela et al, 2021). For instance, Bilgel (2012) conducted a comprehensive study using data from 24 countries over 14 years. The study considered variables like health expenditure, death rates, legislation, legal systems, family consent practices, civil rights, and donor registry systems. The key findings were intriguing, presumed consent laws significantly increased donation rates only when family consent was consistently sought or consistently not sought. The impact of presumed consent laws varied based on whether a combined registry system was used or no registry system was in place. In other scenarios, presumed consent laws did not significantly affect deceased donation rates, emphasising the importance of contextual factors. Furthermore, researchers argue that isolating the impact of opt-out systems from other influences is challenging. Factors like public attitudes, HCP’s knowledge, disease patterns, hospital infrastructure, media coverage, and family roles in decision-making all play a role (Rithalia et al, (2009); Steffel et al, (2019); Saab et al, (2019); Etheredge, (2021). Arguably, unless governments implement opt-out laws as *experiments*, attributing changes in organ donation rates solely to the consent system remains difficult. Additionally, most research in this area is observational rather than experimental, making it hard to establish causality. Therefore, opt-out systems may not be the sole or primary factor behind higher donation rates in some countries (Bilgel, (2012); Coppen et al, (2010); Costa-Font et al, (2021); Bea, (2021)).

2.7. Media Portrayal and Public Perception

The complexities surrounding organ donation and the opt-out system highlight the role of media in shaping public perceptions. Media stories often emphasise positive aspects of organ donation, featuring heartwarming accounts of children becoming 'superheroes' through transplantation or individuals receiving 'miracle' transplants (Faherty et al, 2022). However, reader comments reveal a different perspective. Some express fears related to 'losing freedom' and a lack of trust in the donation system. This discrepancy highlights the need for accurate and relevant information dissemination to combat misinformation and disinformation. In Wales, the introduction of the soft opt-out system (2015) influenced public attitudes toward both the system and organ donation (Dallimore, 2019). While media plays a key role in raising awareness, individuals critically evaluate messages rather than passively absorbing them. There is a need for further research to validate these findings and determine if shifts in opinion lead to behavioural changes that increase organ donation rates.

Cantarovich (2004) emphasises the important role of doctors and nurses, likening them to a mandatory bridge between the donor's family and the recipient. He advocates for education to develop a new philosophy that could alleviate organ shortages. A well-informed society might change its behaviour and respond positively to organ donation after death. Cantarovich (2002) also recommends incorporating organ donation and transplantation into school curricula to combat ignorance and fear, thereby altering social behaviour and prejudices. Strategies like media campaigns and public education are seen as effective in addressing concerns and promoting positive attitudes towards organ donation (Wright, 2007). Understanding the interplay between media narratives, public trust, and informed decision-making is essential for promoting effective organ donation practices.

2.8. Enhancing Organ Donation Practices: Strategies and Ethical Considerations

Organ donation is vital for saving lives, but numerous challenges persist. Examination of the literature reveals several key issues. The following section will explore historical strategies and ethical considerations. NHSBT is the sole NHS service across four nations responsible for organ donation. Within the Organ and Tissue Donation Directorate (OTDT), various professionals contribute to the strategic goal of saving and improving lives. These include Specialist Nurses (employed by NHSBT), Clinical Leads for Organ Donation (reimbursed ICU doctors), Organ Donation Committees (funded by NHSBT), Organ Retrieval (a commissioned national retrieval service), and the Hub responsible for organ matching and allocation. The Department of Health (2008) Organs for Transplant (2008-2013) strategy was for donation to be a 'usual part of end-of-life care'. The strategy was a huge success and saw a 50% increase in deceased organ donation.

One of the fundamental recommendations was to encourage multidisciplinary training and working relationships as a three-way partnership involving Specialist Nurses, Clinical Lead-Organ Donation, and Donation Committees; otherwise known as a triumvirate (Walton et al, 2020). The strategy stipulated regular updates and ongoing learning opportunities to reinforce the idea that organ donation is a 'usual' as opposed to 'unusual' occurrence. The report revealed that organ donation is a rare event in many of the smaller Hospital Trusts. Many critical care staff complete their entire training without ever taking care of a single potential organ donor. This lack of experience does not help professionals to acquire skills or even familiarity with the donation process. This is different from the situation in Australia, where one of the compulsory elements of critical care training is related to organ donation and the 'Core Family Donation Conversation Workshop' (Potter et al, 2017).

To ensure a consistent approach was adopted for education, NHSBT established an internal education team for Specialist Nurse education and training in 2013, and each of the 12 UK regions had a regional Professional Development Specialist (PDS) assigned to them. This national and consistent approach of educational support for Specialist Nurses, complemented the three-way partnership implemented in the Hospital Trust, helping to guarantee that expertise was accessible even in the hospitals where organ donation remains infrequent. Donation of organs after death is a complex and sensitive issue that raises ethical dilemmas. One of the most controversial forms of donation is DCD, where the death of the donor is determined by the irreversible loss of heart and lung function, rather than brain function (Louis and Sharp, 2015). Navigating complexities around timing of retrieval and conflict of interests requires ongoing education, collaboration, and ethical awareness. To address these issues and provide guidance for different jurisdictions a UK-wide Donation Ethics Committee was established (Murphy et al, 2012).

The Potential Donor Audit, which was conducted by the Specialist Nurses and enabled them to gather data on donation performance and generate key metrics for comparison and tracking purposes. This helped to identify and address the gaps in donation opportunities and implement strategies to increase the number of donors. The 2020 strategy focussed on marketing and media to raise public awareness. The dedicated PDS team created as part of the previous strategy, focussed on a multi-disciplinary (triumvirate) approach for organ donation. The opt-out law changes also came into force during this strategy, in Wales in 2015.

2.8.1. Advancing Organ Donation: Strategies from 2013 to 2030

The 2013–2020 strategy, *Taking Organ Transplantation to 2020* (NSHBT, 2013), placed strong emphasis on improving donation performance through systematic data collection. The Specialist Nurses in Organ Donation led the Potential Donor Audit, enabling consistent evaluation of donation activity, comparison of key metrics, and identification of missed donation opportunities. Insights from this audit informed targeted initiatives to increase donor numbers. During this period, the national approach also expanded to include marketing and media campaigns designed to raise public awareness of organ donation.

Building on the multidisciplinary teamwork established in the previous strategy, the dedicated Potential Donor Surveillance (PDS) team strengthened collaboration across clinical specialties. A major milestone during these years was the introduction of opt-out legislation, first implemented in Wales in 2015. Building on this foundation, NHS Blood and Transplant launched *Organ Donation and Transplantation 2030: Meeting the Need* (NHSBT, 2021), a strategy designed to address the ongoing imbalance between organ supply and the rising demand for transplantation. Central to this vision is the integration of organ donation into standard End-of-Life Care, with the aim of making donation a routine and compassionate part of care planning. The strategy assumes that all families will be offered the opportunity to consider organ donation, ensuring that no potential donor is overlooked. Through enhanced education, clearer communication, and strengthened awareness, the 2030 strategy seeks to increase donation opportunities and ultimately save more lives. A timeline illustrating these key policy developments is shown below in figure 9.

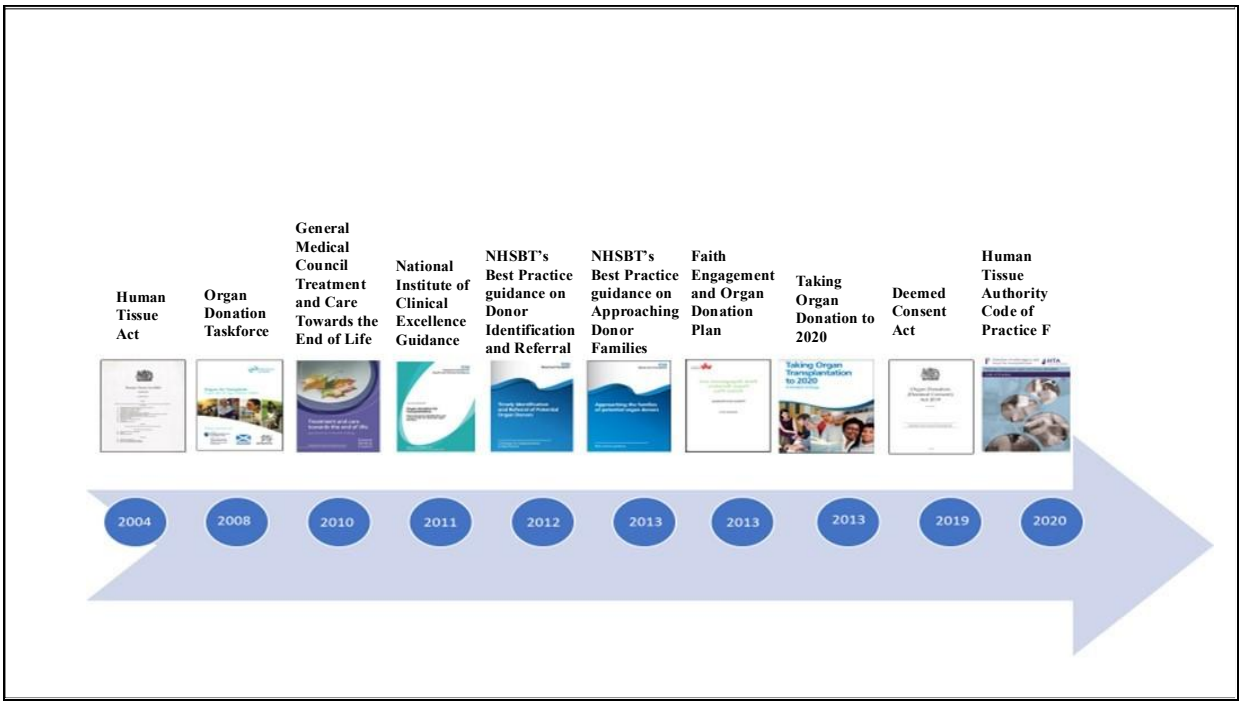

Figure 9 - Timeline of policy documents in relation to consent for organ donation

2.8.2. Learning from Wales – Deemed Consent Act 2015

In 2015, Wales became the first UK country to introduce deemed consent legislation, despite limited evidence of its potential impact. While opt-out countries boast high donation rates, causality remains unproven (Parsons, 2018). The impact of the introduction of a soft opt-out system of consent in Wales took 33 months to reach a significant increase in consent for donation (Noyes et al, 2019; Madden et al, 2020). Since Wales have a comparatively small population (3 million versus 55 million in England), any valid assessment will probably take several years. The Welsh Government, however, claim that the change in legislation has been hugely successful and has already saved dozens of lives (Gurner, 2017; Morris, 2016).

In Wales, analysis from the consent data has shown an increase in the percentage of cases where there was consent for donation (either deemed consent, express consent where the patient was on the ODR or consent from a nearest relative). Consent rates rose from 44% in 2014 to 65% in 2018. Noyes et al. (2019) conducted a process evaluation of Specialist Nurse implementation of the soft opt-out in Wales, revealing that uncertainty often surrounds whether the final organ donation decisions reflect the deceased person's wishes or their family's views. Specialist Nurses may struggle to gather detailed information from grieving families, who might impulsively refuse organ donation due to their emotional state. This opt-out default can lead to a weak or assumed choice not to donate, rather than a strong or explicit choice to donate. The study highlighted the need for a practical solution for Specialist Nurses to meet the regulatory standard of evidence required to override a donation decision. The evaluation also found that Specialist Nurses appeared to apply the legislation based on what they perceived was best for the family members. Before the law change, they adopted a presumptive approach, but now a response to the predictive dialogue is needed to establish the deceased person's decision, separate from the grieving family's views. Similarly, Neades (2009) found that the legislation and its implementation by HCPs were not aligned. HCPs did not fully adhere to the full *tenets* of the legislation, instead using it as a reference until the family decided to proceed with organ donation.

There are clear benefits to having family members and longstanding friends providing input into the donation process, as there are genuine situations where donation should not proceed, such as when the deceased has changed their mind about donation, after they have registered a decision (Shaw et al, 2017). However, it is imperative to try and ensure that the deceased's final wishes about organ donation is the main factor driving the family members support for donation (or not). Spain demonstrates changing to an opt-out system takes time (10 years) and needs to be accompanied by public awareness, education, and investment in infrastructure (Matesanz and Domínguez-Gil, 2019). Similarly, the process evaluation of Specialist Nurses implementation of a soft opt-out organ donation system in Wales, took time and research and concluded:

> 'Despite retraining, SNOD practice did not radically change overnight to accommodate the new soft opt-out system' (Noyes et al, 2019 p.17).

Additional modification of processes and on-going training and support was recommended to help with continual implementation (Noyes et al, 2019). It seems that legislation alone has not made the concrete difference it was intended to make. It may be that a more focused strategy for public awareness and further investment into Specialist Nurse and interdisciplinary training was needed to realise the full impact of this legislative change. The new legislation serves only as an indicator of the Welsh Government's commitment to organ donation, rather than a cause of change, according to Parsons, (2021). Wales's pioneering move away from an opt-in system for organ procurement has shown positive outcomes namely, more registered donors, fewer family refusals and an increased in living donors. However, monitoring actual donor numbers remains key as the situation evolves.

Other challenges include Specialist Nurses navigating family dynamics and ensuring the deceased's final wishes drive donation decisions. Ongoing training and public awareness are crucial for realising the full impact of this legislative change.

2.9. Agency and Family Ideal versus Reality

This research explores the gap between the ideal and the reality of England's new opt-out law, focusing on its impact on Specialist Nurses involved in organ donation. It examines the challenges and opportunities of developing an education program to support this legislative change, especially during a global pandemic, and addresses ethical and moral issues arising from personal values conflicting with the law. The literature review shows that, although the legislation provides the legal framework, family dynamics remain a decisive factor in whether organ donation proceeds. Studies show that family members often override the donor's wishes, creating a gap between the demand and supply of organs. This gap persists regardless of whether the system is opt-in or opt-out, as families are always consulted (Bilgel, 2012; Rosenblum et al, 2012; Neades, 2009). The opt-out law aims to bridge the gap between people's intentions and actions regarding organ donation. However, family members have an emotional connection and a personal stake in the decision, which policymakers may not fully appreciate (Cherry, 2019). Research indicates that family attitudes towards donation are more influential than the donor's registration status (Shepherd, O'Carroll, and Ferguson, 2023). Moreover, Delgado et al (2019) and Molina-Perez et al (2022) argue that the family's role in organ donation decisions is more important than the law itself.

People's current emotions and moods often influence their thoughts and actions, making it difficult for them to anticipate how they or others will react or feel in future emotional situations (Greene et al., 2001; Loewenstein et al., 2005). This phenomenon is known as a hot–cold empathy gap, where *hot* means being in a strong emotional state and *cold* means being in a relaxed or neutral state (Loewenstein, 2005). When people face medical decisions regarding organ donation for example, they may be in a negative emotional *hot* state due to receiving tragic news about the sudden death of a loved one and feeling stressed by having to choose between *undesirable* options. People in this state may not realise how much their emotions are influencing their choices and may overestimate how long they will keep feeling the same way. Specialist Nurses play a fundamental role in helping families make enduring decisions rather than hasty ones based on their current emotional state. Empowering family members in the organ donation process, rather than making them feel coerced by the new law, is essential. Under opt-out laws, if a person has not expressed their preference, the family's role is to confirm if their loved one objected to being an organ donor. Some European organisations respect the family's wishes over the potential donor's wishes (Janssen and Gevers, 2005; Neades, 2009). Over 10% of registered donors have their decision overruled by family members, highlighting the need to understand emotional influences and bridge the gap between intentions and actions for effective organ donation practices.

Morgan et al. (2018) identified several factors that lead family members to override their loved one's decision to be an organ donor: the absence of Specialist Nurses during the approach, donation after circulatory death, and the family's background. The legacy of colonisation and systemic racism has fostered mistrust in the medical profession (Tennankore, Klarenbach, and Goldberg, 2021). Although efforts are underway to rebuild trust, much work remains. Therefore, engaging with BAME populations and discussing donation as an end-of-life choice is essential. Since the scarcity of organs for transplantation poses a significant challenge. Cantarovich (2002) argues that relying solely on altruism and solidarity is insufficient. Spain's success with its opt-out system is attributed to robust resources, incentives and public awareness campaigns, whereas England faces hurdles such as limited awareness and myths surrounding transplantation. Education is essential for fostering societal understanding of organ needs and the role of donation. Maximising positive decisions hinges on raising public awareness and ongoing education and training for healthcare professionals involved in supporting donor families. The NHS App, launched in 2019, simplifies joining the Organ Donor Register and expressing preferences regarding donation and faith.

2.10. Education and Awareness- Social Responsibility

NHSBT's two-year public awareness campaign, funded by the government (£12 million), aimed to inform people about the law change, encourage decision-making, and facilitate family discussions. In hindsight, urging registration on the ODR might have enhanced its impact. Despite around 80% support for organ donation in principle, actual ODR registration lags behind (Nguyen et al, 2021). Nguyen's study reveals that while 56% passively support tissue donation after death, only 9.1% actively register as donors. Factors influencing tissue donation include education, healthcare system knowledge, confidence in safety, readiness to receive tissue, and personal connections to recipients. Govert den Hartogh's moral analysis suggests a shift in mentality, viewing organ donation as a duty and reciprocal act rather than charity (Ravelingien and Krom, 2005). Cantarovich (2002) argues that relying solely on altruism and solidarity is insufficient, advocating for education to raise awareness about organ donation as a social responsibility and moral duty.

Public awareness about organ donation remains low, with stagnant transplantation rates over recent decades (Cantarovich, 2004). Educational efforts should focus on modifying societal behaviour and fostering willingness to donate. Comprehensive information about organ donation should be conveyed through education programs, reaching all segments of society (Cantarovich, 2002). Dijker et al.'s (2019) study highlights that sympathy motivates individuals to donate, while anxiety negatively impacts willingness. Emphasising both pro-social and socio-political aspects can foster balanced opinions on organ donation systems. A recent study by Miller, Currie, and O'Carroll (2019) explored reasons behind planned choices to opt-in or opt-out following deemed legislation. Personal experiences related to loved ones receiving or needing transplants motivated individuals to opt-in or allow deemed consent.

Specialist Nurses play a key role in supporting patients and their families through the organ donation process, requiring knowledge of the legal framework (Winsett, York, and Cuppes, 2008). Reactions from family members towards deemed consent are sometimes tainted by perceptions of 'unwarranted government control' (Miller et al, 2019). Nursing values such as human dignity, integrity, autonomy, altruism, and social justice are essential in this context (Fahrenwald, 2005). There is ongoing debate about the meaning of consent and whether silence can be interpreted as consent (Organ Donation Taskforce). Consent in healthcare is usually based on autonomy and requires formal written consent (Price, 2009).

2.11. Evidence to show Opt-Out legislation is working

Spain enacted its presumed consent law over 40 years ago, in 1979. Initially, there was no measurable impact on transplant rates until the establishment of the robust Organización Nacional de Trasplantes (ONT) in 1989. The ONT committed significant resources to support specialised intensive care physicians and nurses in transplant centres. Spain's 'long-contact' model involves early identification of potential donors and building relationships with families, allowing time for trust-building and inclusion of faith leaders when needed. This approach helps overcome challenges related to religious families' unclear stance on organ donation. Specialist Nurses in the UK collaborate with physicians to discuss organ donation with families, while in Spain, physicians handle this role. Reimbursement is offered for funeral expenses in Spain. Evidence on the knowledge and awareness of the NHS workforce regarding organ donation is scarce. Missed donation opportunities in critical care may result from HCPs lacking confidence in identifying potential donors and communicating with donor families. Education tailored to nurses can increase their confidence levels in supporting potential donors and their families. Spain's approach to organ donation is however nuanced and Spanish experts themselves do not consider Spain to be an opt-out country (Matesanz and Domínguez-Gil, 2019). While it's often associated with an opt-out system, the reality is more complex.

Spain implemented a soft opt out system, where it is presumed that individuals want to donate their organs unless they actively opt out. Significantly, unlike the UK, Spain does not maintain an opt-out register for those who choose not to donate. Instead, families are always consulted to authorise organ donation, which diverges from the typical opt out model. Spain have learnt to focus on the on actual barriers to increasing organ donation, rather than on presumed consent alone. Wales' success in implementing opt-out legislation significantly increased donor consent rates to 80.5%, compared to the rest of the UK at 66.2% (Welsh Government, 2018). The success in Wales suggests that opt-out systems can positively influence factors associated with higher donation, such as public awareness, registration of wishes, and family support for donation. A systematic review comparing consent rates in opt-out versus opt-in countries revealed that opt-out consent increased deceased donation rates from 21% to 76% over a period of 5–14 years and deceased transplantation rates from 38% to 83% over a period of 11–13 years (Ahmad, Hanna, Mohamed, et al. 2019). Rithalia et al.'s (2009) systematic review examined before-and-after studies from Austria, Belgium, and Singapore.

Although all studies showed an increase in deceased donation, the Belgian study is most relevant because it implemented a soft opt-out system. Over a three-year period after the 1986 legislation change, kidney transplantation rates (from both deceased and living donors) increased from 18.9 to 41.3 per million population per year (Roels, 1991). Predictors associated with higher organ donation rates are not universally present in countries with low donation rates. Catholicism, for instance, has been identified as a major predictor, and in five of the six studied countries, Catholicism was the predominant religion (Sprung et al., 2007). Mortality from road traffic accidents, gross domestic product per capita, education, and health expenditure per capita also correlated with high organ donation rates (Rithalia et al., 2009). Religion could interact positively with opt-out policies in specific contexts. Interestingly, the six countries with opt-out policies and the highest number of donors on a register (ranging from 66% to 94%) predominantly follow Catholicism (Mone, 2017). However, mere registration numbers do not necessarily indicate an effective opt-out system, and there is no firm evidence that Catholicism significantly impacts individual donation decisions (Mone, 2017). While official positions of key religious groups in the UK broadly support organ donation (with no formal opposition), religion is still perceived as a barrier (Davis, 2006). Studies have more often identified religious opposition (23 studies) than religious support (10 studies) for organ donation (Oliver & Ahmed, 2012).

The top three countries for donors per million population depicted above are Spain, Belgium, and Portugal, all of which work under opt-out systems. However presumed consent legislation alone, is unlikely to explain the variation in organ donation rates between countries, as each country attributes their success because of good infrastructure, not solely the legislation (Sharif, 2018; Hawkes, 2018; Arsad et al 2019). So far, Spain holds the highest deceased donation rates in the world and have had a presumed consent policy in place since 1979 (Abadie and Gay, 2006). However, according to Rafael Matesanz, Director of the National Transplant Organisation ONT) attributes Spain's success to multiple factors including media communications and health care professionals working in the hospitals (Badcock, 2015). Wales's success in implementing opt-out legislation significantly increased donor consent rates to 80.5%, compared to the rest of the UK at 66.2% (Welsh Government, 2018).

In summary, some countries with opt-out systems see higher organ donation rates because everyone is considered a potential donor unless they explicitly opt out, increasing the pool of available organs. This leads to more organs being available for transplantation, which can save lives and improve recipients' quality of life. Opt out systems arguably simplify the process by reducing the burden on individuals to register as donors, aligning with the general public support for organ donation. It also encourages family discussions about donation wishes, ensuring that the deceased's preferences are respected. Additionally, it emphasises the social responsibility and moral duty to help others, framing organ donation as a shared societal benefit rather than just an individual choice.

2.12. Evidence to show opt-out is not a magic bullet

However, it's essential to note that merely increasing awareness and the number of people on a donor register does not guarantee a proportional increase in transplants. The time lag between registration and actual donation, along with demographic differences, affects the impact. While presumed consent has been associated with increased organ donation rates, some nuances exist. Biela's (2011) systematic review highlights this association, even when accounting for other factors. A secondary retrospective data analysis by Saab et al. (2019) concurs, showing significant increases in liver donation rates across six countries (Argentina, Chile, Finland, Poland, Slovakia, and Uruguay) that adopted presumed consent. However, only four out of these six countries experienced increased kidney donation rates. Notably, the study's generalisability may be limited due to the smaller population sizes of the included countries compared to developed nations. The mean population size of transitioned countries was 19 million, with Argentina having the highest population (less than 50 million residents). Combined, these six countries represent over 100 million people, but this pales in comparison to the USA's estimated population of over 327 million in 2018. Interestingly, the top three countries for donors per million population (Spain, Belgium, and Portugal), all operating opt-out systems, were not part of the study. Rithalia et al.'s (2009) systematic review examined before-and-after studies from Austria, Belgium, and Singapore. Although all studies showed an increase in deceased donation, the Belgian study is most relevant because it implemented a soft opt-out system. Over a three-year period after the 1986 legislation change, kidney transplantation rates (from both deceased and living donors) increased from 18.9 to 41.3 per million population per year (Roels, 1991).

Predictors associated with higher organ donation rates are not universally present in countries with low donation rates. Catholicism, for instance, has been identified as a major predictor, and in five of the six studied countries, Catholicism was the predominant religion (Sprung et al., 2007). Mortality from road traffic accidents, gross domestic product per capita, education, and health expenditure per capita also correlated with high organ donation rates (Rithalia et al., 2009). Religion could interact positively with opt-out policies in specific contexts. Interestingly, the six countries with opt-out policies and the highest number of donors on a register (ranging from 66% to 94%) predominantly follow Catholicism (Mone, 2017). However, mere registration numbers do not necessarily indicate an effective opt-out system, and there is no firm evidence that Catholicism significantly impacts individual donation decisions (Mone, 2017). While official positions of key religious groups in the UK broadly support organ donation (with no formal opposition), religion is still perceived as a barrier (Davis, 2006). Studies have more often identified religious opposition (23 studies) than religious support (10 studies) for organ donation (Oliver & Ahmed, 2012). Presumed consent legislation alone, is unlikely to explain the variation in organ donation rates between countries, as each country attributes their success because of good infrastructure, not solely the legislation (Sharif, 2018; Hawkes, 2018; Arsad et al 2019). So far, Spain holds the highest deceased donation rates in the world and have had a presumed consent policy in place since 1979 (Abadie and Gay, 2006).

However, according to Rafael Matesanz, Director of the National Transplant Organisation ONT) attributes Spain's success to multiple factors including media communications and health care professionals working in the hospitals (Badcock, 2015). While an opt-out system for organ donation has many benefits, there are also potential drawbacks. One concern is whether presumed consent truly reflects an individual's wishes, as some people might not be aware of the need to opt out if they do not wish to donate. This can lead to trust issues, potentially eroding trust between patients, doctors, and families if they feel organs are taken without explicit consent (Moorlock and Draper, 2022). Ethical considerations arise about balancing individual autonomy with societal goals, with some believing it infringes on personal freedom (Price, 2012). Family distress can occur if families are unaware of the deceased's wishes or disagree with presumed consent (McLaughlin et al, 2024). Cultural and religious sensitivities may also lead to resistance, as the system might not align with various beliefs (Yunus et al, 2018). Additionally, implementing and maintaining an opt-out system requires significant administrative effort to ensure everyone is informed and their choices are accurately recorded and respected. Although presumed consent alone may not fully explain increased donation rates, embracing such a policy could benefit countries with consistently low organ donation rates. Rithalia et al.'s (2009) systematic review concurs that implementing presumed consent legislation is not a panacea for increasing organ donation. It is therefore imperative to communicate why presumed consent is needed, how it will be implemented practically, and the safeguards for the vulnerable in our society to help people make an informed decision about opting in or out (Behi, 2009).

2.13. Health Care Professionals (HCP's) Knowledge, Attitudes, Awareness and Education

The second phase of the literature search focused on education and will be discussed in the following sections. While much is known about public opinions on organ donation and legislative changes, there is limited evidence on the knowledge and awareness of HCP's. Walton et al. (2020) emphasises the importance of HCPs in critical care understanding the opt-out law and their role in it. Knowledge of legal acts and regulations is essential to respect potential donors' wishes and protect physicians legally. I will begin by highlighting international research on HCPs' knowledge of organ donation, then focus on Wales, and conclude with England. In Poland, Kiel-Puślecka et al, (2022) assessed the knowledge of physicians and lawyers regarding transplantation law, finding a need for improved understanding of the legal aspects of post-mortal donation. Missed donation opportunities in critical care may result from HCPs' lack of knowledge and confidence in identifying potential donors and communicating with families (Pelleriaux et al, 2008). Studies by Pelleriaux et al, (2018) and Stadlbauer et al. (2013) showed high support rates for donation among HCPs, with previous training improving attitudes and reducing educational needs. Both studies concluded that tailored educational efforts could increase nurses' confidence in supporting potential donors and their families. Camut et al. (2016) explored non-therapeutic intensive care for patients in hopeless conditions to protect organs for donation after brain death.

Despite limited education on brain death and non-therapeutic care, HCPs showed 'fairly good' acceptance of this practice, provided there was assurance of the patient's consent and family approval. Knowledge and attitudes of HCPs significantly influence organ donation (Glasper, 2018). A study in Malaysia (Tumin, 2019) revealed that nearly half of the HCPs surveyed would object to a presumed consent system, indicating a negative attitude towards its implementation. In Qatar, Alsaied et al. (2012) found that while most HCPs supported organ donation, there were misconceptions about eligibility and legal aspects. Similarly, in Ireland, a study found that most HCPs would consider donating their organs and had discussed it with their next of kin, though only a third had registered as donors. Stadlbauer et al. (2013) also found that ICU nurses in Austria unaware of the opt-out law were most critical of it, emphasising the need for broader education on organ donation legislation. These studies suggest that more education is needed to fully accept organ donation and transplantation in the medical community. The knowledge and attitudes of HCPs are major factors influencing organ donation (Glasper, 2018).

Stadlbauer et all's, (2013) survey on the knowledge and attitudes towards the Austrian opt-out system found a high level of information on Austrian organ donation legislation. Intensive Care Unit nurses and those who did not know the law prior to the introduction of opt out, were most critical towards the existing legislation. It could be argued, informing, and educating a wider range of the general population would lead to an increased positive attitude. The results of Stadlbauer et all's, (2013) survey showed that participants, who are aware of the opt-out law, showed a positive at attitude towards organ donation. Therefore, educational programs for professionals and public information could be a possibility to increase the support for the current legislation. The study, however, was not able to answer the question what should be considered education, and what factors other than lack of education could contribute to the critical attitude of ICU nurses towards organ procurement policies and procedures.

2.13.1. Wales's soft opt out system

A Welsh Government survey showed more supportive attitudes among NHS staff in Wales towards the opt-out law change, with increased awareness and support post-implementation. The survey highlighted the importance of information campaigns in educating staff unfamiliar with organ donation. Most staff supported the law change before implementation (71%), which increased to 89% post-implementation. The survey also identified that most staff felt the move to opt-out would have little impact on them. Staff awareness of the change was high before implementation (89%) and increased to 96% post-implementation (The Welsh Government, 2017). Both awareness and self-related knowledge increases were highest among staff not working directly with organ donors (e.g., GPs and nurses outside critical care units). This highlights the importance of information campaigns in educating staff unfamiliar with organ donation to increase awareness. The Welsh impact evaluation emphasised the need for NHS staff to have a clear understanding of the opt-out system and recommended continuous training, especially for those in critical care areas (Noyes et al., 2019).

Noyes (2019) noted that despite re-training, nursing practice did not change overnight to accommodate the new system. Therefore, it should not be assumed by policymakers and health service managers that Specialist Nurses simply need more time to implement the soft opt-out as intended. Ongoing training and support are essential.

2.13.2. England's soft opt out system

A recent study of 5,789 NHS staff in England, regarding awareness, attitudes and actions towards the change in organ donation law in England highlighted that the staff were well informed about the change in organ donation legislation and levels of support were high (Coe et al, 2023). Overall, 83% of the NHS staff participants were supportive of the change in legislation, 6% were against, 6% needed more information and 5% were unsure (Coe et al 2023). Moreover, NHS staff were six times more likely, than the general population, to have a conversation with their family about their organ donation choices and more likely to be on the ODR. Those working in a transplanting centre were most aware and supportive and those working in the ambulance service were most likely to 'opt-in' following the change in legislation. Importantly, the size and ethnic diversity of the NHS workforce in England offers an opportunity to enable and support NHS staff to be advocates for organ donation and raise awareness of the change in legislation amongst their communities (Coe et al, 2023). Rodger and Stewart-Lord (2020) explored students' perceptions of the educational value of debate and found that engaging in debate encouraged students to critically reflect on their prior beliefs about organ donation, sometimes leading them to reconsider their original positions. The findings suggest that debate can be a valuable pedagogical tool for developing non-technical skills in healthcare education (Daniel and Stewart-Lord, 2020). Additionally, non-technical communication skills were highlighted as vital for training when implementing the deemed consent legislation in England, due to changes in how organ and tissue donation conversations with families were conducted (Miller et al., 2020).

2.14. Healthcare professionals' experiences of communicating with families about organ donation

From a European perspective, Neade's (2009) phenomenological study in Norway, Portugal, and Belgium explores the lived experience of HCPs under presumed consent legislation, highlighting the importance of public confidence. The study shows that HCPs involve family members in the decision to accept or reject their deceased relative as an organ donor, asking if they have any personal objections. This practice goes beyond the legal requirement to confirm the deceased's views on organ donation, revealing a disconnect between the law and practice. HCPs reported involving families to ensure there were no objections and to protect vulnerable individuals from becoming organ donors by default. Interestingly, Belgium was the only country in the study where the deceased's recorded decision to be a donor was respected, regardless of family veto.

The study also highlighted differences in how the legislation was applied: Portugal and Belgium have computerised registers of objections to organ donation, while Norway does not. In Norway, HCPs approach family members to confirm that the deceased had not expressed an objection to organ donation. Respondents from all three countries believed that presumed consent legislation maintained individual autonomy, allowing people to donate their organs as an altruistic act or record their objection. In England, the Specialist Nurses support the family in respecting the individuals last known donation decision. The Human Tissue Authority (HTA) Code of Practice F, (2020) acknowledge that the potential donor family are integral in supporting the decision to donate, this was a key addition to the ODDC Act, 2019 to help reassure the public. The new legislation is a permissive law, allowing donation to proceed in the presence of appropriate consent, but it does not mandate that it must (Human Tissue Authority Code of practice F:13:104, (2020). Potential donor family members may choose to support the new legislation or not:

> 'Where there is a risk to public confidence outweighing the benefit of donation proceeding, donation should not proceed, even though it is permissible under the new law' (HTA CoP F, 2020, para 14).

The most readily modifiable factor in Curtis et all's, (2021) study focussed on increasing consent, was involving the specialist Nurse in a collaborative approach with the clinicians, along with less than six family members present during the formal approach. In Italy citizens express their willingness or refusal to donate organs after death and their choice is then recorded in the national organ donor registry. By law, the absence of such declaration is considered consent. However, this law has never been enforced, and a mix of 'opting-in' and 'opting-out' exists. Although there has been a steady increase in organ donation following the introduction of the presumed consent law, the changes are attributed to organisational changes in the field, at national and regional hospital level. International evidence also supports the notion that training key HCP's is important to support the legislation change, enabling effective communication with families about organ donation. It is important that staff are knowledgeable, confident and competent to achieve higher donation rates (Pelleriaux, et al, 2008). Some researchers go as far to say that education on donor management and how to communicate with families should be part of the specialist training for HCPs (Sula et al, 2012).

2.14.1. Specialist training requirements for communicating with potential donor families

It is clear from international evidence that communication and knowledge is vitally important to support a legislation change and where there is staff support there is more likely a greater understanding and overall support for organ donation (Smudla et al, 2012; Symvoulakis, 2014). Despite this, health care staff do not always receive the training they need. Many respondents in Neades (2019) study reported a lack of preparation in their training for the *psychological* care of potential donor families. Similarly, respondents in Belgium and Norway had received a short training course designed to meet the training needs of critical care staff in breaking bad news, caring for the bereaved, and requesting donation available on-line from the European Donor Hospital Education Programme (EDHEP) (Blok et al, 1999).

Interestingly, in most countries, it appears the tenets of the law are not fully applied, since the law implies involvement of the relatives, as interpreters or *surrogates* of the deceased wishes where they are unknown (Jansen and Gevers, 2005; Molina-Perez, et al, 2022). Relatives' involvement, irrespective of the law, is to care for and respect the feelings of a family in the acute stages of grief, following a sudden or unexpected death of a loved one (Jansen and Gevers, 2005). Additionally, there is a risk that negative publicity about organ donation could lead to a loss of public support, reducing donor numbers and negatively impacting transplantation rates. Noyes (2019) found that HCPs were unable to define a process whereby they were able to distinguish the family's views on organ donation from that of the deceased, in the absence of an expressed or recorded decision. Unanimously, however, the importance of involving the family was evident and one respondent went so far as to say,

> 'It would be suicide for the transplantation activity not to involve the relatives.' (Neades, 2009, p.275).

Bea's (2020) study highlights the complex arrangements that bring together people and politics in the assembling of organ donation at the hospital setting, through each stage e.g., detection, evaluation and maintenance of eligible donors to the consent request with their families and final organ retrieval. A participant in Bea's (2020) study emphasises how,

> 'you simply cannot carry out any program of donation and transplantation if the HCPs in the hospital are not properly informed about it, because this is essential, they are the ones that will help you, when there is a death, when there is a donor, talking in general here, when there is a potential donor, because they are the key people that can either make your job possible or on the contrary put insurmountable impediments to your job (TC 1 p6.)'.

Bea (2020) illustrates the complexity of donation, as

> 'a progressive and indeterminate process which might fall through and become disassembled at any given time.' (p.2).

Therefore, organ donation should be undertaken as a collective accomplishment and situated both in and as a hospital practice.

2.14.2. Managing Expectations of Deemed Consent in Increasing Donor Numbers for Recipients Waiting

Urquhart et al, (2023) conducted a study to understand ICU and ED nurses' knowledge, confidence, and attitudes towards organ donation, transplantation, and deemed consent, following the law change in England. Among the 198 participants, 98% supported organ donation, and 86% had signed an organ donor card. Additionally, 89% were in favour of the new deemed consent legislation, though 13% viewed it as a violation of freedom and autonomy. The study identified three main themes for ongoing training: coordination of the donation process, clinical management of donors, and family issues in decision-making.

Bailey et al. (2022) investigated the views of a mixed stakeholder group, including people with kidney disease, family members, and HCP's on the expected impact of the new legislation on both deceased and living donor transplantation. The study highlighted three main themes and six subthemes. Patients were 'hopeful' about the law change, anticipating more transplant opportunities, while HCPs were more 'cautious' and continued to promote living donation. Divergent views and unchanged clinical recommendations were noted regarding living donor transplantation. Participants emphasised that media campaigns should have a single message focusing on the impact on organ recipients. Bailey et al. (2022) recommended that clinicians help manage patients' and families' expectations about the law change, noting that current evidence does not support a greater likelihood of receiving a deceased-donor transplant. Managing expectations in this way may also help prevent declines in living-donor transplantation, which have been observed in other countries with similar legislation. They also advised that media campaigns should emphasise the positive impact of receiving an organ. Hobeika et al, (2009) surveyed a group of 106 U.S. physicians and found that around two-thirds were willing to donate their own organs, although this willingness was lower than in the general public. Fewer than half had signed organ donor cards, and some physicians reported that prior experiences with donation had influenced them to refuse donation. Because the public often looks to physicians for guidance, the authors argued that strengthening physicians' knowledge and attitudes is essential for improving donation rates.

In Canada, Weiss et al. (2020) surveyed 235 critical care physicians to understand their knowledge of, and attitudes toward, legislation governing deceased organ donation. In this context, N refers to the total number of survey respondents. The majority supported opt-out consent and mandatory referral, although many remained neutral or opposed. Most believed opt-out consent would increase donation rates; however, most also indicated that it would not change how they approached families about donation. Together, these studies highlight the importance of providing healthcare professionals with strong education and support. Improving their knowledge and confidence enables them to give families clear, evidence-based information and to better manage expectations under deemed consent legislation. Bailey et al, (2022) recommended that clinicians manage patients' and families' expectations of the law change based on current evidence, as an increased likelihood of receiving a deceased-donor transplant is not currently supported by evidence.

This approach may help prevent a decline in living-donor transplantation seen in other countries with similar legislation. Media campaigns should highlight the impact of organ receipt. Hobeika et al. (2009) surveyed 106 U.S. physicians and found that 64% were willing to donate their own organs, though this willingness was lower compared to the general public. Less than half had signed organ donor cards, and previous procurement experiences influenced some to refuse organ donation. As the public relies on physicians for guidance, efforts must be made to improve physician attitudes toward organ donation to increase donation rates. A Canadian survey of critical care physicians, caring for potential organ donors was conducted to understand their knowledge and attitudes regards the legislation governing deceased organ donation (Weiss et al, 2020).

While the majority n61% (144/235) of critical care physicians supported opt-out consent and mandatory referral, many were neutral or against it. Many were unaware of existing laws and had variable opinions on how to ensure accountability. A majority n 77% (181/235) stated they believed opt-out consent would increase donation rates. However, when asked if opt-out consent would change their practices, a majority of n71% (166/235) stated an opt-out model would not change how or if they approach families to discuss donation. These studies highlight the valuable role of educating healthcare professionals (HCPs) in improving their knowledge and attitudes towards organ donation under deemed consent legislation. By enhancing HCPs' understanding, they can more effectively manage expectations and provide patients and families with clear, evidence-based information.

2.14.3. Organ donation as an expected part of end-of-life care

UK guidelines recommend discussions about organ donation are conducted as an expected part of end-of-life care (NICE 2014). However, Khiroya etal's paper (2021) found several barriers exist around organ donation conversations, impacting the shortage of donors, despite the presumption of donation now in force in England, a 'conspiracy of silence' exists, where some clinicians find it too difficult to have the conversation. Furthermore, such conversations are considered 'unusual' to talk about donation in settings other than critical care. Arguably, there is both an ethical and a legal imperative to make donation an *expected* part of end-of-life care conversations. Albeit, conducting such sensitive and complex conversations, takes expertise and skill, a role of the Specialist Nurse in collaboration with intensive care colleagues. Confidence in having successful donation conversations is directly linked to exposure and experience, however simulation-based education can also help in relation to deliberately practicing communication skills (Siminoff et al, 2015; Potter et al 2017).

Jawoniyi, et all's, (2018) systematic review reveals the global organ shortage is owing to a failure to convert potential donors to actual donors. To convert potential donors to actual donors, requires HCPs to be aware of the benefits of organ donation and transplantation and their role within the process, aligned to the legal framework. Since, HCP's have a pivotal position on the front-line between organ donors and transplant recipients and are professionally situated as the implementers of organ donation and transplantation processes, they are therefore often answerable for the global organ shortage. Furthermore, Olbrisch (1989) emphasises the importance of examining one's own personal attitudes towards organ donation before assessing the attitudes of the public and organ procurement personnel. This self-reflection is fundamental to understanding the barriers that hinder making a significant impact on improving many lives.

2.14.4. Raising awareness in the community about tissue donation

Nurses, representing the largest part of health care organisations, play a pivotal role in disseminating the right information and raising awareness regards organ and tissue donation (Kumar, Dhawan, Chaudhary; Dwivedi and Kumari, 2021).

District Nurses working in the community delivering end of life care and verifying death are in a unique position to promote tissue donation. However, Alker's (2021) study found, due to a lack of awareness about the law change the nurses are not actively promoting this practice. Alker (2021) recommends education and guidance for having complex and difficult conversations, exploring patients end of life wishes, to enable an increase in referral and proceeding tissue donors. Similar, Collins (2005) survey of ICU staff in the UK, highlights a significant number of nurses unable to identify which tissues can be donated and the contraindications. The participants also lacked confidence in approaching families for consent, reasons cited were, deficits in brain stem death testing and donor criteria. Most of the participants stated their knowledge of organ and tissue donation would improve if a bespoke educational programme were developed.

A study by Rodger and Stewart-Lord, (2019) exploring students' perceptions of the educational value of debate, found that engaging in debate encouraged students to critically reflect on their prior beliefs about organ donation, and in some cases leading them to reconsider their original position. The findings suggest that debate can be a valuable pedagogical tool to develop non-technical skills to incorporate into healthcare education (Daniel and Stewart-Lord, 2020). Notably, non-technical communication skills were highlighted as an important aspect for training when implementing the deemed consent legislation in England, due to a modification in the way that the organ and tissue donation conversation with families was conducted (Miller et al, 2020). It is important to separate the rhetoric that an opt out law will save hundreds of lives, from the reality. It is vital when considering the reality, to acknowledge the compelling evidence from Spain offering two evidence-based strategies:

1. Substantial public awareness campaigns encouraging people to become organ donors and urge families to have a conversation about organ donation (Matesanz, 2017).
2. Specialist training for nurses and doctors to engage in conversations with patients and families (Blair, Sadler and Sadler, 2018).

2.15. Conclusions from the literature review

Opt-out systems are designed to save and improve lives. With the right public support and infrastructure, there is evidence that these systems can lead to higher donation rates (Rithalia et al., 2009). Reviews by both the Welsh Government (Palmer, 2012) and the Scottish Government (Niven, 2018) found a positive association between opt-out systems and higher donation rates. An essential component for the success of an opt-out system is the need for increased publicity and education. Furthermore, Rithalia's (2009) study suggests that a powerful campaign explicitly illustrating the impact on individuals waiting for a transplant is necessary. Opt-out systems are legally permissible, but they face practical challenges. Under a soft opt-out system, families are still consulted and have overriding powers (Neades, 2009; McLaughlin et al, 2024).

These systems need strong government support and adequate infrastructure to work well (Veatch and Ross, 2015; Etherege et al, 2018). Efforts to increase understanding of how legislative models influence practice are required for any law to achieve its desired effect (Weiss et al, 2020). Opt-out systems risk eroding public trust in healthcare if implemented poorly or forcefully (Yan and Yates, 2019). Therefore, such policy changes should be approached with caution. Some people genuinely do not want to donate their organs after death due to medical mistrust and beliefs in an illegal organ trade (Morgan et al, 2009). Changing the default option to donation does not mean that people's preferences or willingness have changed (Veatch and Ross, 2015). Thus, the social acceptability of opt-out policies needs to be carefully examined and understood.

Efforts to increase organ donation rates should focus on actively engaging and encouraging the public. One effective approach could be the concept of mandated choice, as proposed by Thaler and Sunstein (2008). This method involves requiring individuals to make a clear decision about organ donation, thereby promoting informed and voluntary participation. In contrast, pursuing ‘routine salvaging’ under the guise of ‘presumed consent’ (Bell, 2006) can be problematic. This approach assumes consent unless explicitly opted out, which may not accurately reflect individuals’ true wishes and can lead to ethical concerns and public distrust. What remains unclear in the literature is what effective education looks like for implementing complex legislative changes in an already complex healthcare system. There are references to the difficulties of implementing the opt-out system in practice and the need for retraining (Noyes et al, 2019). To address this gap, this thesis aims to examine the education program implemented for Specialist Nurses and assess its effectiveness.

Chapter 3. Methods

3.1. Introduction

This chapter outlines the study's aims and the methodological approach that was taken to evaluating the implementation of the Organ Donation (Deemed Consent) Act (2019) in clinical practice. It begins by identifying gaps in our existing knowledge in the area and discusses the research problems that animate the study, as well as the study aims and research questions. Next it discusses the theory that underpins the research. To inform and shape both the instructional design of the Organ and Tissue Donation Education Programme (OOEP) and the evaluation processes that underpin this evaluation, the study employs a layered theoretical framework that integrates the following established models in the field: Bloom's Taxonomy to structure cognitive complexity, the Capability, Opportunity, Motivation–Behaviour (COM-B) model to explore behavioural change, and the Learning Transfer Evaluation Model (LTEM) to assess how learning translates into practice. Within LTEM, the Situational Evaluation, Decision, and Action (SEDA) component provides insight into real-time clinical decision-making, while the emerging concept of phronesis, practical wisdom in ethical decision-making, offers a lens for addressing moral complexity.

The evaluation is grounded in the Medical Research Council's Framework for Complex Interventions (Moore et al, 2015), which recognises that legislative change unfolds within dynamic systems. This systems-based approach enables the study to account for the educational, behavioural, organisational, and societal factors that shaped how Specialist Nurses interpreted and applied the law following its introduction. By moving beyond linear cause-effect models, the evaluation captures the influence of context and individual agency, offering a detailed understanding of training effectiveness and identifying areas for improvement in practice.

3.2. The Literature: Knowns and Unknowns

3.2.1. What is known about the opt out legislation

The urgency of evaluating the ODDC Act (2019) lies in its potential to address a persistent global challenge: the shortage of transplantable organs. As discussed in Chapter 2, many countries have adopted opt-out donation systems in response to this challenge (Ahmad et al., 2017). The UK followed suit, introducing is own deemed consent legislation with the expectation that it would increase donation rates. However, this policy shift occurred despite international evidence showing that opt-out organ donation legislation does not automatically translate to higher donation rates. Initial government projections of the likely effects of the legislation were optimistic, aiming to raise consent rates to 80% and generate an additional 700 transplants annually. Yet, recent data depicted in figure 10, paints a more concerning picture. Consent rates have declined to 61%, and the transplant waiting list has grown to nearly 7,000 patients.

Although 2022/2023 saw modest improvements, a 2% rise in donors and a 5% increase in transplants, figures remain below pre-pandemic levels. With the waiting list expanding, surpassing previous performance benchmarks is not just desirable but essential.

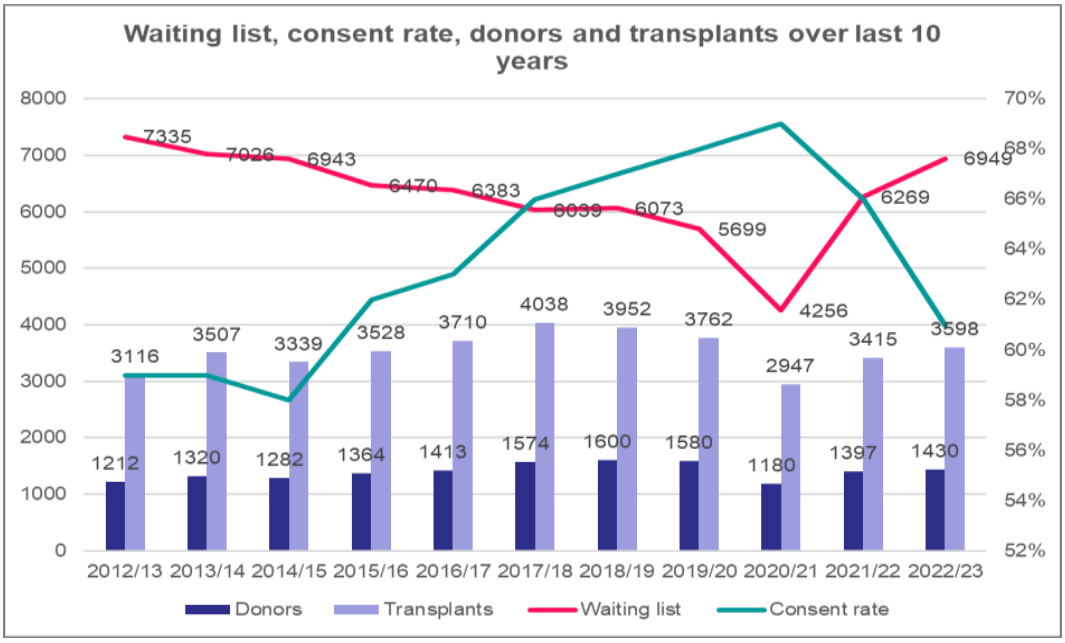

Figure 10 - Annual Activity Report – 2024/25: NHSBT - A ten-year timeline showing the number of people on the waiting list, donors, transplant recipients, and the decline in consent rates.

Compounding this challenge is a significant erosion of public trust in NHS services, with confidence levels falling from 70% during the pandemic to just 25% in its aftermath. This decline in trust may shape public perceptions of organ donation, especially amid concerns over prolonged ambulance response times, limited access to in-person medical care, and ongoing industrial action by healthcare professionals. These factors risk undermining the altruistic foundations upon which organ donation relies, as public trust is a critical component in individuals' willingness to donate and in the ethical functioning of donation systems (Martínez-López et al., 2023). The decline in public trust for the NHS is illustrated below and has seen a correlating downward trajectory in deemed consent rates (Figure 11 below).

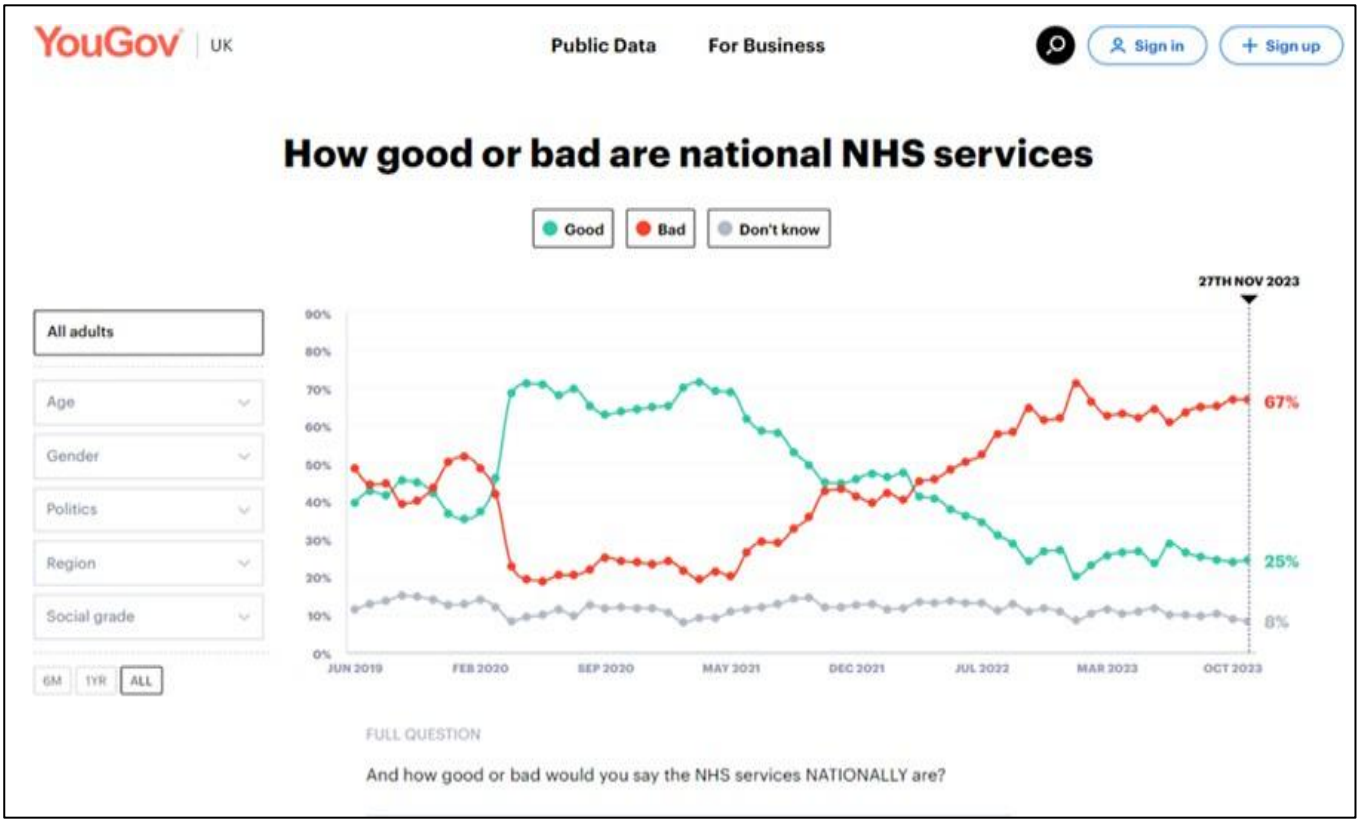

Figure 11 - YouGov survey showing how good or bad the NHS services are Nationally

Opt-out systems are designed to bridge the gap between individuals' passive intentions to donate and their actual behaviour. However, they raise complex ethical questions (Rieu, 2010), and the evidence linking such systems to improved consent rates remains inconclusive (Bea, 2020). While some studies report higher donation rates in opt-out countries (Abadie and Gay, 2006; Neto et al., 2007; Healy et al., 2005; Gimbel et al., 2003; Ahmad et al., 2019; Rithalia et al., 2009), others, such as the Welsh Government review (Palmer, 2012), highlight that countries like Bulgaria, Turkey, Cyprus, and Greece still struggle with low consent rates despite having opt-out policies. This suggests that legislation alone is insufficient to increase donation rates. Countries with high donation rates, such as Portugal, Belgium, Croatia, and Spain, succeed not merely because of their legal frameworks but due to sustained investment in infrastructure, public education, and professional training (Ahmad et al., 2019). Within this context, Specialist Nurses play a pivotal role. They are the professionals who lead donation conversations with families, often in emotionally sensitive and ethically complex situations. Yet there is a notable gap in research on how best to support Specialist Nurses through targeted education and training (Noyes et al., 2019; Neade's, 2019).

This complex evaluation research study is therefore an important step in understanding the effectiveness of the training provided to Specialist Nurses and its broader implications for practice. It seeks to understand whether current training equips Specialist Nurses to navigate the demands of deemed consent legislation effectively and ethically. Furthermore, by examining learning transfer from classroom to clinical practice, this study clarifies what works, what does not, and what must change.

A maxim widely attributed to O'Brien, Buxton and Ferguson (1987) captures this challenge: *it is always too early to evaluate a new technology, until suddenly it is too late*. In organ donation reform, this highlights the need for timely and rigorous evaluation as policy shifts move rapidly into practice.

3.2.2 What is yet unknown about the opt-out legislation

Despite the widespread adoption of opt-out organ donation legislation across many countries, fundamental questions remain unanswered. What truly drives its success, education, societal norms, media influence, or cultural and religious acceptance? What training strategies most effectively support Specialist Nurses and healthcare teams in managing ethically complex organ donation discussions? And, critically, how effective is the opt-out model within England's specific legal, social, and healthcare context? This evaluation is designed to address critical questions surrounding the impact of education and training on Specialist Nurses' ability to facilitate donation conversations within the framework of deemed consent legislation. It responds to a notable gap in the literature, specifically, the absence of empirical evidence in this area, as highlighted by Walton et al. (2023) in their international consensus recommendations on consent models and donor registries. While the policy shift aims to increase donation rates, its practical implementation depends heavily on the skills, confidence, and ethical sensitivity of those delivering it, particularly Specialist Nurses, who lead these emotionally sensitive discussions with bereaved families. Although public awareness of the opt-out organ donation system is relatively high, estimated at around 75%, understanding of its legal implications remains limited, with many individuals mistakenly believing they are automatically registered or unaware of the need for active decision-making (Coe et al, 2023).

In reality, England operates a dual system of expressed and deemed consent, which requires careful interpretation and sensitive communication. Data from the Potential Donor Audit (PDA) reveals that families often express uncertainty about their loved one's wishes or claim the deceased did not want to donate. It is unclear whether these responses reflect genuine preferences, familial interpretation, or personal beliefs shaped by prior experiences with the NHS. For families who do support donation under deemed consent, it remains unknown whether their decision is influenced by the legislation or whether they would have consented to the donation regardless. These ambiguities highlight the need for skilled facilitation and ethical clarity. Embedding the law into practice is not automatic, it requires time, deliberate effort, and professional competence. Specialist Nurses must be equipped with hands-on experience, new communication tools, and the ability to anticipate and respond to refusal with empathy and precision. As Moore et al (2015) argue, understanding how an intervention drives change is essential for identifying and strengthening weak links in the causal chain. Behavioural insight is therefore not just a theoretical concern; it is central to both the implementation and evaluation of policy. In this context, the study helps clarify how legislation, education, and professional practice work together, providing useful insights to improve organ donation in England.

3.3. Aim, Problems and Research Questions

3.3.1. Aim of the Study

This study aims to evaluate (OOEP) how the Opt-Out Education Programme functioned and supported Specialist Nurses in implementing the Organ Donation (Deemed Consent) Act (2019), and to generate system-level insights into the strengths and limitations of the UK organ donation system under deemed consent.

3.3.2. The Problem

Prior to the legislative change, if an individual had not formally registered their decision to become a donor, Specialist Nurses approached organ donation conversations with families from a neutral standpoint, seeking to understand whether the deceased had ever expressed a wish to donate. Under deemed consent, the default assumption is that donation will proceed unless the individual has registered an objection. This legislative shift brings a profound change to the nature of donation conversations. Discussions around organ donation have always centred on securing donations, provided they are ethical, legal, and medically practical. Before the law change, the thrust of donation conversations was to actively support families to consent to donation; however, after the law change it became a new kind of conversation: explaining the law to families and persuading them to go along with the law's presumption that their family member was willing to donate.

The law change means that Specialist Nurses are now required to work within a legal framework that leaves less choice and is more directive that donation should take place, while still continuing to respond with compassion to the grief, uncertainty, and emotional complexity families may experience. This presents a demanding challenge. Simply knowing the law is not enough. Specialist Nurses must feel confident in their role, genuinely motivated to support the principles of deemed consent, and aware of the ethical sensitivities that arise in practice. To approach these conversations effectively, they need more than legal understanding, they require practical expertise, advanced communication skills, and emotional awareness to support families with compassion and clarity. The complexity of this task calls for a robust educational strategy that supports behavioural change and learning transfer.

3.3.3. Evolution of the Study Design

The study began as an EdD project evaluating how training supports the implementation of the ODDC Act (2019). As the research progressed, however, the volume and complexity of the data increased, driven by evolving research questions, stakeholder engagement, and external disruptions such as the COVID-19 pandemic. As a result, the scope of the work expanded substantially, ultimately progressing into a PhD study. Given the adaptive nature of the project, a multi-phased mixed-methods complex-systems evaluation design was adopted.

Rather than following a fixed linear pathway, the evaluation was intentionally iterative, allowing research questions to evolve in response to emerging insights. Initial questions, shaped by the literature review, were refined through ongoing engagement with Specialist Nurses and reflective analysis of practice. This flexible methodological approach ensured the study remained responsive, relevant, and grounded in the lived realities of those delivering organ donation conversations, ultimately producing a more robust examination of the impact and effectiveness of the legislation training programme.

3.3.4. Overarching Question

The overarching research question explored was: How did the Opt-Out Education Programme function in practice, and how effectively did it support Specialist Nurses to implement the Organ Donation (Deemed Consent) Act (2019) within the UK organ donation system?

3.3.5. Research Questions

From this, four specific research questions were formulated:

I. How effectively was the Opt-Out Education Programme (OOEP) designed and implemented in respect of the Organ Donation (Deemed Consent) Act 2019?

II. What impact did the OOEP have on Specialist Nurse/Requester organ donation requesting practices?

III. What positive or negative impact did the introduction of the Organ Donation (Deemed Consent) Act 2019 have on these practices?

IV. How can organ donation requesting training or practice be improved following the introduction of the Act?

3.4. Theoretical Frameworks

A central focus of the study was to identify the specific practice changes required of Specialist Nurses, determine what constitutes successful practice change, and examine the processes that enabled, or hindered, these changes following the introduction of the ODDC Act (2019). To support this inquiry, a multi-phased mixed-methods complex-systems evaluation was developed and underpinned by a purpose-built theoretical framework drawing on four well-established models in the field. From the outset, it was clear that the legislative change placed several different demands on Specialist Nurses. First, they needed to update their understanding of the law, reflecting changes in knowledge and cognition. Second, they needed to modify their behaviour and be motivated to apply the new requirements in practice. It was also evident that Specialist Nurses do not work in isolation; the broader organisational environment significantly influences their capability and behaviour.

For this reason, four complementary models were selected to capture the range of changes required. Bloom's Taxonomy helped identify the cognitive expectations placed on learners, while the COM-B model (Capability, Opportunity, Motivation–Behaviour) provided a lens for understanding the behavioural conditions necessary for effective application of the law. The Learning Transfer Evaluation Model (LTEM) was then used to assess whether learning acquired during training translated into practice, with particular emphasis on the SEDA (Situational Evaluation, Decision, and Action) component to highlight real-time decision-making under pressure. Finally, the emerging concept of *phronesis*, practical wisdom, highlighted the ethical judgement Specialist Nurses draw upon in emotionally complex clinical environments, particularly during organ donation conversations. Together these models provide the conceptual tools to underpin a complex systems evaluation, grounded in the MRC's Framework for Complex Interventions (Moore et al, 2015), enabling the study to account for the dynamic, multi-layered context in which organ donation conversations occur. The following section outlines the key models in greater detail.

3.4.1. Bloom's Taxonomy

To effectively address both the cognitive and behavioural aspects of implementing the ODDC Act 2019, the Specialist Nurses' training programme, known as the 'Tri-modular Opt Out Education Programme' (OOEP), adopted a multi-theoretical framework, with Bloom's Taxonomy at its core. Despite its origins in 1956, Bloom's remains a foundational tool in nurse education, valued for its structured approach to learning progression. The taxonomy, later revised by Anderson and Krathwohl (2001), outlines six ascending levels of cognitive engagement: remembering, understanding, applying, analysing, evaluating, and creating. These stages informed the pedagogical design of the programme. During the training, it would be necessary for the Specialist Nurses to progress from basic recall of deemed consent legislation to complex problem-solving and reflective practice (Fig.12). This approach emphasised active learning and real-world application, equipping Specialist Nurses to handle the nuanced demands of their role with confidence and compassion.

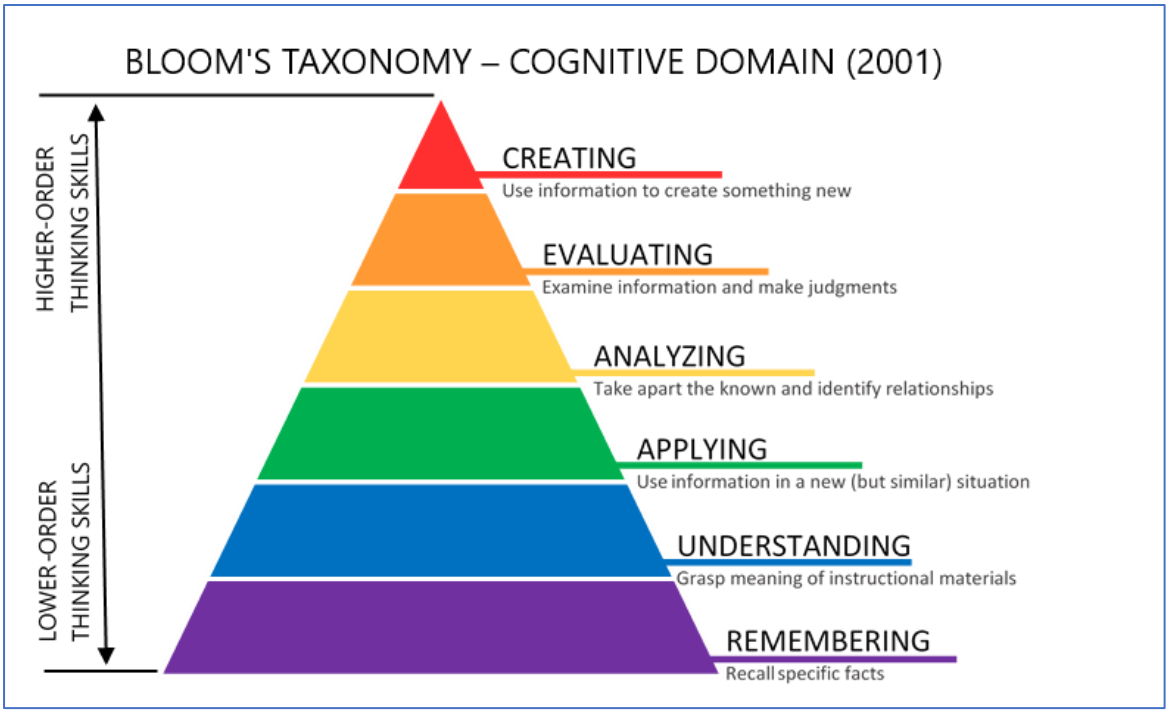

Figure 12 - The six levels of Bloom's Taxonomy

For example, Specialist Nurses were supported in remembering inclusion and exclusion criteria, understanding the rationale behind legal safeguards, applying the law in bedside conversations, analysing emotional and clinical contexts, evaluating ethical dilemmas, and creating new approaches based on reflective practice. This structured approach ensured that the training was not only educationally sound but also practically relevant to the distinct realities of organ donation conversations. At the base level, the training focused on helping Specialist Nurses recall key facts about the deemed consent system. This included memorising the inclusion and exclusion criteria, such as who qualifies for deemed consent and who does not. Specialist Nurses learned to identify individuals excluded from deemed consent, including those under 18, not ordinarily resident in England, recently released from prison, under mental health sections, or those lacking capacity to understand the legislation. This foundational knowledge was essential for ensuring legal compliance and safeguarding vulnerable populations. Building on recall, the curriculum supported Specialist Nurses in understanding the rationale behind these safeguards. Training modules explored why exclusions exist, linking them to ethical principles such as autonomy, informed consent, and protection of vulnerable groups. Specialist Nurses were encouraged to reflect on the intent of the legislation, not just its wording, generating a deeper appreciation of its ethical and legal foundations.

At the applying stage, Specialist Nurses practiced using their knowledge in clinical settings. Role-play scenarios and case studies helped them demonstrate their ability to explain and discuss the legislation with consultants, bedside nurses, and family members. This included guiding conversations about donation, clarifying legal status, and responding to questions with confidence and sensitivity. Application was especially critical during bedside conversations, where Specialist Nurses had to balance legal clarity with emotional support.

Training also developed Specialist Nurses' ability to analyse complex situations in real time, particularly during the breaking bad news conversation, which often precedes donation discussions. Specialist Nurses learned to assess emotional cues, family dynamics, and clinical context to determine the right moment to transition into the donation conversation. This involved leading with benefits of donation, such as legacy, comfort, and helping others, before introducing the legal framework of deemed consent. The ability to analyse these moments was key to ensuring conversations were both ethical and effective. At this level, Specialist Nurses were equipped to weigh ethical dilemmas, such as determining whether deemed consent applies to a person seeking asylum. These scenarios required critical thinking, legal interpretation, and ethical judgement. Specialist Nurses had to evaluate multiple factors including, residency status, capacity, and cultural sensitivity, before making informed decisions. This evaluative skill was essential for navigating grey areas in practice. Finally, the training encouraged Specialist Nurses to generate new solutions based on experience and reflection. This included adapting communication strategies, refining approaches to complex cases, and sharing lessons learned from previous challenges.

By adopting a creative approach, the curriculum empowered Specialist Nurses to improve practice continuously, ensuring that the deemed consent process remained compassionate, legally sound, and responsive to diverse clinical realities. Incrementally building on Bloom's Taxonomy supported both curriculum design and evaluation, with simulation and real-world scenarios used to assess understanding and application of deemed consent legislation. 'It ensured that Specialist Nurses were not just informed, but prepared to act with confidence, empathy, and ethical clarity in one of the most sensitive areas of clinical care. In this study, Bloom's Taxonomy was used to structure the training curriculum for Specialist Nurses, ensuring a progressive learning pathway from foundational knowledge to advanced clinical reasoning. It supported the design and evaluation of modules that enabled Specialist Nurses to recall and understand the inclusion and exclusion criteria of deemed consent, apply this knowledge in bedside conversations, analyse emotional and ethical contexts in real time, evaluate complex dilemmas, such as cases involving asylum seekers, and ultimately create adaptive solutions informed by experience.

Next to Bloom's Taxonomy that helped us conceptualise the cognitive structure of the training programme and that structured both curriculum design and evaluation through simulation and real-world practice, three further models shaped our thinking: the COM-B model (West & Michie, 2020) helped us to conceptualise the behaviour change needed in Specialist Nurse practice and the Learning Transfer Evaluation Model (LTEM) (Thalheimer, 2023), gave a framework for thinking about how effectively learning was applied in practice. Finally, the Situational Evaluation, Decision, and Action (SEDA) framework, helped us to conceptualise real-time ethical decision-making during emotionally complex organ donation conversations. These three models are discussed next.

3.4.2. Behavioural Change Capability, Opportunity, Motivation and Behaviour (COM-B) Model

The Capability, Opportunity, Motivation and Behaviour (COM-B) model (West & Michie, 2020) offered a powerful lens for understanding the behavioural shifts required of Specialist Nurses under the ODDC Act (2019). According to the COM-B model, behaviour (B) occurs as a result of an interaction between three components: Capability (C), Opportunity (O), and Motivation (M). In this model, the behaviour is the kind of action that the actor should perform, the capability is the psychological and physical ability to perform this action successfully, the opportunity is the physical and social factors in which the action is appropriate, and the motivation is the psychological drive or will to perform the action (Fig.13). The COM-B model states that for any behaviour to occur, an individual must have the capability (C) to perform it, the opportunity (O) to engage in it, and the motivation (M) to do so at that moment. In this context, the required behaviour is to engage in an appropriate donation conversation and, to do so, Specialist Nurses need all three of capability, opportunities and motivation.

In a context where silence may imply consent, the model highlights the need for Specialist Nurses to actively shape conversations with families, balancing legal clarity with emotional sensitivity. Studies such as McLaughlin et al, (2025) and Neades, (2009) reveal how inaction or rigid adherence to policy can confuse or distress families, reinforcing the importance of relational competence and behavioural adaptability. The COM-B model provided a robust behavioural framework for this evaluation, offering a structured way to understand how Specialist Nurses enacted training under the ODDC Act, (2019). Rather than viewing behaviour as procedural compliance, COM-B enabled a more complex analysis of practice within emotionally charged, context-dependent environments. It framed behaviour as the product of three interacting domains: (C) Capability, encompasses legal knowledge, skilled communication, and the ability to emotionally connect in the situation; it is essential for navigating complex donation conversations with sensitivity and confidence. (O) Opportunity is shaped by organisational culture, team dynamics, access to resources; their emotional state, prior knowledge of organ donation, and relational dynamics with clinical staff directly influenced how Specialist Nurses navigated the conversation. Families were not passive recipients of information but active participants whose responses, needs, and expectations created the conditions within which opportunity for effective practice either expanded or contracted, (M) Motivation, as framed within the COM-B model, encompasses ethical commitment, professional identity, and personal values, all of which played a complex role in how Specialist Nurses engaged with the deemed consent legislation. The COM (B) model holds that behaviour change requires all three of capability, motivation and opportunity. While many Specialist Nurses viewed the law change as a positive step toward increasing transplant opportunities and saving lives, others expressed concern about its timing and public visibility, particularly during the COVID-19 pandemic, when national campaigns were paused and public understanding was limited.

For some, the legislation felt like a progressive move; for others, it risked being perceived as a quiet shift in policy that bypassed meaningful public engagement. COM-B's relevance is therefore heightened by the emotionally charged nature of donation conversations, where families are not passive recipients but active participants whose responses shape the course of interaction. Behavioural change is not simply a matter of training uptake; it requires a shift in how Specialist Nurses perceive and enact their role. The Behaviour Change Wheel (BCW) (West and Michie, 2020), built around COM-B, offers a structured way to design and evaluate interventions that address deficits in capability, opportunity, and motivation. Its application in national health strategies further validates its application in complex systems.

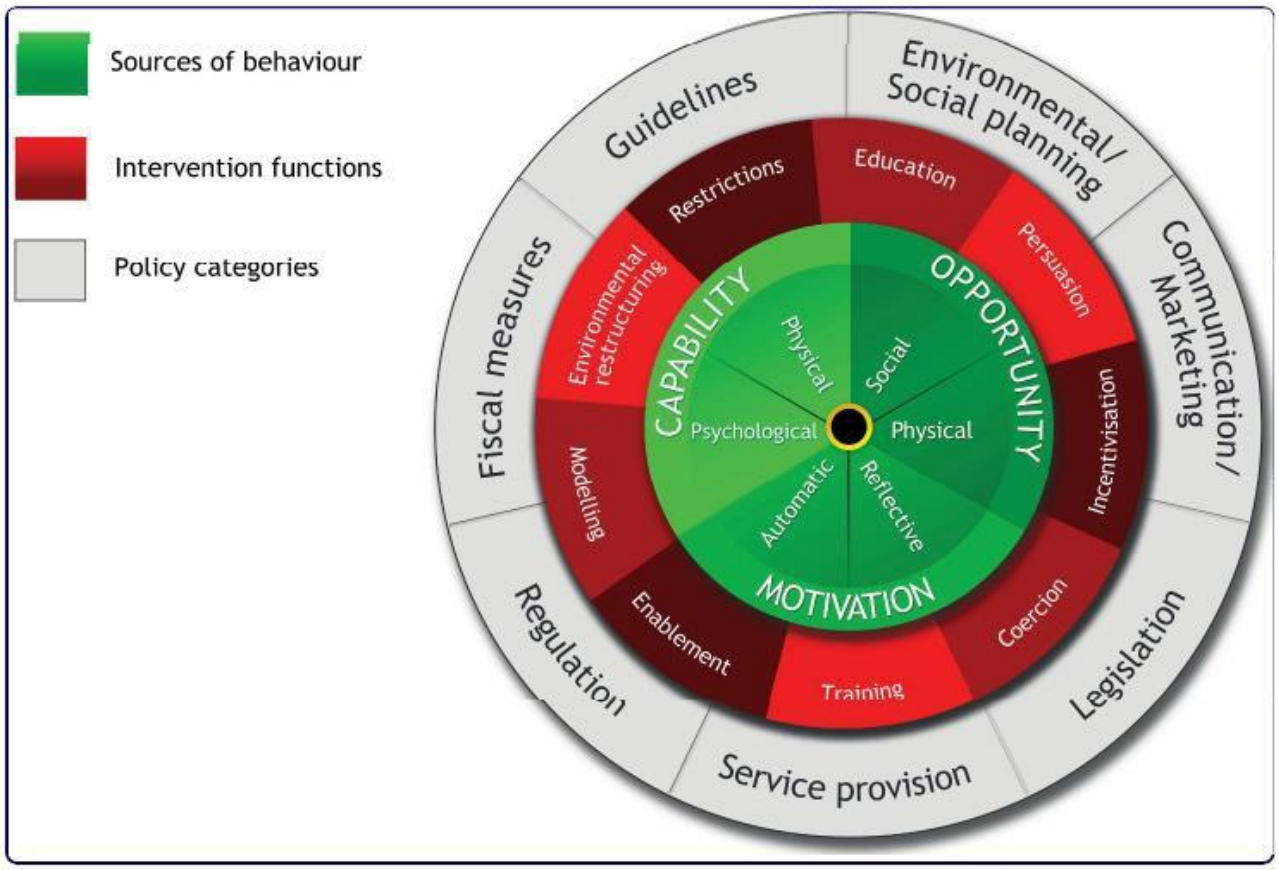

Figure 13 - The COM-B Model of Behaviour Change Wheel (West and Michie, 2020)

The COM-B Model of Behaviour Change Wheel provides a valuable foundation for this evaluation by framing the behavioural dimensions of Specialist Nurse practice. It supports an understanding of how Capability, Opportunity, and Motivation interact to shape behaviour, in this case, how Specialist Nurses facilitate organ donation conversations under deemed consent legislation. COM-B helps highlight the tensions Specialist Nurses face as they navigate their dual roles: not merely as legal informants, but as relational advocates operating within emotionally sensitive clinical environments. Motivation, in particular, emerged as a complex and context-sensitive factor. Specialist Nurses' willingness to apply the law was influenced not only by professional obligations but also by personal beliefs about autonomy, consent, and the emotional needs of grieving families. This often required balancing the legislative intent with the detailed realities of bedside conversations, where empathy and discretion outweigh strict legal adherence.

The COVID-19 pandemic further complicated this dynamic, amplifying emotional strain and reducing public awareness, making motivational alignment with the law more fragile and situational. By applying COM-B, the evaluation captures how behavioural drivers shape practice in real time, offering a structured lens to assess how education and training support Specialist Nurses in fulfilling their roles as both legal and emotional advocates. This behavioural framing is especially pertinent given the sensitive nature of organ donation, where Specialist Nurses must simultaneously honour the wishes of donors and support families through grief and uncertain times. Encouraging reflection on the benefits of donation, both for recipients and for families seeking meaning in loss, can enhance motivation and support enduring decisions. As West and Michie (2020) argue, behaviour change occurs when interventions address all three COM-B domains. This was evident in Neades' (2019) European study, which found that behaviour change was less likely when perceived as difficult or emotionally fraught. Similarly, Noyes et al. (2019) observed that Specialist Nurses in Wales adapted the legislation to prioritise empathy and dialogue over strict legal adherence, reflecting a values-driven approach to practice. This highlights the importance of designing training that supports not just procedural knowledge, but behavioural readiness. The Specialist Nurse's motivation is often rooted in lived experience, the tangible benefits of donation for recipients and the comfort it can offer grieving families. This intrinsic motivation, combined with professional identity and ethical commitment, forms a powerful driver for compassionate practice. Yet motivation alone is insufficient without capability and opportunity. Specialist Nurses must be equipped with the legal and communicative skills to manage complex conversations, and supported by organisational structures that enable emotionally sensitive, legally robust practice.

3.4.3. The Learning Transfer Evaluation Model (LTEM) and Situational Evaluation, Decision, and Action (SEDA) Models

To further determine whether the deemed consent training was well-designed and fit for real-world clinical practice, the study built upon the foundational use of Bloom's Taxonomy and the COM-B model by integrating two additional frameworks: Will Thalheimer's (2023) Learning Transfer Evaluation Model and, in particular, the Situational Evaluation, Decision, and Action (SEDA) model that is part of Thalheimer's LTEM model. As we saw above, Bloom's Taxonomy helped structure the cognitive demands of the training, while COM-B framed the behavioural conditions necessary for Specialist Nurses to apply the law effectively.

LTEM (Thalheimer, 2023) added a critical layer by emphasising the importance of evaluating not just knowledge acquisition (Fig14), but the extent to which learning is transferred into practice, particularly relevant for assessing how Specialist Nurses use legislative knowledge during emotionally complex donation conversations.

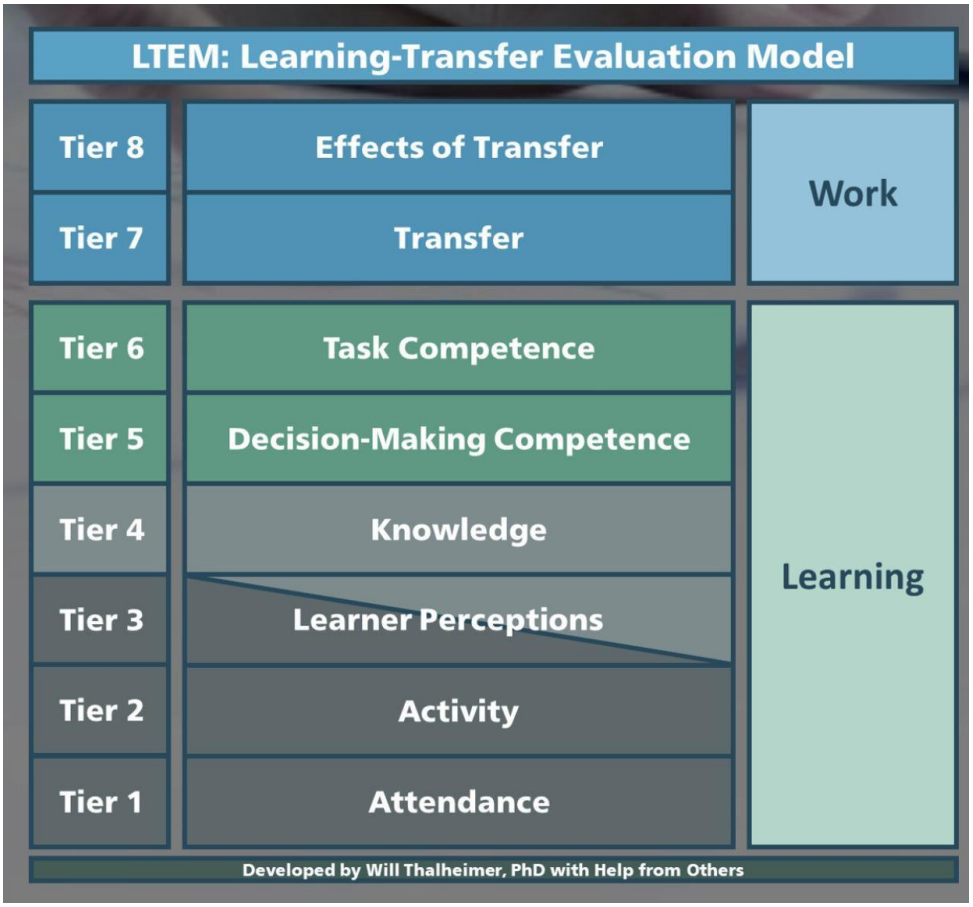

Figure 14 - Learning transfer Evaluation Model Will Thalheimer (2018)

By focusing on higher-tier outcomes such as decision-making competence and behavioural transfer, LTEM supported the development of training that prioritised practical application over theoretical understanding. SEDA further enriched the evaluation by examining how Specialist Nurses make ethical decisions in real time, often under emotional strain, uncertainty, and grief. In practice, these Specialist Nurses must manage the tension between legal obligations and compassionate communication, acting as dual advocates for both donors and recipients. The SEDA framework helped capture this complexity, recognising that decisions are shaped by situational factors, relational dynamics, and ethical judgement. Together, LTEM and SEDA extended the behavioural and cognitive foundations laid by COM-B and Bloom's, enabling an evaluation approach that was both practical and context-sensitive, reflecting the realities of bedside conversations where legislation, empathy, and discretion must be carefully balanced. Together, these frameworks justify a training approach that goes beyond knowledge transmission to support reflective, emotionally intelligent, and context-sensitive behaviour, essential for implementing deemed consent legislation within the NHS's complex system.

This integrated approach is illustrated in the diagram below, which maps each framework contributing to the design, delivery, and evaluation of the training programme.

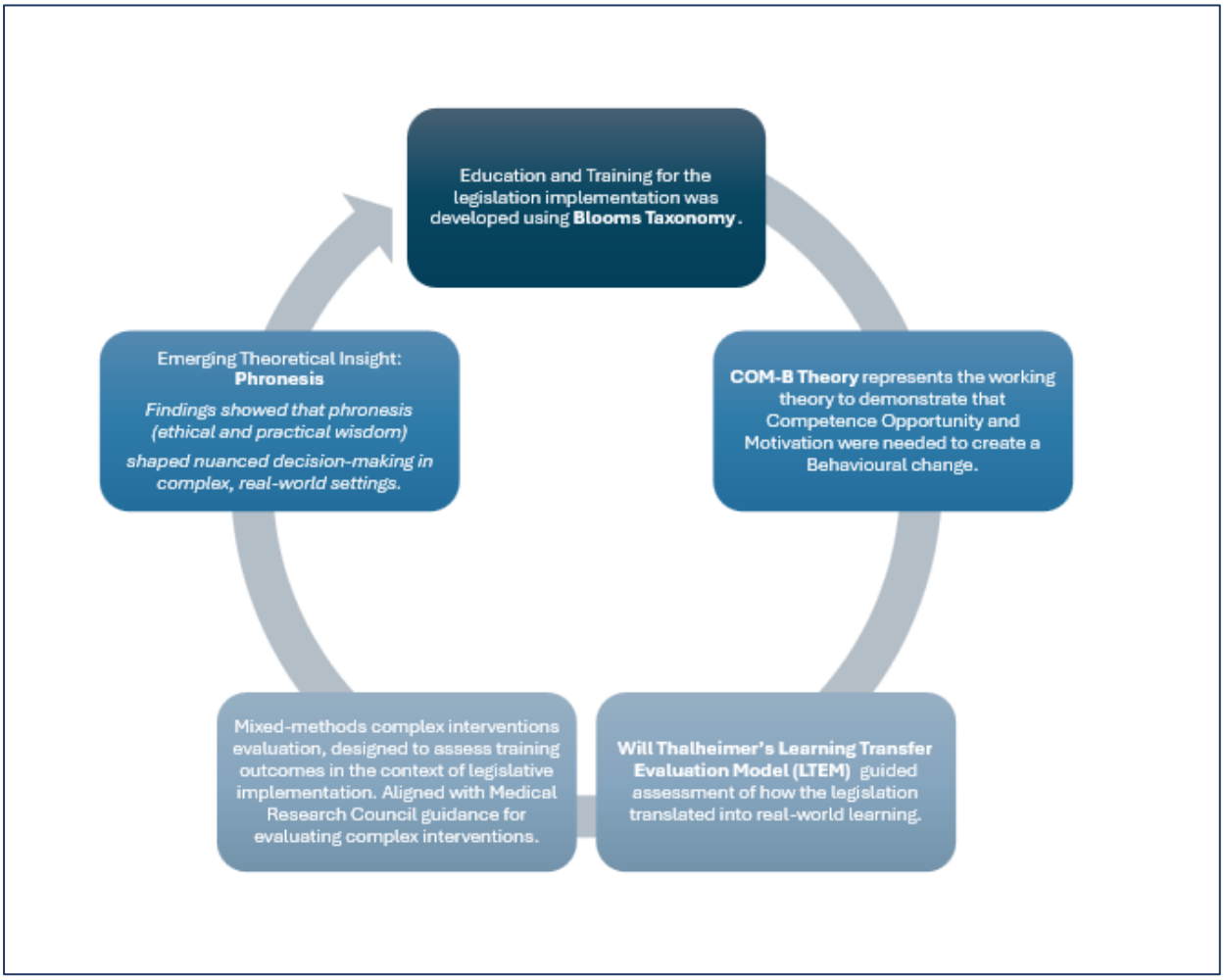

Figure 15 - Foundational Theories Informing Mixed Methods Complex Systems Evaluation: Bloom's, COM-B, LTEM & Phronesis as an Emerging Construct

3.4.4. Phronesis

Phronesis, or practical wisdom, is an Aristotelian concept that goes beyond *techné*, the technical skills needed to perform tasks. While *techné* focuses on procedural competence, *phronesis* involves reflective judgment in morally complex situations where rules or protocols alone are insufficient. Kotzee and colleagues describe it as 'medicine's indispensable virtue,' because it enables clinicians to integrate ethical reasoning with practical judgment when facing dilemmas that cannot be solved by guidelines alone (Kotzee, Paton & Conroy, 2017). *Phronesis* helps Specialist Nurses combine reasoning, emotions, and motivation to make decisions that fit the context and support the patient's overall wellbeing (Kristjánsson et al., 2021). In healthcare, *phronesis* has gained renewed attention as the foundation of professional ethics, particularly in medicine and nursing, where clinicians frequently encounter situations that technical skill or rigid protocols cannot resolve. For example, in Donation after Circulatory Death (DCD) cases, clinicians must balance respect for patient autonomy with the imperative to avoid prolonging suffering, while also considering the potential for organ donation under deemed consent legislation.

Phronesis helps reconcile these competing values and guides actions that are ethically sound and contextually appropriate. Kaldjian's five-step model, provides a practical framework for applying phronesis: clarifying goals of care, understanding circumstances, considering virtues, deliberating, and acting with courage (Kaldjian, 2014). When treatment withdrawal coincides with organ donation, these steps become more complex. Goals must align patient dignity and comfort with the societal benefit of transplantation. Clinicians need to assess prognosis, patient wishes, and legal criteria for death while ensuring transparency and avoiding coercion. Virtues like honesty and compassion guide the Specialist Nurses in conducting sensitive conversations with families during times of grief, while careful deliberation helps balance key ethical principles, such as autonomy, beneficence, and justice, within donation protocols like DCD, which raise complex questions about timing and adherence to the 'dead donor rule' (Magnus, 2021). Acting with courage means implementing withdrawal and donation plans ethically, maintaining palliative care and dignity throughout. Integrating *phronesis* with Kaldjian's framework bridges the gap between moral principles and clinical action in end-of-life care (Gelain Olsen, 2025; AMA, 2022).

Specialist Nurses require *phronesis* because their role involves managing highly emotional and ethically complex conversations with clinicians and families. These conversations usually happen after death has been confirmed using neurological criteria or once a decision to withdraw life-sustaining treatment has been made and organ donation planning begins. In these moments, Specialist Nurses must circumnavigate tensions between respecting patient autonomy, supporting grieving relatives, and meeting legal and clinical requirements. *Phronesis* enables Specialist Nurses to combine clinical facts with moral values and emotional sensitivity, ensuring communication is compassionate and transparent (Kristjánsson et al., 2021). Specialist Nurses prepare thoroughly for donation discussions by understanding the family's circumstances and working closely with clinicians to plan the approach. This includes clarifying roles, deciding who will speak, when and how the conversation will transition from breaking bad news to discussing donation, and anticipating possible family responses along with strategies to manage them. Virtues such as honesty and empathy guide conversations that balance hope with realism, while courage and compassion sustain Specialist Nurses in addressing family distress and their response to the option of organ donation as part of end-of-life care. Without this integrative judgment, donation discussions risk becoming *procedural* rather than *person-centred*, undermining trust and consent quality (Kaldjian, 2014; Rady & Verheijde, 2016). Although not formally included in the training programme, the growing prominence of *phronesis* in the health-sciences literature highlights the importance of ethical reasoning and experiential insight. In the context of deemed consent, where emotional, relational, and legal complexities vary from case to case, rigid protocols alone are insufficient. Specialist Nurses must draw on context-sensitive judgement shaped by values, experience, and cultural understanding. This study therefore acknowledges the need for training that supports such ethical discernment, and the role of *phronesis* in guiding practice will be explored further in the Discussion chapter.

3.5. Research Design

Evaluation, as defined by Clarke and Dawson (1999), is a purposeful, action-oriented process aimed at assessing the value or impact of a policy, programme, or intervention. Notably, its ultimate goal is improvement, not merely to prove or disprove effectiveness. In this research, the evaluation conducted was a multi-dimensional, evidence-informed process that explores how Specialist Nurse training under the ODDC Act 2019 was delivered, enacted, and experienced in real-world clinical settings. Applied to the ODDC Act 2019, this evaluation investigates the impact of deemed consent legislation on Specialist Nurse education, focusing on how well training equips Specialist Nurses to conduct sensitive organ donation conversations. The aim is to identify strengths and areas for development that can inform improvements in educational delivery, clinical practice, and policy. To achieve this, the evaluation adopts a transdisciplinary approach, integrating methodologies from education, sociology, and health sciences. As Greene (2007) notes, evaluation is inherently pluralistic, shaped by diverse paradigms and methodological choices rather than fixed procedures. This flexibility allows evaluators to creatively and appropriately apply different methods to address specific challenges (Clarke & Dawson, 1999).

Such methodological adaptability is essential when examining the behavioural dimensions of Specialist Nurse practice under the ODDC Act. (2019) While legal knowledge, such as understanding exclusions for individuals under 18, those lacking capacity, or not ordinarily resident, is foundational, it does not alone ensure effective practice. Behavioural competence is equally important. Specialist. Nurses must apply their legal understanding with emotional intelligence, especially during sensitive conversations with families. This involves introducing the legal framework judiciously and framing organ donation in a way that resonates in a tangible and relatable way, often by highlighting its life-saving legacy and the comfort it can bring through meaning-making in loss. Effective practice also requires navigating complex scenarios, such as cases involving individuals recently released from prison, sectioned under mental health legislation, or seeking asylum. These situations demand tailored approaches informed by legal, ethical, and emotional considerations. The COM-B model (Michie et al., 2011; West & Michie, 2020) highlights the importance of aligning capability, opportunity, and motivation to support behavioural change. Without addressing these behavioural components, training risks remaining theoretical rather than transformative.

3.5.1. Evaluation Design

In the context of this research, our evaluation was a multi-dimensional, evidence-informed process that examined how Specialist Nurse training under the ODDC Act, (2019) was designed, delivered, and experienced in clinical practice. Rather than focusing solely on outcomes, the evaluation traced the full trajectory of training, from its initial development to its influence on Specialist Nurse behaviour and family engagement.

A mixed methods design was used, combining quantitative measures with qualitative insights to capture both systemic patterns and individual experiences (Creswell & Plano Clark, 2017). The evaluation was structured around four interconnected stages, each informed by established theoretical frameworks:

I. Process Evaluation assessed the structure and delivery of training, using Bloom's taxonomy to explore cognitive engagement and SEDA principles to examine the educational context.

II. Implementation Evaluation investigated how training was enacted in practice, applying the COM-B model to identify behavioural enablers and barriers, and SEDA to evaluate facilitation and support.

III. Impact Evaluation focused on short- to medium-term changes in Specialist Nurse confidence, behaviour, and family interactions, guided by LTEM's emphasis on learning transfer and performance.

IV. Outcome Evaluation considered longer-term system-level effects, such as shifts in consent rates, cultural norms, and policy influence, aligned with goals of sustainable educational development and behavioural change.

This approach was grounded in core principles of utility, credibility, and responsiveness (Patton, 2008), reflecting the interdependent nature of public awareness, clinical practice, and professional education. This evaluation was not a traditional case study. Case studies typically focus on a single, well-defined setting to explore a specific issue in depth (Yin, 2018). In contrast, this study was designed as a multi-phased mixed methods complex systems evaluation, which means it examined how Specialist Nurse training under the ODDC Act (2019) was delivered and experienced across multiple, interconnected domains, professional education, public awareness, and clinical practice. Rather than investigating one isolated context, the evaluation embraced the complexity of real-world implementation. It combined quantitative data (e.g. training reach and fidelity) with qualitative insights (e.g. practitioner experiences and behavioural responses) to understand both broad patterns and individual perspectives. Guided by systems thinking (Hawe, Shiell & Riley, 2009), it recognised that change occurs within a complex system, shaped by feedback loops, evolving conditions, and relationships between people, policies, and environments (Hawe, Shiell & Riley, 2009). Frameworks such as Bloom's taxonomy, COM-B, LTEM, and SEDA supported a structured yet flexible analysis, allowing the evaluation to explore behavioural drivers, learning transfer, and contextual influences.

This approach provided a richer, more responsive understanding than a case study could offer, making it well-suited to evaluating complex policy implementation in a dynamic healthcare environment. The evaluation prioritised the quality, integrity, and adaptability of training, examining its alignment with intended design, accessibility to Specialist Nurses, and responsiveness to emerging needs. Qualitative data, gathered through participant observations, interviews, module evaluations, and debrief themes, enabled inductive analysis of strengths, limitations, and opportunities for enhancement (Rubin & Babbie, 2001).

Quantitative measures assessed fidelity (design alignment), dose (modules completed), and reach (coverage across the on-call workforce), particularly relevant during the shift to virtual training formats prompted by COVID-19 (Carroll et al., 2007; Montgomery et al., 2013). Beyond assessing knowledge and competence, the evaluation explored broader learning capabilities, including adaptability, innovation, and independent decision-making in complex environments (Fraser & Greenhalgh, 2001; Armstrong, 2009). This included navigating unfamiliar challenges, exercising judgement, and applying intuition in practice. Given the evolving status of the Human Tissue Authority's Code of Practice F, still under parliamentary review during early training phases, the evaluation remained iterative and flexible. Continuous feedback mechanisms, such as module evaluations and expert reviews, supported timely adjustments and alignment with anticipated regulatory guidance.

This responsiveness helped maintain fidelity to legislative intent and bolstered Specialist Nurse confidence during a period of legal transition. By triangulating multiple data sources and applying a systems-thinking lens, the evaluation generated a nuanced understanding of how the training was experienced, adapted, and ultimately embedded in practice. It also provided early insight into implementation challenges and helped ensure the programme remained ethically grounded and responsive to the needs of Specialist Nurses within a rapidly evolving policy environment.

3.5.1.1. Process Evaluation

In this study, process evaluation was used not merely to describe the training programme and its intended outcomes, but to understand how it evolved following initial implementation. This approach provided essential context for interpreting outcome measures, particularly in a dynamic healthcare environment (Clarke & Dawson, 1999). By examining how the training was delivered, including its fidelity to design, reach across the Specialist Nurse workforce, dose (e.g. modules completed), and quality of facilitation, the evaluation identified key barriers and enablers to effective practice. These insights were important for understanding variation in engagement and performance across different settings. Importantly, process and outcome evaluation were treated as complementary, offering a more complete picture when combined within a single research design. This integrated approach has been successfully applied in other complex interventions, such as Mair et al.'s (1994) evaluation of intensive probation programmes, demonstrating its value in capturing both implementation dynamics and long-term effects.

3.5.1.2. Outcome Evaluation

Outcome evaluation was a vital component of this study, providing evidence of whether the educational intervention, the Opt-Out Education Programme (OOEP), effectively produced meaningful change among its target population.

While process evaluation focused on how the training was implemented, outcome evaluation assessed the extent to which the intervention influenced Specialist Nurses' behaviours, confidence, and ability to apply the deemed consent legislation in practice. This distinction is important in evaluating complex interventions, where understanding both delivery and impact is essential. Given the timing of the training rollout, it was important to recognise that outcomes may emerge across short, medium, and longer-term phases. Conducting outcome evaluation too early would have yielded limited insight, as behavioural change and legislative impact require time to embed (Social Policy Evaluation and Research Unit (SUPERU), 2017). Once the training had been delivered and operationalised, outcome evaluation became essential for assessing whether Specialist Nurses were able to leverage the legislation effectively in consent conversations, and whether public awareness and consent rates began to shift. The study used interviews, debriefs, and participant observations to explore these outcomes qualitatively, capturing how the training influenced Specialist Nurses confidence, ethical reasoning, and communication strategies.

These insights helped determine whether the intervention achieved its intended behavioural and attitudinal shifts, and whether it contributed to the broader goal of increasing organ donation through informed consent. Outcome evaluation complemented the process evaluation by revealing not only how the training was delivered, but also whether it led to meaningful changes in practice. This provided a strong basis for refining future policies and improving training programmes.

3.5.1.3. Impact Evaluation

In this study, impact evaluation was used to explore the broader effects of the deemed consent education and training intervention, particularly its potential influence on organ donation consent rates over time. Defined as an objective assessment of what changes have occurred as a result of an intervention, and the extent to which those changes can be attributed to it (HM Treasury (2020). Impact evaluation typically draws on theory-based, experimental, or quasi-experimental approaches. However, given the complexity of the legislative change and the relatively short timeframe since implementation, measuring impact at this stage remains exploratory. Evidence from other countries such as Spain, Italy, Austria, and Wales, suggests that increases in donation rates following opt-out legislation often occur gradually and in tandem with infrastructure improvements, such as the introduction of full-time transplant coordinators and public awareness campaigns (Rithalia et al., 2009; Willis & Quigley, 2014). In this context, it is premature to expect definitive shifts in consent rates just five years post-implementation. Nonetheless, early indicators, such as Specialist Nurses' confidence in applying the legislation and the reach of public education efforts, can offer valuable insight into the direction of change.

This study's impact evaluation focused on what could be reasonably measured at this stage. Specialist Nurses reported changes in behaviour, confidence, and perceived effectiveness in deemed consent conversations. These data were gathered through interviews, debriefs, and participant observations, and triangulated with outcome evaluation findings to assess whether the intervention was beginning to influence practice.

Importantly, this approach recognises that impact is not solely about numerical shifts in consent rates, but also about the conditions that enable such change, including training quality, Specialist Nurse capability, public awareness and system readiness. In line with guidance from Hawe, Degeling and Hall (1990), the process evaluation was undertaken both before and alongside the outcome and impact evaluation to ensure a clear understanding of how the intervention was implemented. This sequencing was essential for interpreting any observed changes and for identifying which aspects of the programme contributed to those outcomes.

While Craig et al. (2008) highlight the value of combining process and outcome evaluation, they also note the lack of a replicable template, an issue echoed in McGill et al.'s, (2020) systematic review, which found significant variation in qualitative process evaluation approaches across public health studies. Given the complexity of the intervention, targeting multiple behaviours, Specialist Nurses and Specialist Requesters, potential donor families, health care Specialist Nurses, clinical settings and public awareness, this study adopted a complex systems evaluation approach (Skivington et al., 2021). Process, outcome, and impact evaluation were used in combination to understand how and why the intervention worked (or did not), for whom, and in which contexts. While economic evaluation provided additional insight into resource use, the core focus remained on understanding the mechanisms of change and the conditions under which the deemed consent legislation could be ethically and effectively operationalised.

3.5.1.4. Economic Evaluation

Economic evaluation formed a contextual layer within this study's broader evaluation framework, recognising the importance of assessing value for money in the design and delivery of the deemed consent education and training programme. Given that NHS resources are drawn from the public purse, it was essential to consider how effectively those resources were used to support legislative implementation, particularly in relation to the OOEP and the activities of the training and legislation change teams. While this study did not undertake a full economic evaluation using formal models such as Cost Effectiveness Analysis or Cost-Benefit Analysis (Pandit, 2016), it was informed by key principles of economic evaluation namely, the need to understand opportunity cost, resource allocation, and the balance between inputs and outcomes (GOV.UK, 2018). The evaluation considered whether the training programme reached its intended audience (100% of Specialist Nurses on the on-call rota), whether it was delivered efficiently under pandemic constraints, and whether the outcomes, such as increased Specialist Nurse confidence and legislative readiness, justified the investment. Cost analysis was embedded throughout the programme lifecycle, particularly in relation to the repurposing of training materials for virtual delivery and the use of simulation-based learning. These adaptations were necessary to maintain fidelity and reach while managing resource constraints. By triangulating outcome data with implementation insights, the evaluation offered funders and programme leads a practical lens through which to assess the relative value of the intervention, supporting future decisions about scaling, sustainability, and refinement.

In this way, economic evaluation complemented the process and outcome strands of the study, helping to ensure that the programme was not only effective and ethically sound, but also economically justifiable. In summary, each evaluation type, process, outcome, and impact, offers distinct but complementary insights. Process evaluation clarifies whether the training was implemented as intended; outcome evaluation assesses whether it influenced Specialist Nurses' behaviour in practice; and impact evaluation begins to explore the longer-term effects on consent rates and system-level change. Together, these approaches provide a robust framework for evaluating the effectiveness of the education and training programme within the wider context of legislative reform.

3.5.2. Multi-Phased Mixed Methods Complex Systems Evaluation

This study used a multi-phased, mixed-methods complex-systems evaluation to examine how deemed consent legislation was implemented within the NHS. Initially, distinct strands of process, implementation, impact, and economic evaluation were considered to capture the multifaceted nature of the Specialist Nurse training programme. Process evaluation focused on how the training was delivered, including fidelity to design, reach across the workforce, and responsiveness to context (Clarke & Dawson, 1999). Implementation evaluation explored how the programme was enacted in practice, identifying barriers and enablers to effective delivery. Impact evaluation assessed changes in practitioner confidence, behaviour, and family engagement, while economic evaluation considered resource use and value within a constrained healthcare system. However, as the study progressed, it became evident that these elements were deeply interconnected and could not be meaningfully evaluated in isolation. The NHS was conceptualised as a complex adaptive system, shaped by continuous interactions among legislation, policy frameworks, healthcare professionals, Specialist Nurses, donor families, public engagement efforts, and external pressures (Ketley, 2021). Evaluating the implementation of deemed consent legislation within such a dynamic environment required an approach that acknowledged these interdependencies and the evolving nature of the system. A linear or compartmentalised evaluation would have risked overlooking broader systemic impacts on patients, staff, and organisational culture.

To address this complexity, a mixed-methods design was employed, informed by principles of complex intervention evaluation (Craig et al, 2008) and systems thinking (McGill et al, 2020). This enabled the study to assess not only the effectiveness of the training programme, but also its adaptability in response to contextual challenges. The rollout of the opt-out law coincided with significant disruptions, including the COVID-19 pandemic, suspended public awareness campaigns, and the inherent complexity of clinical environments involving diverse professional roles and emotionally sensitive interactions with families. Qualitative methods, such as interviews with Specialist Nurses and observations of training simulations, were central to capturing how the programme was experienced and adapted in practice. McGill et al.'s (2020) systems-informed framework was tailored to the NHS context to support this inquiry.

The evaluation was structured in two phases: The planned study design (Phase 1) provided a static overview of the organ donation system prior to the introduction of the opt-out law (Fig. 16), while the amended study design (Phase 2) analysed how the system evolved following implementation (Fig. 17). Each phase incorporated structured steps and prompts to guide evaluators, linking qualitative insights with systems thinking (Appendix 4). Following the systems thinking approach described by Arnold and Wade (2015), this evaluation involved identifying the key components of the organ donation system, such as legislation, policy, Specialist Nurse training, family engagement, and public awareness and mapping the relationships between them. This helped clarify the overarching purpose of the system and how its various elements interact and influence one another.

To deepen this understanding, the evaluation drew on Meadows' (2008) work, which emphasises the importance of recognising feedback loops, leverage points, and emergent behaviours within complex systems. By integrating process, implementation, impact, and economic evaluation within this framework, the study was able to capture not only how the training programme was delivered and experienced, but also how it adapted in response to contextual pressures. This approach provided a comprehensive and context-sensitive understanding of the implementation of deemed consent legislation within the NHS, conceptualised as a complex adaptive system.

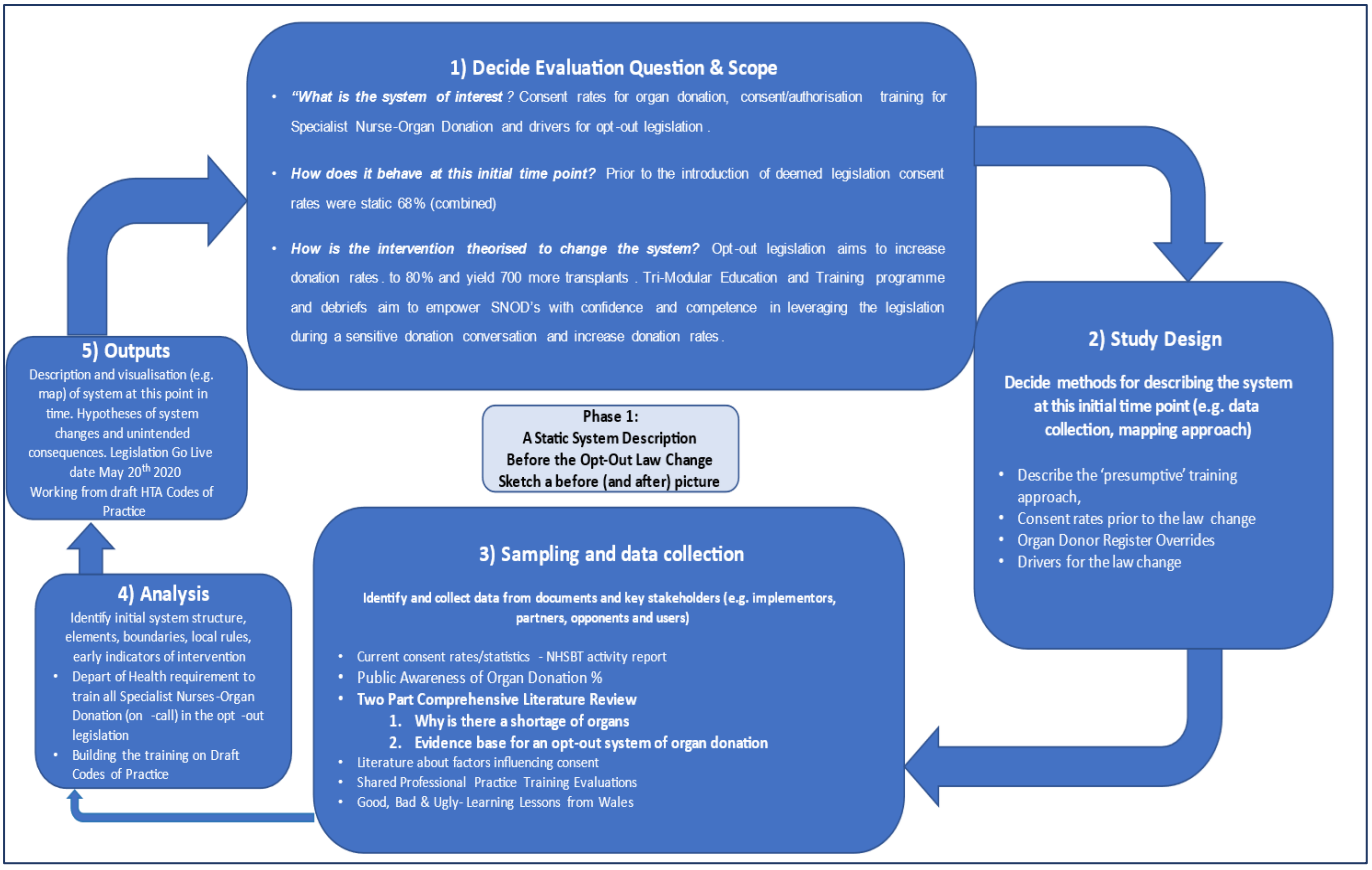

Figure 16 - Planned Study Design: Static System Description Before the Opt-Out Law Change

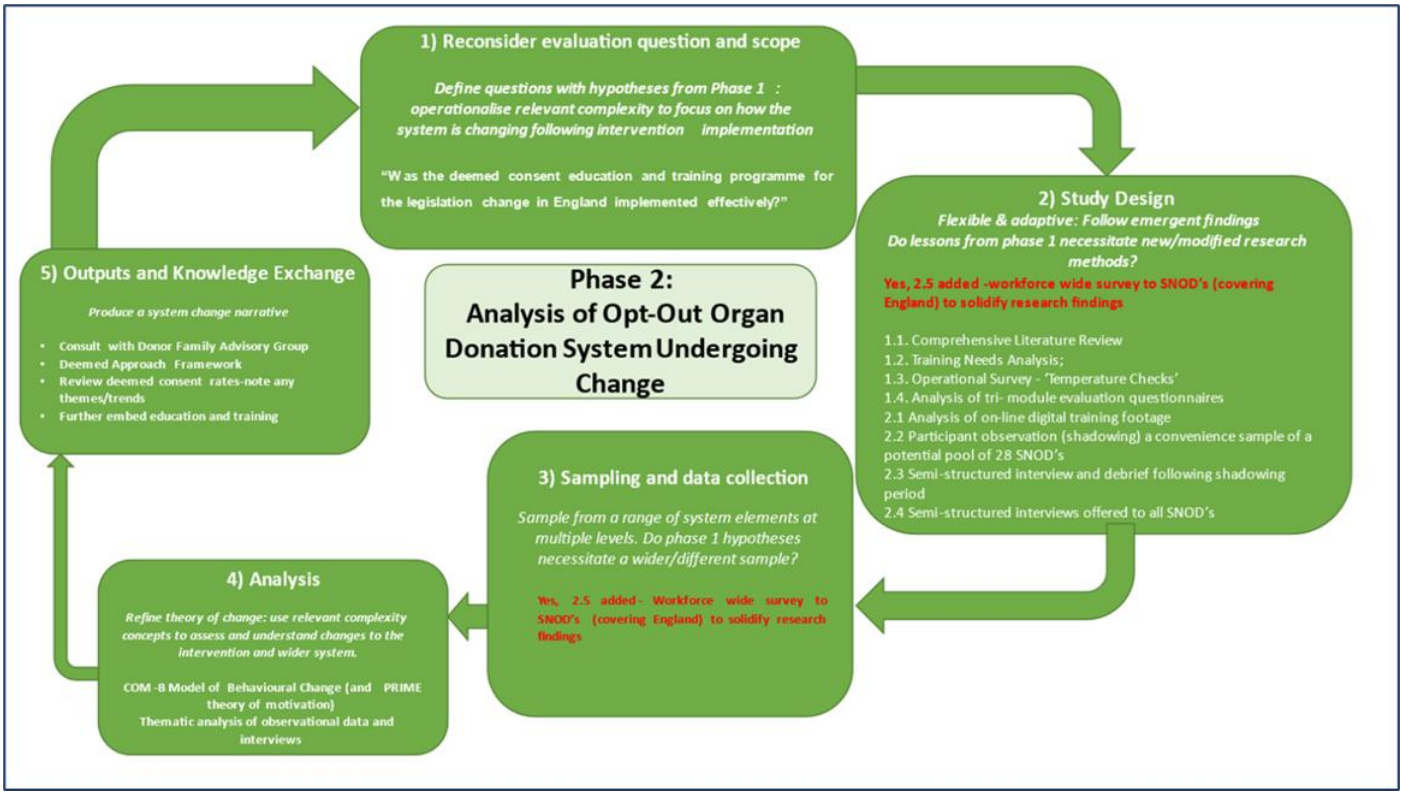

Figure 17 - Amended Study Design: Analysis of opt-out organ donation system undergoing change (Phase 2).

3.5.3. Mechanism of Impact

Understanding how the training intervention generated meaningful change was central to the evaluation. The study focused on the OOEP from the perspective of Specialist Nurses, examining how their engagement with the training translated into practice.

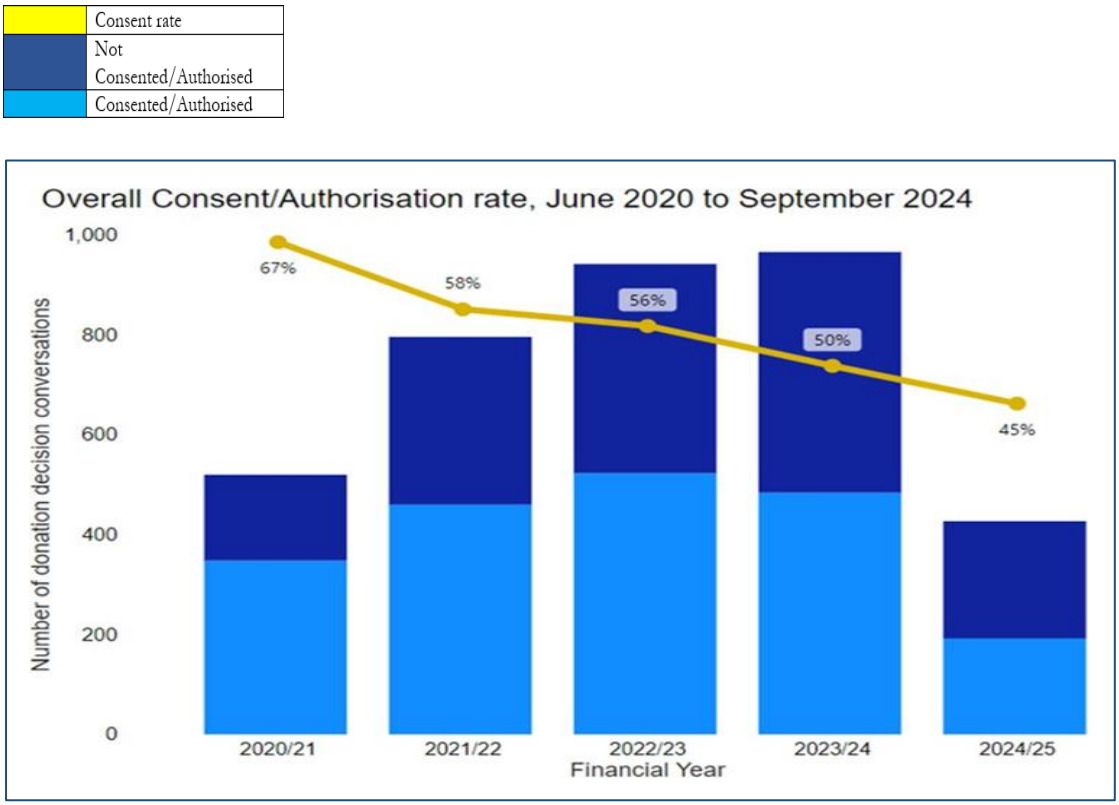

Figure 18 - Overall deemed consent rates declining – June 2020-September 2024

A comparative analysis was conducted using digital recordings of eight Specialist Nurses participating in the annual Continuing Professional Practice Course (CPPC), where they applied the principles of deemed consent legislation. These recordings were contrasted with shadowing observations of Specialist Nurses operating in real-world clinical environments. This dual approach enabled the evaluation to assess the extent to which Specialist Nurses actively engaged with the educational content and applied their learning in practice. Participant responses and interactions with clinical interventions were analysed to explore how specific elements of the training acted as mechanisms that triggered behavioural change and improved outcomes (Grant, Treweek, Dreischulte et al., 2013). In addition, descriptive data on deemed consent rates, instances of unsupported deemed consents, and Specialist Nurse involvement in organ donation planning conversations were collected to assess the broader impact of the intervention. These metrics depicted in figure 18 revealed a gradual decline over time, offering further insight into how training uptake and system-level factors influenced implementation outcomes.

Evaluating complex systems requires assessing whether interventions work effectively in real-world settings. This involves understanding the range and variability of outcomes across different groups, and the factors driving these differences. In the opt-out organ donation programme, this included tracking impact on Specialist Nurses, clinicians, hospitals, and donor families over time. A logic model (Fig.19) was developed to illustrate how the Legislation Change Team (LCT) links to the Organ and Tissue Donation Education Programme (OOEP) and its intended outcomes. It maps the pathway from resources to impact, clarifying how change is expected to occur. The evaluation also considered external influences, notably the COVID-19 pandemic. Shadowing Specialist Nurses revealed how face masks affected emotional communication with bereaved families. The shift to digital training and paused public campaigns reflected wider societal disruptions. By integrating process, impact, and outcome evaluation, the study explored multiple causal layers, from individual interactions to organisational structures, aligning with systems thinking (Keshavarz et al., 2010). This comprehensive approach was vital to understanding how the intervention evolved within a dynamic healthcare system.

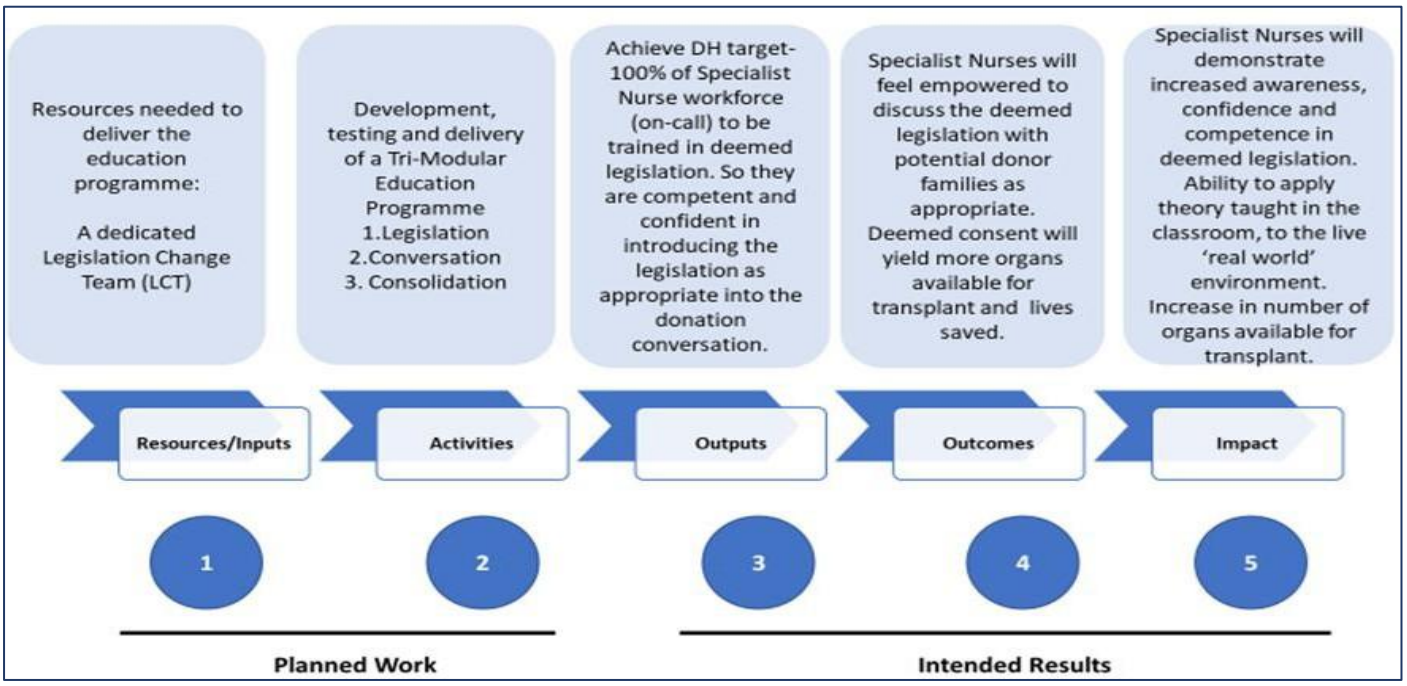

Figure 19 - Logic model adapted from W.K Kellogg foundation (2007)-depicting the education and training program intervention for deemed consent legislation in England in terms of planned work (process) and intended results (outcome and impact).

While Randomised Controlled Trials (RCTs) are widely regarded as the gold standard for evaluating causal relationships due to their ability to minimise bias through randomisation (Hariton and Locascio, 2018), they were not feasible within the context of this study. All participants received the same training intervention, making random allocation impossible and limiting the scope of questions that outcome evaluation alone could address. To overcome this limitation and ensure a robust assessment of the deemed consent education and training programme, the study adopted a comprehensive evaluation strategy aligned with updated guidance from the UK Medical Research Council (MRC), which advocates for the integration of outcome and process evaluation in the study of complex interventions (Moore et al, 2015).

This integrated approach recognises that evaluating whether an intervention 'worked' must be complemented by an exploration of 'how' it was implemented. Understanding the mechanisms of change and the contextual factors that influence outcomes is essential for informing policy, refining practice, and supporting sustainable implementation. In this study, process evaluation was used to examine the delivery, fidelity, and adaptation of the training programme, while outcome evaluation assessed its influence on Specialist Nurses' confidence, competence, and behavioural change. Drawing on the work of Michie and Abraham, (2004), the evaluation also sought to identify the active ingredients within the intervention, those elements most responsible for producing change, and to understand how they exerted their effects across diverse clinical settings. By asking these questions, the study contributed to a cumulative understanding of causal mechanisms and supported the design of more effective, context-sensitive interventions for future application.

3.6. Research Methods Employed

Policy developers often face difficult decisions when recommending complex interventions within unpredictable health systems, where outcomes are shaped by multiple interacting factors. In response, researchers increasingly combine quantitative and qualitative evidence to better understand how interventions function in specific contexts (Noyes et al, 2019). This study adopted such an approach through triangulation, using multiple methods and data sources to confirm findings, reduce bias, and enhance credibility (Noble and Heale, 2019; Thurmond, 2001). While cross-sectional surveys may quantify perceptions or knowledge, they often lack the depth needed to understand implementation dynamics or causal mechanisms (Health Knowledge, n.d.). Similarly, case studies offer rich contextual detail but are limited in generalisability and may not capture system-wide patterns (Paparini et al, 2020). In contrast, this study combined qualitative methods, including interviews, debriefs, and clinical observations, with quantitative measures of fidelity, dose, and reach, enabling a more nuanced understanding of how the intervention was delivered, experienced, and adapted within a shifting legislative and clinical context. By integrating interviews, observations, module evaluations, and survey data, the study addressed the limitations of single method designs and allowed for a deeper, more nuanced understanding of implementation and impact.

Triangulation not only strengthened the validity of the findings but also ensured that the data were complete and interpretable (Williamson, 2005), offering policy-relevant insights into how training interventions can be adapted and sustained within real-world healthcare systems. The following section focusses further on the methodological framework of the research, emphasising the standard methods for evaluating training interventions. It outlines the multi-phased study approach I employ to assess the intricate nature of training evaluation, combined with the complexities of a values- driven law change within the NHS's complex system. Fig. 20 presents the Internal and External Interaction Wheel, representing the interactions and relationships between key stakeholders involved in organ donation processes. Each line connects two entities, indicating a form of collaboration, influence, or communication. The different colours distinguish types of interactions, such as policy influence, operational collaboration, communication flow, or educational support.

The lines visually map how internal bodies (e.g. NHSBT, Specialist Nurses, Governance) and external stakeholders (e.g. Government, Public, Media, Donor Families) are interconnected in implementing and supporting deemed consent legislation and organ donation practice.

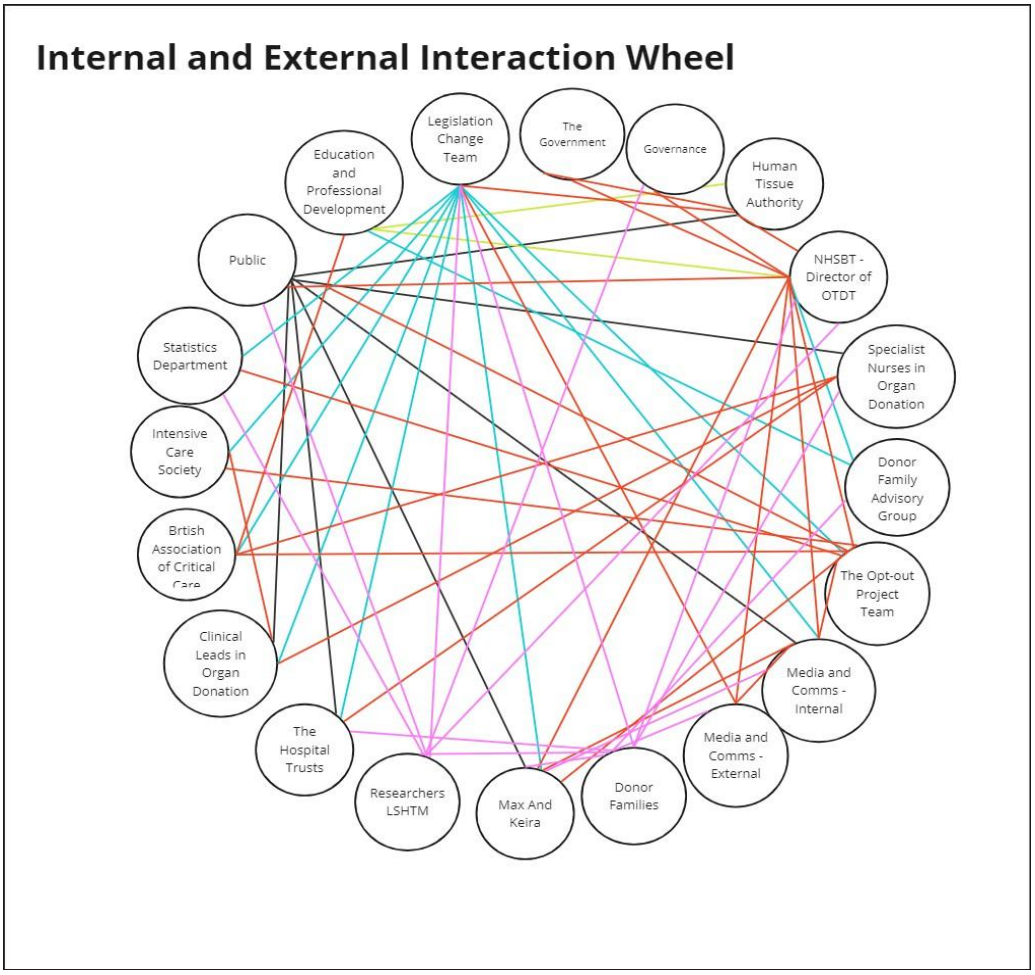

Figure 20 - Internal and External Interaction Wheel

Building on this integrated design, the next section focusses on the two distinct yet interconnected strands of inquiry that shaped the study's evidence base. Workstream 1 consisted of desk-based analysis, offering insights into the policy landscape and educational content, while Workstream 2 captures the realities of clinical practice through field research (Fig.21). Together, they highlight the multifaceted nature of Specialist Nurse training under the ODDC Act 2019 and provide a foundation for understanding its implementation in context.

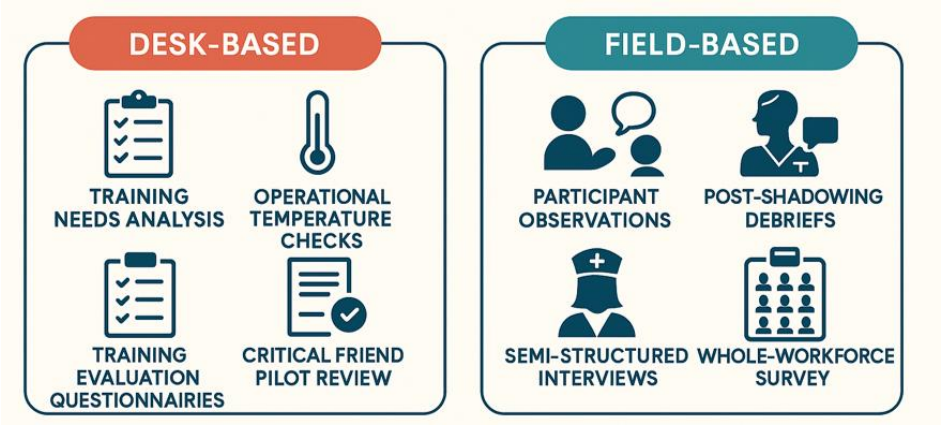

Figure 21 - Mixed Methods Complex Systems Evaluation Design

Desk-based methods included training needs analysis, operational temperature checks, evaluation questionnaires, and a critical friend pilot review to assess early implementation. These tools helped build a foundational understanding of training design and delivery. Field-based methods captured the lived experience and adaptive behaviours of Specialist Nurses. This involved participant observations of family conversations, post-shadowing debriefs, and semi-structured interviews. To extend the reach of the evaluation and enhance its validity, a whole-workforce survey was conducted. This survey assessed staff understanding of the deemed consent legislation and revealed variation in how it was interpreted and applied across clinical settings. Given the unprecedented disruptions caused by the COVID-19 pandemic, which affected training delivery, clinical practice, and public awareness, a multi-dimensional approach was essential. The mixed methods design provided a robust framework for examining how training was understood, adapted, and applied within a shifting healthcare and legislative landscape.

Rather than adopting a traditional case study, this research employed a mixed methods complex systems evaluation. Drawing on Creswell and Plano Clark's (2017) framework, the approach integrated quantitative breadth with qualitative depth, capturing both systemic patterns and individual experiences. Informed by systems theory (Hawe et al., 2009), the evaluation recognised that Specialist Nurse practice was influenced by many connected factors, such as the impact of the pandemic, emotional demands of the role, and limited public awareness of the legislation. Instead of using a traditional case study approach (Yin, 2018), which focuses on fixed settings, this systems-based method revealed how practice changed in response to shifting conditions. It helped show not just what happened, but also how and why training was adapted in real-life situations. The evaluation considered not only the outcomes but also how training was experienced and adapted within everyday clinical practice. The pandemic imposed significant constraints, including the suspension of face-to-face training, which curtailed opportunities for experiential learning, peer interaction, and reflective coaching. While remote delivery was necessary, it often diminished emotional nuance and relational depth, with similar reflections noted by Boutros et al. (2023). At the same time, clinical teams faced pressures from staff redeployment, fluctuating ICU demands, and heightened emotional strain, all of which influenced how training was received and applied.

Public engagement with the legislation also faltered as national awareness campaigns were paused, leaving many families to encounter the new consent framework without prior understanding. This placed additional communicative and emotional demands on Specialist Nurses during already sensitive conversations. These layered challenges underscore the need for an evaluation capable of capturing both systemic disruption and relational complexity. Practice was not static; it evolved through a dynamic web of influences, where one adjustment often triggered others. This perspective revealed feedback loops in which practitioner actions, contextual pressures, and relational responses continuously shaped one another. It highlighted how learning and decision-making developed over time, how communication strategies were refined through real-world experience, and how organisational practices adapted to frontline challenges (Al-Haboubi et al, 2025).

By highlighting these ongoing patterns, the evaluation captured the complex nature of putting the training into practice, especially during the unpredictable challenges brought on by the COVID-19 pandemic. In evaluation research, it is important to understand that there are various different levels and forms of evaluation. My study incorporated aspects of different forms of evaluation and evolved over time, culminating, finally, in being a true complex evaluation. To explain the different aspects evaluated, and to explain the evolution of the research design, I now step through the different forms of evaluation in health and how they informed my study. Although the mixed-method design incorporated nine distinct studies to evaluate the implementation of the OOEP, it's important to note that not all were equally complex. Some, such as temperature check surveys and post-course evaluations, were straightforward tools aimed at capturing quick snapshots of workforce readiness and training satisfaction. These were complemented by more in-depth components, including qualitative fieldwork and comparative analysis, which provided richer insights into how the programme was experienced and adapted in practice. In full, the methods used during this research were:

Workstream 1 (Desk-based):

1.1. Training Needs Analysis – Identified baseline training requirements.

1.2. Operational Survey Temperature Checks – Gauged workforce preparedness for the legislative shift.

1.3. Post-course Training Evaluations – Measured participant satisfaction and engagement.

1.4. Critical Friend Pilot Evaluation – Offered a comprehensive review of course design and delivery.

Workstream 2 (Field-based):

2.1. Comparison of Online Training Footage with Real-world Observation – Assessed alignment between training content and clinical practice.

2.2. Participant Observations – Captured Specialist Nurses' interactions during donation conversations.

2.3. Debriefs with Observed Nurses – Explored reflections and ethical reasoning post-observation.

2.4. Semi-structured Interviews – Investigated Specialist Nurses' understanding and attitudes toward deemed consent.

2.5. Workforce-wide Survey – Compared findings across the full cohort working under the new legislation.

Figure 22 below outlines the stages of each workstream.

Workstream 1 Specialist Nurse Organ Donation Training Data		Workstream 2 Data gathered from the Specialist Nurses-Organ Donation in the real world	
	**1.1 Training Needs Analysis** Assessment of Training Requirements: Microsoft Form Survey Distributed to Specialist Nurses Across England (n117 responses)		**2.1 Evaluation of a 3-hour online training session** Featuring n8 Specialist Nurses practicing approach and deemed consent conversations
	**1.2 Operational Survey Temperature Checks** Operational Survey Temperature Checks were conducted to assess the understanding of the deemed legislation among staff. These checks helped identify any gaps in knowledge and addressed training needs to ensure compliance and effective implementation of the legislation		**2.2. Participant Observations Shadowing** Convenience sample of participants from a potential pool of n28 Specialist Nurses. The researcher observed Specialist Nurses on 13 occasions in the Intensive Care Unit, where they requested organ donation under deemed consent
	**1.3 Analysis of tri-modular evaluation questionnaires** 1.3 a. Module 1 Legislation Theory n298 completed the evaluation 1.3 b. Module 2 Conversation Practice n248 completed the evaluation 1.3 c. Module 3 Consolidation n215 completed the evaluation		**2.3 Debrief Post Shadowing** The researcher conducted debriefs and semi-structured interviews with all Specialist Nurses that were shadowed/observed within the region under study n13.
	**1.4 Critical Friend Pilot Evaluation** A panel of six experts in Palliative Care, along with a Donor Family Member, conducted a of Module 2. This sense check and pilot run-through were performed prior to the training rollout for Specialist Nurses.		**2.4 Semi-Structured Interviews:** 2.4 a. Post Shadowing and 2.4 b. Whole Cohort of Specialist Nurses in the region under study n28, n24 interviews conducted in total (due to lack of capacity/leave).
			**2.5 Whole Workforce Survey (covering England).** To consolidate research findings n230. 51% response rate n115.

Figure 22 - Desk and Field Based Workstream Outline - Longitudinal Complex Evaluation

While the number of studies may appear extensive, their varied complexity and purpose allowed for a layered and proportionate evaluation of both implementation fidelity and experiential impact. To clearly identify which data collection method corresponds to each aspect of the complex evaluation, whether it pertains to process, impact, outcome, or a combination, figure18 above provides this information in a structured format.

Workstream 1 - Specialist Nurse Organ Donation Training Data			Workstream 2 - Data gathered from the Specialist Nurses in the real world		
Workstream stage	**Methodology**	**Evaluation**	**Workstream stage**	**Methodology**	**Evaluation**
1.1 Training Needs Analysis (TNA) Survey	TNA survey quantitative method to identify the legislation training requirements. Microsoft Forms semi-structured questionnaire designed to determine the skills, knowledge, and abilities Specialist Nurses need to improve performance, helping to pinpoint gaps and design effective training programs	Process Evaluation	**2.1. Evaluation of a 3-hour online training session** Compare and contrast learning environment with real world context	A mixed-methods research methodology was used, combining quantitative and qualitative data for a comprehensive assessment comparing the learning environment with the real world. Quantitative analysis measured how well training outcomes aligned with real-world requirements. Qualitative insights helped understand the practical applicability of the training content and identified gaps between the training environment and real-world scenario	Process Evaluation
1.2. Operational temperature checks to gauge workforce readiness for the law change	Operational temperature checks gauged workforce readiness for the law change using a mixed-methods approach with a semi-structured Microsoft Forms questionnaire. This combined quantitative and qualitative methods, providing a comprehensive understanding through both numerical data and detailed personal feedback	Process Evaluation	**2.2 Participant Observations** (shadowing) a convenience sample of a potential pool of 28 Specialist Nurses.	Participant observations of a convenience sample of 28 Specialist Nurses, using a qualitative research methodology, involved the researcher observing and sometimes participating in their daily activities. This approach gathered in-depth insights into their behaviours, interactions, and work environment, providing detailed, contextual data and a rich understanding of their experiences and practices. It is particularly useful for exploring complex social processes and gaining a firsthand perspective.	Process/ Outcome/ Impact Evaluation
1.3 Analysis of tri-modular training evaluation questionnaires	Analysis of tri-modular training evaluation questionnaires, a quantitative method, involved collecting and analysing numerical data to evaluate training effectiveness across three modules. Structured questionnaires gathered data on participants' responses, measured learning outcomes, and assessed overall program effectiveness, allowing for statistical analysis to identify trends and areas for improvement.	Process Evaluation	**2.3 Debrief – Post Shadowing**	Debriefing post-shadowing, a qualitative research methodology, involved discussing and reflecting on observations made during the process. The debriefing session gathered detailed insights, clarified ambiguities, and validated observations with participants. This method enhanced the depth and accuracy of the data collected, providing a richer understanding of observed behaviours and interactions.	Process/ Outcome/ Impact Evaluation
			2.4 Semi-Structured Interviews: 2.4 a. Post Shadowing 2.4 b. Whole Cohort of SN's in the region under study	Semi-structured interviews, a qualitative research methodology, used a flexible interview guide with predetermined questions, allowing for in-depth exploration of participants' responses and adaptation to new topics. **Post Shadowing**: Conducted after shadowing sessions, these interviews gathered detailed insights and reflections on participants' experiences and observations. **Whole Cohort of Specialist Nurses**: Interviews with the entire cohort in the region provided a comprehensive understanding of their perspectives, experiences, and practices. This methodology was particularly useful for capturing rich, contextual data and understanding complex social phenomena.	Process/ Outcome/ Impact Evaluation
			2.5 Whole Workforce Survey	A whole workforce survey to consolidate research findings used a mixed-methods approach, collecting numerical and narrative data from a sample of 115 employees. Structured Microsoft Forms surveys measured the effectiveness of training for the implemented legislation changes. This method allowed for statistical analysis to identify trends, patterns, and correlations within the entire workforce, not just the region under study.	Process/ Outcome/ Impact Evaluation

Figure 23 - Overview of Methodology for data gathered about training of the Specialist Nurses and data gathered in the field about Specialist Nurses practice, depicting the type of evaluation measure.

The data collection occurred over a longitudinal period from April 2019 to February 2022, as depicted below (Figure 24).

Figure 24 - Research timeline for workstreams 1 (desk) and 2 (field)

As outlined previously, a mixed-methods approach was used, combining desk-based and field-based data collection techniques. While the range of methods may appear broad, several were relatively light-touch and served specific operational or contextual purposes. Desk-based methods included a Training Needs Analysis (TNA), an operational temperature check, and a structured review of tri-modular OOEP. Field-based methods involved evaluation of the three-hour online training, participant observations during practice, debriefs post-shadowing, semi-structured interviews, and a whole workforce survey. Each method will now be discussed in turn to illustrate its distinct contribution to the overall evaluation. At the same time, I will also explain how the data gathered through these data collection methods were analysed.

3.6.1. Training Needs Analysis (Workstream 1.1)

A Training Needs Analysis (TNA) survey was developed using Microsoft Forms in advance of the formal rollout of deemed consent training, with the purpose of shaping educational and support materials to reflect the requirements of the Specialist Nurse workforce. To ensure clarity, rigour, and contextual relevance, the survey underwent a pilot phase with members of the legislation change team responsible for implementing the Organ Donation (Deemed Consent) Act (2019).

Feedback from this pilot informed refinements to the survey's structure, content, and wording, ensuring alignment with legislative priorities and the operational realities of practice. Adjustments also enhanced accessibility, cultural and contextual sensitivity, and the practical applicability of survey items within the wider training programme. The final version of the survey was disseminated electronically to approximately 300 Specialist Nurses across the UK, accompanied by an invitation for voluntary participation. A total of 117 responses were received, providing a meaningful dataset regarding perceived training needs, preferred learning formats, and expectations of the forthcoming educational offer. The timing of the TNA followed a targeted literature review and incorporated insights from the implementation of deemed consent legislation in Wales, where early staff engagement and tailored training were identified as essential for supporting sustainable practice change.

Although not intended as a standalone research instrument, the TNA contributed to the broader evaluative process by identifying gaps in knowledge, levels of confidence, and role-specific competencies related to deemed consent. Delivered digitally, it generated both quantitative and qualitative data, offering a detailed understanding of the skills, resources, and support required to operationalise the revised approach (Appendix 5). The findings were used exclusively to inform the development of targeted training resources and to contextualise regional data, ensuring that the educational content remained responsive, evidence informed, and reflective of Specialist Nurse experiences.

3.6.2. Operational Survey Temperature Checks (1.2)

Operational temperature checks were created and distributed by the operational workstream lead as part of routine workforce monitoring for the opt-out project. Using a semi-structured Microsoft Forms questionnaire, these checks assessed organisational and staff readiness for implementing deemed consent legislation. The mixed-methods design combined quantitative measures, such as confidence and knowledge ratings, with open-ended qualitative questions, allowing both measurable trends and richer narrative feedback to be captured. Numerical data were analysed to identify overall levels of confidence and readiness, while qualitative responses were thematically reviewed to explain the underlying factors shaping these patterns.

3.6.3. Tri-modular (OOEP) course evaluations (Workstream 1.3 a, b & c)

Course evaluations were integral to shaping the responsiveness and effectiveness of the OOEP. Prior to implementation, evaluation tools were piloted with a small group of Specialist Nurses and members of the legislation change team prior to full rollout. This pilot phase aimed to test the clarity, relevance, and usability of the evaluation forms, which included both quantitative rating scales and open-ended qualitative questions.

Feedback from participants was used to refine the structure, language, and focus of the evaluations, ensuring they captured meaningful insights into training delivery, engagement, and perceived impact. The revised tools were then embedded into the training programme to support ongoing evaluation and continuous improvement. Delivered via Microsoft Forms and accessed through QR codes at the end of each training session, these structured questionnaires captured real-time feedback from Specialist Nurses, particularly those directly affected by the legislative change. Completion of the evaluation form marked the conclusion of each module and triggered the issuance of a certificate of participatory hours, contributing to Nursing and Midwifery Council (NMC) revalidation. The tri-modular evaluation design enabled systematic analysis across three core components of the training. Module 1 received 298 responses, Module 2 gathered 248, and Module 3 collected 215 responses.

This progressive decline in response rates reflected both the timing of delivery and operational pressures within clinical settings. Despite this, the data provided a robust foundation for assessing engagement levels, learning outcomes, and perceptions of training relevance. Automatically generated reports facilitated timely review and ensured consistency across responses. The quantitative data revealed trends and highlighted areas for improvement, allowing the training content to be refined in response to workforce needs. These insights supported Specialist Nurses in building confidence and competence in applying the new legislation, while also confirming that 100% of on-call staff had completed the training, meeting the Department of Health's target for workforce preparedness. This milestone was a key indicator within the logic model underpinning the implementation of deemed consent legislation. Participant observations added further depth, illustrating how Specialist Nurses translated their learning into practice during real-world consent conversations. The training was specifically designed to strengthen knowledge and confidence when engaging families under the new legal framework, helping shift the default position from uncertainty toward informed consent. The evaluation process created a sense of ownership and collaboration, with participant feedback directly informing ongoing improvements. This iterative feedback loop ensured the training remained dynamic, evidence-informed, and responsive to the evolving needs of both the HTA CoP F and the wider Specialist Nurse community, ultimately supporting the successful operationalisation of the deemed consent legislation. Palliative Care and Donor Family Evaluation of Module 2 (Workstream 1.4). Inviting a group of 6 'critical friends', including palliative care experts and a representative from the donor family network, to observe and evaluate the pilot of the Organ and Tissue Donation Education Programme (OOEP) was a strategically valuable and methodologically robust component of the evaluation. Grounded in principles of purposeful sampling (Palinkas et al, 2015), this approach involved selecting a small, highly relevant group to provide credible, experience-based insights (Miles & Huberman, 1994; Kelly, 2010). Through their observation of Specialist Nurses participating in simulated deemed consent conversations using forum theatre role-play (Boal, 1995), these experts assessed not only the training content but also its emotional realism, ethical sensitivity, and practical relevance.

Using a mixed-methods approach, the observation tool was piloted in collaboration with the legislation team, combining structured surveys and open-ended feedback to gather insights and refine it ahead of wider implementation. This allowed the team to measure satisfaction and engagement levels, while also exploring how Specialist Nurses communicated, responded emotionally, and handled ethical issues. The qualitative responses were grouped into key themes that showed what was working well and what could be improved. These insights helped make targeted changes to the training before it was rolled out nationally, ensuring it was both practical and ethically sound.

3.6.4. Evaluation of 3-hour on-line training session (Workstream 2.1)

As a targeted evaluation strategy, the retrospective review of the National Annual Consent Course Continued Professional Practice Course (CPPC), offered a valuable opportunity to assess the alignment between classroom-based training and real-world practice. Using a mixed-methods approach, the evaluation combined quantitative measures of training outcomes with qualitative insights into the practical applicability of the content. All eight Specialist Nurses participating in the CPPC were invited to consent to the research one week prior to the session. At the start of the training, they agreed to the recording of their online simulation exercises with professional actors, which focused on deemed consent conversations and served as a testbed for the participant observation tool.

The observation tool was piloted through retrospective reviews of a recorded training sessions on Microsoft Teams. These reviews were facilitated by the researcher in collaboration with NHSBT colleagues and an expert panel from nursing and medical education. Playback enabled detailed notetaking and feedback collection, which informed the refinement the observation proforma. This process tested the tool's suitability for clinical environments and allowed comparison between simulated and real-world practice. By identifying strengths, gaps, and areas for improvement, the pilot ensured the tool supported contextually relevant and transferable training aligned with the goals of preparing Specialist Nurses for family conversations under the new deemed consent legislation.

3.6.5. Participant Observations (Workstream 2.2)

This study employed participant observation as a core qualitative method (Kawulich, 2005; DeWalt & DeWalt, 2010), enabling direct engagement with clinical practice through the shadowing of Specialist Nurses. The approach was designed to capture both the explicit and tacit dimensions of practice, particularly in emotionally sensitive contexts involving organ donation conversations under deemed consent legislation. The pool of potential participants in the region under study comprised 28 Specialist Nurses. Of these, 24 were interviewed; four were unable to participate due to time off work. Participants were selected using purposive sampling based on on-call availability and willingness to take part (Creswell & Plano Clark, 2018; Stratton, 2021).

This highly experienced cohort contributed substantial clinical expertise and frontline insight into organ and tissue donation practice, positioning them well to inform the evaluation. Notably, only two Specialist Nurses declined to take part in direct observation, yet agreed to be interviewed, reflecting both the sensitivity of the observational element and the robustness of the study's consent processes. This high level of engagement highlights both the relevance of the research and the robustness of its ethical approach. Recruitment was initiated via an engagement meeting held on Microsoft Teams, where the study aims were presented and questions addressed. Follow-up personalised emails (Appendix 6) and promotional posters (Appendix 7) were distributed to encourage participation. During normal conditions, two to three Specialist Nurses are on call in the region, responding to approximately ten hospital callouts per week. As it was not possible to predict which Specialist Nurse would be deployed, I remained on standby, ready to travel and observe any consenting participant. This on-call arrangement required logistical flexibility and rapid responsiveness to avoid disrupting clinical workflows. Participant observation involved immersion in the daily activities, interactions, and events surrounding Specialist Nurses and their collaborators, family members, doctors, and bedside nurses. This naturalistic approach provided rich insights into the varied application of deemed consent legislation and the emotional labour involved in supporting acutely bereaved families. Observations were conducted in ICU settings, where Specialist Nurses manage the entire donation pathway, including referral, patient assessment, donor characterisation, consent, donor optimisation, theatre care, and family follow-up. In contrast, Specialist Requesters (also trained Specialist Nurses) focus more narrowly on consent conversations, offering a complementary perspective. To ensure transparency and emotional sensitivity, a standardised script was developed in consultation with participating Specialist Nurses and approved by the Research Ethics Committee (REC) (see section 3.8 below for more on the Research Ethics process that was followed). The script read:

> 'Hello, my name is [Specialist Nurse], and I'm working with Cathy today. Cathy is observing me as part of her research. She's particularly interested in seeing how our training impacts our practice. Would you be willing to allow Cathy to observe me? She will not be collecting any data that would identify you or your loved one. Do you have any questions?'

This wording was carefully crafted with Specialist Nurses from the region under study, to avoid disrupting the emotional flow of the conversation or prompting premature discussions about donation before the family had fully grasped the reality of their loved one's death. The REC had requested that the researcher's presence be clearly explained, with reference to the legislative change and the nature of data collection. In response, I emphasised the importance of the approach to the conversation remaining uninterrupted, allowing Specialist Nurses to offer full support to families, without external interference. Concerns raised by the REC regarding seeking permission prior to the donation conversation were discussed with the University sponsor.

We highlighted the ethical implications of premature disclosure by drawing a parallel to a Macmillan Nurse researcher being introduced before a cancer diagnosis is known to the family. In the context of organ donation, explaining the purpose of the research too early would have pre-empted the donation conversation, potentially undermining the Specialist Nurse's ability to raise the issue in a sensitive and structured way. This could cause confusion, distress, or mistrust for the family, and ethically, it could also harm transplant recipients if an ineffective approach led to missed donation opportunities. Such sequencing risks provoking a knee-jerk refusal and later regret, potentially impacting donation outcomes (Rodrigue, 2006). To accommodate the REC's request for transparency, we proposed offering families an optional debrief document (Appendix 8) after the conversation, should they wish to learn more about the research. Notably, no families declined my presence as an observer, and all families were offered the debrief document.

The REC also requested assurance that no personally identifiable data would be collected. I confirmed that the study focused exclusively on Specialist Nurse practice. Contextual details, such as the patient's sex, approximate age, cause of death, number of family members present, and their relationship to the patient, were recorded in an anonymized format to support analysis of how the legislation is applied in practice. Observation data was gathered immediately following each approach using a participant observation tool (Appendix 9), underpinned by best practice assessment guide, based on standards introduced during classroom training (Appendix 10) and tested and refined during workstream phase 2.1. Each Specialist Nurse was assessed against the six levels of Bloom's Taxonomy (Fig.12), which I adapted to reflect the behavioural expectations specific to deemed consent conversations. These evaluations fed directly into the debrief process outlined in workstream 2.2. While online training (workstream 2.1) provided a foundational grasp of how Specialist Nurses understand and implement deemed consent legislation, it lacked the immersive, context-rich perspective afforded by real-time shadowing. Participant observation illuminated both clarity and complexity, what DeWalt and DeWalt (2010) refer to as, 'the scales falling from your eyes', offering rare insight into the emotional and communicative dynamics that shape consent conversations.

Thematic analysis followed a hybrid methodology, combining inductive and deductive coding techniques. Although NVivo facilitated the organisation and retrieval of data, the analytical work remained a hands-on, interpretive process. Using Braun and Clarke's (2006, 2021) six-phase model of reflexive thematic analysis, the process unfolded through: (1) familiarisation, (2) initial coding, (3) theme identification, (4) theme refinement, (5) definition and naming, and (6) report production. This framework guided a thorough engagement with the data, by reading, annotating, and interpreting each transcript and observation to build a coherent and nuanced thematic structure. Functioning primarily as a digital archive, NVivo enabled efficient storage, cross-referencing, and visualisation of coded data.

It did not generate codes or themes autonomously, nor did it replace the interpretive judgement required to decipher emotionally layered content. Instead, it supported analytical rigour by allowing systematic clustering of ideas and mapping of thematic relationships. Inductive coding surfaced patterns directly from the data, such as how consent conversations were sequenced or how emotional sensitivity was expressed, while deductive coding applied established categories drawn from training resources, Bloom's Taxonomy, and legislative guidance. This integrative approach ensured the analysis remained rooted in both lived Specialist Nurse experience and theoretical frameworks, as illustrated in figure 25 below. Ultimately, the richness of the findings emerged not from the software, but from my active and reflective engagement with the data, interpreting language, context, and behaviour to generate insights that aspire to inform future training and practice.

Phase	Study Application	Example from Observation Forms
1. Familiarisation	Engaging closely with handwritten notes and observation records immediately following each approach, ensuring detailed recall and contextual sensitivity in the subsequent analysis.	Reading Specialist Nurse interactions where death was explained using metaphors such as "preserve his dignity" or "prevent putting him through the mill".
2. Generating Initial Codes	Observation sheets were manually annotated to capture salient behaviours and language patterns, forming the basis for initial coding. These annotations were then transcribed and uploaded to NVivo to support data organisation and retrieval.	Coding examples: *"sequencing consent conversation"*, *"legislation withheld until readiness"*, *"emotional pacing"*.
3. Searching for Themes	Codes were grouped into broader thematic categories that reflected recurring patterns in practitioner behaviour and decision-making.	Grouping *"emotional pacing"* and *"non-verbal reassurance"* under a theme like *"emotional sensitivity"*.
4. Reviewing Themes	The coded data was revisited to ensure that the themes were clearly articulated, internally coherent, and consistently aligned across the dataset.	Noticing that *"legislation withheld until readiness"* sometimes overlapped with *"protective framing"*, prompting theme adjustment.
5. Defining & Naming Themes	Each theme was clearly defined and linked to relevant training outcomes or legislative frameworks, highlighting its practical and policy-based significance.	Naming themes like *"Sequencing and Sensitivity"*, *"Legislation as Support, Not Lead"*, *"Tacit Emotional Competence"*.
6. Producing the Report	Themes were integrated into the findings and mapped against Bloom's Taxonomy, COM-B, LTEM, and relevant training outcomes. This layered approach revealed not only behavioural and cognitive patterns, but also surfaced phronesis, practical wisdom, as a central, emergent theme shaping emotionally attuned and ethically grounded practice.	Demonstrating how Specialist Nurses operated at a *create-level* of thinking by generating new conversational strategies in real time, reshaping scripts, reframing donation language, and tailoring their approach to meet the emotional and cultural needs of each family.

Figure 25 - An illustration of how Braun and Clarke's (2006, 2021) six-phase model of reflexive thematic analysis was applied in the research

3.6.6. Debrief Post Observation (Workstream 2.3)

In this study, debriefing was embedded as a formal qualitative method that enhanced analytic rigour, reflexivity, and ethical responsiveness across Workstream 2.3. When integrated as a formal element of qualitative methodology, debriefing transcends its role as a mere post-interview routine; it becomes a structured and reflective practice that strengthens the rigour, responsiveness, and ethical foundation of both data collection and analysis (Vindrola-Padros & Johnson, 2020). Conducted immediately after each observed donation approach, debriefs enabled the capture of emotional tone, Specialist Nurse intentions, and contextual nuances not evident in transcripts, supporting real-time reflexivity and informing early coding decisions.

This immediate engagement with handwritten notes and observational records preserved subtle shifts in language, behaviour, and relational dynamics, enriching subsequent interpretation and contributing to the emergence of *phronesis* as a key analytic concept. Specialist Nurses also participated in structured reflective debriefs designed to promote psychological safety, clarify uncertainties, and explore their reasoning and emotional responses. These sessions were guided by Rolfe, Freshwater and Jasper's (2001) *What? So What? Now What?* model, which provided a familiar and NMC-aligned framework encouraging descriptive reconstruction, interpretive analysis, and forward-looking reflections on practice. Using Braun and Clarke's (2006, 2021) six-phase model of reflexive thematic analysis, the analytic process unfolded iteratively as I moved from data familiarisation to inductive coding in NVivo (v12), to developing, reviewing, defining, and naming themes that captured patterned meanings across the dataset. This reflexive approach acknowledged my positionality as an insider researcher and supported the integration of debrief, observational, and reflective data into a coherent interpretive narrative. The final thematic map positioned Deemed Consent Conversations at its centre, surrounded by five interrelated domains, *Navigating Emotional Terrain*, *Legislation as a Double-Edged Tool*, *The Complexity of Consent*, *End-of-Life Rituals and Cultural Respect*, and *Operational Fluidity and Role Negotiation*, illustrating how emotional labour, legal interpretation, cultural considerations, and operational constraints intersect to shape Specialist Nurses' capacity to deliver ethically grounded, compassionate donation conversations.

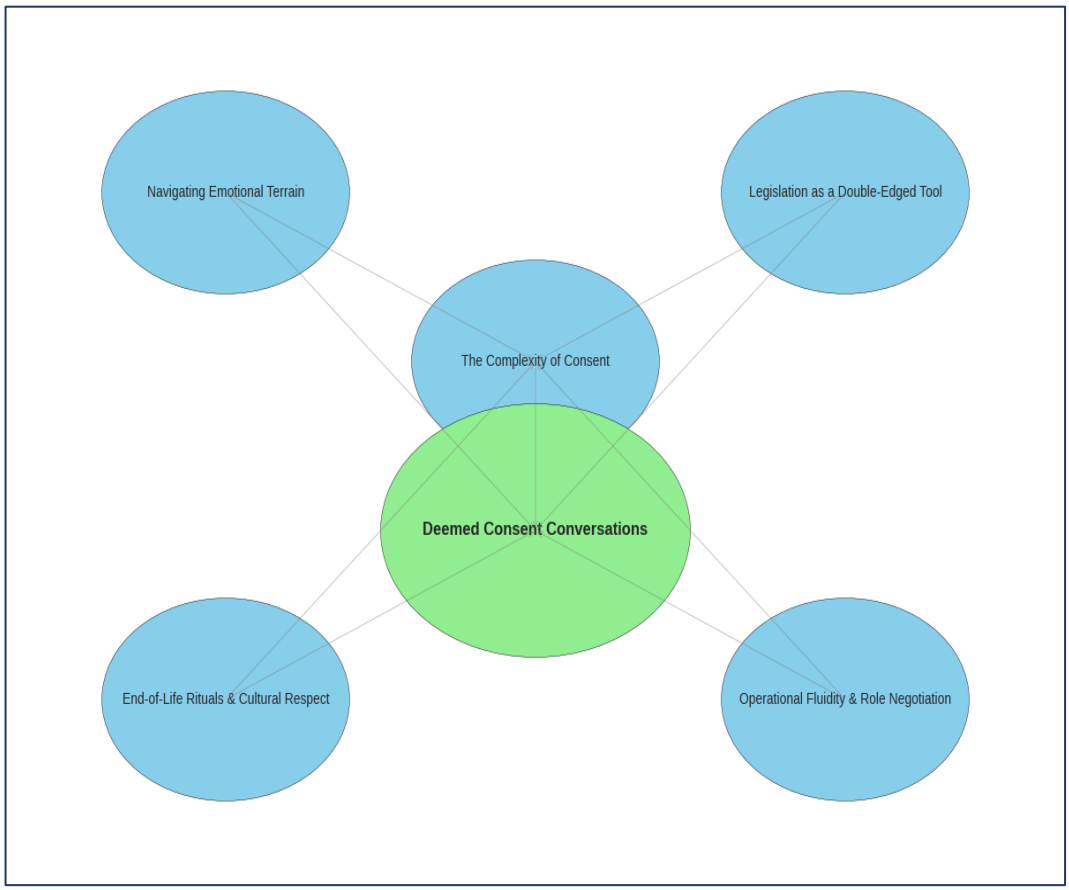

Figure 26 - Emergent Themes from Debrief Analysis of Donation Approaches

At the centre of the thematic map sits *Deemed Consent Conversations*, capturing all surrounding activity and representing the emotionally charged, ethically complex environment in which Specialist Nurses operate. Encircling this core are five interrelated thematic domains, each visualised as a distinct bubble. *Navigating Emotional Terrain* (top left) highlights SRs' sensitivity to grief, discomfort, and the nuanced art of rapport-building. *Legislation as a Double-Edged Tool* (top right) captures how legal framing, whether empowering or alienating, shapes family responses depending on its delivery. *The Complexity of Consent* (centre top) serves as a connective hub, reflecting the interpretive, evolving nature of deemed consent conversations and linking all other themes. *End-of-Life Rituals & Cultural Respect* (bottom left) emphasises the integration of faith, tradition, and symbolic gestures that influence donation feasibility and family comfort. Finally, *Operational Fluidity & Role Negotiation* (bottom right) explores how planning clarity, decoupling breaking bad news conversation from the approach for donation conversation and Specialist Nurse agency affect the timing and confidence of the approach. Arrows between these themes illustrate key interconnections and complexity, for instance, how emotional sensitivity, influences consent outcomes, or how legislative framing intersects with cultural respect. The map also reveals how Specialist Nurse operational positioning directly impacts their ability to navigate both emotional and legal considerations with sensitivity and skill.

3.6.7. Semi-structured Interviews (Workstream 2.4a and 2.4b)

Interviewing was central to the qualitative aspect of this evaluation, with semi-structured interviews conducted with all observers and offered to the entire cohort within the region under study. Before implementation, the structured interview schedule was piloted using Bryman's (2016) checklist for designing effective interview instruments (p.262). This involved reviewing the clarity, neutrality, and sequencing of questions to ensure they were not leading, ambiguous, or overly complex. The draft schedule was tested with members of the legislation change team, who provided feedback on the relevance and phrasing of each item. This process allowed for refinement of the tool, improving its validity and ensuring it was fit for purpose in capturing meaningful data from Specialist Nurses. This inclusive approach ensured broad representation and minimised sampling bias (Creswell & Plano Clark, 2018). Interviews were scheduled following the Specialist Nurses' on-call rest period and conducted either face-to-face or via Microsoft Teams. Recruitment was initiated through an engagement meeting, followed by personalised email (Appendix 6) invitations and promotional posters (Appendix 7). Prior to each interview, participants received clear information about the study's purpose (Appendix 11), their rights, and data protection measures. Informed consent was obtained (Appendix 12), and participants were given the opportunity to ask questions or opt out without consequence. These procedures aligned with best practice in qualitative research ethics, as outlined by the Health Research Authority (2023), and upheld principles of autonomy, confidentiality, and transparency. Interviewing is a foundational method in qualitative evaluation, described by Guba and Lincoln (1985) as central to fieldwork and naturalistic inquiry.

Dexter (1970, p.136) identifies three principal forms of interview structure: structured, semi-structured, and unstructured. Structured interviews involve asking each participant the same set of questions in a consistent, systematic order, thereby exposing all respondents to an identical stimulus and enabling comparability across responses, a format particularly useful when the researcher is confident in the relevance and clarity of the questions (Denzin, 1978). In contrast, semi-structured interviews offer greater flexibility. While certain demographic variables (e.g., age, sex, role) may be standardised, open-ended questions are used to elicit richer, more nuanced data. These questions need not follow a fixed sequence, and the interviewer retains discretion to vary phrasing or order, encouraging probing and allowing participants to elaborate or digress where appropriate. Unstructured interviews are entirely qualitative and emergent, with questions and follow-up probes generated in real time. This format, often described as a conversation with a purpose (Burgess, 1984), facilitates deeper insight into the participant's perspective. In this study, semi-structured interviews were conducted following observation sessions, using a flexible guide with preformulated questions (Appendix 13). This approach enabled detailed exploration of participants' reflections and experiences, while allowing space for new themes to emerge organically.

Including semi-structured interviews with the full cohort in the region strengthened the study's validity and reliability by enabling a comprehensive and consistent exploration of participants' experiences. The semi-structured interview schedule was tested in advance with members of the Legislation Change Team to ensure its clarity, relevance, and practical suitability for the evaluation. This piloting phase allowed the researcher to refine the tool based on expert feedback, incorporating additional probes to deepen responses and better capture the emotional, ethical, and procedural nuances of deemed consent conversations. Testing the interview guide in this way aligns with established qualitative research principles, ensuring the instrument was both context-sensitive and methodologically robust before being deployed with Specialist Nurses (Miles & Huberman, 1994; Kelly, 2010).

The flexible interview format allowed for rich, contextual responses while ensuring that key topics were addressed across all interviews. This consistency supported reliability by making the data collection process transparent and replicable. At the same time, the open-ended nature of the interviews enhanced validity by capturing authentic perspectives and allowing participants to elaborate on complex social dynamics in their own words. Together, these features contributed to a robust and trustworthy understanding of the phenomena under study. Each interview was transcribed verbatim and carefully checked against the audio recordings to ensure accuracy, helping the researcher fully engage with the data. Similar to the debrief and participant observations mentioned previously, the transcripts and field notes were then uploaded into NVivo (Version 12), which helped organise and manage the large amount of qualitative material. NVivo made it easier to sort, code, and group related ideas across different cases. The researcher carried out thematic analysis using Braun and Clarke's (2006) six-step process: getting familiar with the data, creating initial codes, identifying themes, reviewing and refining them, and writing up the final analysis.

NVivo supported both inductive coding, where themes naturally emerged from what participants said, and deductive coding, where existing ideas were used to guide the analysis. This combined approach kept the findings closely tied to the data while also reflecting the study's aims, leading to a rich and reliable understanding of the issues explored (Hatta et al, 2020; Proudfoot, 2023). The semi-structured interviews enriched the observational and debrief data by adding reflective depth and practitioner insight, strengthening both validity and reliability. They allowed participants to clarify intentions, elaborate on emotional and ethical reasoning, and revisit key moments with greater context. This triangulation of data sources, real-time observation, immediate debrief, and reflective interview, enhanced validity by capturing authentic, multi-layered perspectives. Reliability was supported through consistent interview structure, near-complete cohort participation, and systematic coding in NVivo, which helped organise and compare responses across cases. Together, these elements produced a robust, credible account of practice.

3.6.8. Whole workforce survey – of Specialist Nurses covering England

To support and triangulate findings from the region under study, a national workforce survey was conducted using a mixed-methods design (Appendix 14), combining quantitative and qualitative data to enhance both breadth and depth of analysis. All Specialist Nurses covering England were invited to participate, resulting in 115 responses and a 50% response rate. This is considered a strong return in organisational research, particularly within healthcare settings, where competing demands often limit participation (Pressbooks, 2023). To encourage engagement, the researcher sent personalised follow-up emails and reminders, adopting a warm and professional tone to reinforce the value of each contribution. Recruitment was monitored weekly, with regional response rates tracked and targeted outreach initiated where uptake was low. This proactive strategy helped mitigate the risk of non-response bias, which, as Fowler (2014) cautions, can significantly distort findings if non-respondents differ meaningfully from those who participate. Structured surveys administered via Microsoft Forms enabled consistent data collection across the cohort, supporting reliability, while open-ended questions captured narrative insights that added depth and context (Cresswell and Plano Clark, 2018). The combination of statistical analysis and thematic exploration allowed for robust comparison with regional data, strengthening the validity and credibility of the overall evaluation. The table below summarises data collection methods, participant roles and numbers, and how information and consent were obtained.

3.7. Sampling and Recruitment

Sampling and recruitment strategies were tailored to the nature and purpose of each data collection method, consistent with guidance on mixed methods sampling by Creswell and Plano Clark (2018). Desk-based methods, including the Training Needs Analysis (n=117), Operational Temperature Checks (participant number unknown), and tri-modular evaluation questionnaires (Module 1: n=298; Module 2: n=248; Module 3: n=215), relied on voluntary completion of Microsoft Forms distributed via email or accessed through QR codes. These methods enabled broad engagement across England and supported certification and NMC revalidation. A Critical Friend Pilot Evaluation involved seven purposively selected experts, including a donor family member, recruited via direct invitation. Field-based methods, comprising evaluation of a three-hour online training session (n=8), participant observations and debriefs (n=13), and semi-structured interviews (n=24), used a convenience sample drawn from a potential pool of 28, highly skilled Specialist Nurses and Requesters actively engaged in practice. Creswell and Plano Clark (2018) emphasise that while convenience sampling may limit generalisability, it can be appropriate in applied settings where participants possess relevant expertise and contextual knowledge. A whole workforce survey (n=115) was also distributed nationally via email. Across all methods, participant information sheets and consent procedures were appropriately tailored to meet ethical standards. The sampling and recruitment procedures for each workstream are summarised in the table below.

Table 2 - Overview of Data Collection Methods, Participant Details, and Informed Consent Procedure

Workstream Data Collection Method	Number of Participants	Job Role	Recruitment	Participant Information	Consent
1.1 Training Needs Analysis	**117**	Specialist Nurses/Requesters	Assessment of Training Requirements: Microsoft Form Survey Distributed to Specialist Nurses Across England	Email to request participation: By completing the Microsoft Form your participation by voluntarily completing the attached Microsoft Form. Your responses will be anonymous, and by completing the form, you consent to the confidential use of your data for this study.	
1.2 Operational Survey – Temperature Checks	Unknown	Specialist Nurses/ Specialist Requesters	Operational Survey Temperature Checks were conducted by the operational project lead to assess the understanding of the deemed legislation among staff. These checks helped identify any gaps in knowledge and addressed training needs to ensure compliance and effective implementation of the legislation	People responded anonymously to a Microsoft Forms Survey.	
1.3 Analysis of tri-modular evaluation questionnaires	1.3 a Legislation Theory Module = **298** 1.3 b. Conversation Practice Module =**248** 1.3 c. Consolidation Module =**215**	Specialist Nurses/ Specialist Requesters	1.3 a. Module 1 Legislation Theory n298 completed the evaluation 1.3 b. Module 2 Conversation Practice n248 completed the evaluation 1.3 c. Module 3 Consolidation n215 completed the evaluation	Each Specialist Nurse scanned a Quick Reader (QR) code at the end of the training session and completed the Microsoft Evaluation form. Completion of the evaluation form signified completion of the training and a certificate of participatory hours contributing towards their Nursing and Midwifery Council (NMC) revalidation was emailed.	
1.4 Critical Friend Pilot Evaluation	**7**	A panel of six experts in Palliative Care, along with a Donor Family Member.	Conducted a peer review of Module 2. This sense check and pilot run-through were performed prior to the training rollout for Specialist Nurses.	Email to invite experts and feedback collated.	
2.1 Evaluation of 3hour online training session	**8**	Specialist Nurses/ Specialist Requesters	Specialist Nurses involved in National Continued Professional Practice/Specialist Requester training were invited at the start of the session to participate in the research, knowing that the recording of the online/digital training with professional actors, focusing on deemed consent practices, would be compared and contrasted with the real world.	Participant Information Sheet Provided (Appendix 15)	Informed Consent Obtained from Each Participant (Appendix 16)
2.2 Participant Observations - Shadowing	**13**	Specialist Nurses/ Specialist Requesters	Convenience sample of Specialist Nurses from a pool of 28 Specialist Nurses working on-call in the region under study	Participant Information Sheet Provided (Appendix 17)	Informed Consent Obtained from Each Participant (Appendix 18)
2.3 Debrief Post Shadowing	**13**	Specialist Nurses/ Specialist Requesters	Each time a Specialist Nurse/Specialist Requesters were shadowed they were invited to participate in a debrief	Participant Information Sheet Provided (Appendix 17)	Informed Consent Obtained from Each Participant (Appendix 18)
2.4 Semi-Structured Interviews	24	Specialist Nurses/ Specialist Requesters	Email (Appendix 6) and poster to recruit participants (Appendix 7) shared along with a presentation at the region under study's Organ Donation Team Meeting on Tuesday 13th October 2020.	Participant Information Sheet Provided (Appendix 11)	Informed Consent Obtained from Each Participant (Appendix 12)
2.5 Whole Workforce Survey (Covering England)	**115**	Specialist Nurses/ Specialist Requesters	Email and reminders	Statement at the beginning of the Microsoft Form: As part of my Doctoral studies evaluating the deemed consent education and training for England, I would like to better understand how the deemed consent approach conversation flows in practice. Please could you complete this short survey (estimated time to complete 4 minutes) to help me gain further insight. By completing this survey, you voluntarily agree to take part in this study. All information you provide for this study will be treated confidentially. Many thanks, Cathy Miller. Participant Information Sheet (Appendix 19).	

3.8. Research Ethics

3.8.1. Ethical Application Process and Timeline

Ethical integrity and scientific rigour were central to the research design, ensuring accountability to donor families, healthcare professionals, participants, NHS Blood and Transplant (NHSBT), and the University of Birmingham. The study followed the Health Research Authority's UK Policy Framework for Health and Social Care Research (2023), which emphasises safety, competence, transparency, public involvement, and responsible dissemination. These principles were vital for maintaining trust and ensuring that findings could be ethically applied to future practice. Given the sensitive nature of observing donation conversations with bereaved families, where emotional vulnerability, ethical complexity, and legal considerations intersect, the ethics application underwent rigorous scrutiny. It required clear articulation of how participant dignity, psychological safety, and informed consent would be protected, especially during real-time observations of Specialist Nurses in emotionally charged clinical settings following sudden or traumatic loss.

Submitted in July 2020, the application went through multiple rounds of review and refinement, including a substantial amendment to address safeguarding, data protection, and emotional impact concerns. This process involved close collaboration with NHSBT, the University of Birmingham, and the Health Research Authority, ensuring the study met the highest ethical and scientific standards. Final approval was granted in December 2021, 17 months later, reflecting the complexity of balancing research access with participant protection. This extended timeline highlighted the importance of ethical reflexivity, which shaped the development of observation protocols, debriefing procedures, and consent processes that were both legally sound and emotionally sensitive. The thorough ethical review strengthened the study's integrity and supported its potential to inform practice and policy responsibly. The next section outlines the specific ethical procedures followed, along with the challenges encountered.

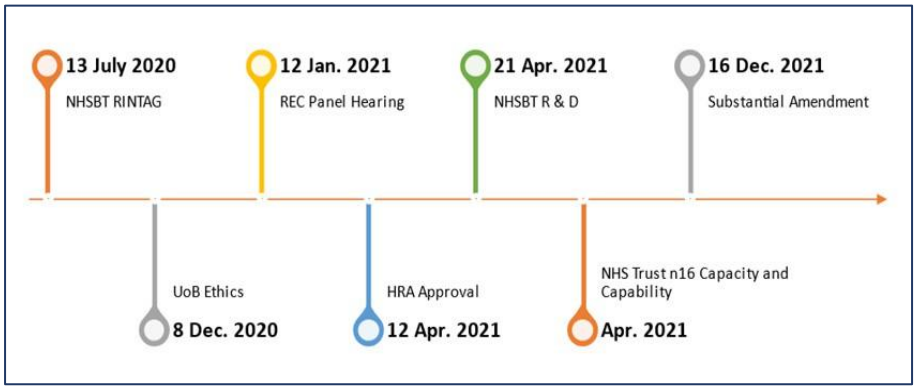

Figure 27 - Timeline for ethical application process from July 2020 to December 2021

3.8.2. NHS Blood and Transplant and University of Birmingham Ethical Governance and Approval Process

Given the sensitive nature of this study, particularly the observational components involving Specialist Nurses during organ donation conversations with bereaved families, the ethical approval process was necessarily complex, multi-layered, and prolonged. The study aimed to evaluate a tri-modular education programme developed by NHS Blood and Transplant (NHSBT), while also contributing to doctoral research at the University of Birmingham. This dual-purpose design required alignment with both institutional and national ethical standards. Approval was first sought through NHSBT's Research Innovation and Novel Technologies Advisory Group (RINTAG), which granted permission on 13 July 2020 (Appendix 20). Simultaneously, the University of Birmingham approved the programme evaluation (Appendix 21), recognising its academic and applied significance. The study was formally classified as 'research' by the Health Research Authority (HRA), triggering the completion of the Integrated Research Application System (IRAS) submission. The HRA focused on legal and governance compliance, while the Research Ethics Committee (REC) concentrated on ethical considerations, including participant welfare, consent, and data protection (Appendix 22). Following iterative revisions and responses to queries (Appendix 23), final approval was granted by the HRA (Appendix 24), with NHSBT's Research and Development department providing final sign-off (Appendix 25).

3.8.3. Research Ethics Committee Meeting

Each phase of the study was evaluated against the UK Policy Framework for Health and Social Care Research (2023) (Appendix 26), which outlines principles such as safety, competence, transparency, and public involvement. Observing Specialist Nurses during donation conversations required particular ethical scrutiny due to the emotional vulnerability of donor families and the potential for distress. My professional competence and familiarity with the regional context were reviewed and approved, and data collection was conducted under a Memorandum of Understanding between NHSBT and participating Hospital Trusts. To mitigate potential distress, explicit consent was required for my presence during clinical interactions, and an optional debrief information sheet was developed to support family members post-observation (Appendix 8). Transparency and confidentiality were prioritised through the use of pseudo-anonymised data, and all Specialist Nurses involved in the study received tailored Participant Information Sheets for each component: Retrospective observation of Continuing Professional Practice Course (CPPC) footage (Appendix 15); Shadow on-call observations, semi-structured interviews, and debriefs (Appendix 17), including Semi-structured interviews for non-shadowed participants; Wider workforce survey via Microsoft Forms (Appendix 19).

These sheets included HRA-recommended wording on data use, ensuring participants understood the limitations around accessing or altering their data post-submission, thereby maintaining research reliability.

3.8.4. Consent and Data Management

Consent procedures were designed to uphold ethical standards and ensure participant autonomy throughout the study. Formal consent was obtained from each Specialist Nurse, with the process clearly outlined during team meetings and reiterated prior to each shadowing session. Verbal agreement was recorded, and participants were encouraged to ask questions and were reminded of their right to withdraw at any stage. To support this, a secure document linking names to pseudonyms was stored separately, allowing for confidential data management. Participants were given up to six weeks post-participation to request data deletion, after which removal was no longer feasible due to the longitudinal design and its implications for data integrity. Notably, two Specialist Nurses declined to be observed but consented to participate in interviews, demonstrating the flexibility and robustness of the consent process in accommodating individual preferences while maintaining methodological rigour.

3.8.5. Decision Time for Participation

Participation was entirely voluntary, and Specialist Nurses were reassured that declining or withdrawing would not affect their educational progression. While pseudo-anonymity protected individual identities, it also posed challenges for data removal. The six-week withdrawal window was designed to balance participant autonomy with the practical requirements of longitudinal research. After this period, data were fully integrated into the analysis, and removal was no longer possible without compromising the study's validity. This rigorous ethical process reflects the study's commitment to safeguarding participants, maintaining transparency, and upholding the principles of ethical research in emotionally complex clinical settings.

3.8.6. Data Management

All data collected throughout this study was managed in strict accordance with the General Data Protection Regulation (GDPR), the Data Protection Act (2018), and the University of Birmingham's Research Data Management Policy (2018). Given the sensitive nature of the research, particularly involving bereaved families and Specialist Nurses in emotionally complex clinical settings, data handling protocols were designed to uphold confidentiality, security, and integrity at every stage. Data were pseudo-anonymised at the point of collection, with identifiers stored separately in a secure location to allow for withdrawal requests within the permitted timeframe.

Access to raw data was restricted to the researcher, and all digital files were stored on encrypted NHS secure server work lap-top with password protection. All data was managed according to GDPR, the Data Protection Act (DPA) (2018), and the University of Birmingham Research Data Management Policy (2018).

3.8.7. Long-Term Data Storage

In line with GDPR and institutional policy, all research data, including scanned consent forms, observation notes, debrief summaries, and interview transcripts, were securely stored on my NHS-issued, password-protected work laptop. Paper-based materials were digitised and then disposed of as confidential NHS waste, ensuring no physical records remained. Data will be retained for a period of ten years following study completion, after which it will be securely and permanently destroyed. This retention period allows for potential audit, secondary analysis, and verification, while maintaining compliance with ethical and legal standards.

3.8.8. Choice and Right to Withdraw

Participation in the study was entirely voluntary, with informed consent obtained from all Specialist Nurses prior to involvement in observations, interviews, or surveys. The study's aims, procedures, and potential risks were clearly communicated, and participants were given opportunities to ask questions and withdraw at any stage. Withdrawal was permitted up to six weeks post-participation, with a secure document linking pseudonyms to identifiers maintained to facilitate this process. After this stage, data were fully anonymised and incorporated into the analysis, making removal impractical without compromising research integrity. Transparency remained central throughout; donor families were informed of the study's observational nature, and any data withdrawal was formally recorded. Importantly, premature disclosure could have disrupted the donation conversation and, ethically, risked harm not only to families but also to transplant recipients if it led to missed donation opportunities.

3.8.9. Capability and Capacity - Green Light Process

Following ethical approval from the HRA and REC, the study entered the Green Light phase, which involved securing operational permission from individual NHS Trusts across England. Sixteen Trusts were contacted via email, with follow-up communications and phone calls used to clarify the study's purpose and provide Local Information Packs (LIPs) containing all necessary documentation and data collection tools. This process ensured that each participating site had the capacity, governance clearance, and clinical engagement required to support the research. Figure 28 illustrates the NHS Trusts that formally granted permission for the study to proceed.

Hospital	Capability and Capacity Status	Comments
1	Green Light	
2	Green Light	
3	Green Light	
4	Green Light	
5	Green Light	
6	Green Light	
7	Unable to give the green light for capability and capacity	
8	Green Light	
9	Green Light	
10	Green Light	
11	Green Light	
12	Green Light	
13	Progressing R&D Facilitator	
14	Green Light	
15	Green Light	

Figure 28 - Depicts NHS Hospitals that had given the green light for the research to be undertaken

3.8.10. Impact of COVID-19

The COVID-19 pandemic had a significant impact on the study's implementation. Specialist Nurses, including myself and the Legislation Change team were urgently redeployed to Intensive Care, and face-to-face training sessions were transitioned to virtual platforms. These changes affected both staff availability and the emotional landscape of donor families, many of whom experienced heightened distress due to visitation restrictions and communication barriers. In response, virtual interviews and debriefs were introduced to maintain continuity while respecting safety protocols. Additionally, the temporary suspension of the public awareness campaign may have influenced Specialist Nurses' perceptions of public understanding and readiness for the deemed consent law change.

3.8.11. Post-REC Meeting

Ethical approval was formally granted in April 2021. The study aimed to complete ten shadowed observations. However, progress was slowed down, due to the need to align researcher availability with on-call donation activity while working full-time. A non-substantial amendment (Appendix 27) added Oxford University Hospitals as a potential site, though all observations ultimately remained within the original region. Thirteen callouts were attended, resulting in ten completed observations; three were unable to proceed due to clinical contraindications or delays awaiting family arrival, which extended activity into the following day.

3.8.12. Substantial Amendment and Future Recommendations

To enhance the generalisability of findings and support national policy development, a substantial amendment was submitted to expand the scope of the workforce survey across England. This broader reach aimed to capture regional variation in training experiences, confidence levels, and implementation challenges, thereby informing future iterations of the education programme and supporting continuous improvement in legislative training delivery.

3.8.13. Engagement with Clinical Leads - Organ Donation

Engagement with the Hospital Consultants - Clinical Leads Organ Donation was an important component of the study's implementation strategy. The researcher attended regional meetings to present the study, respond to queries, and build trust with operational teams. These discussions helped clarify the observational process and ethical safeguards, paving the way for site-level approvals. Once individual Hospital Trusts granted permission, shadow on-call observations commenced, allowing for real-time insights into how Specialist Nurses navigated deemed consent conversations in practice.

3.8.14. Reflective Debriefing

To support Specialist Nurse wellbeing and learning, each Specialist Nurse who participated in shadowed observations received a structured debrief using the 'What? So What? Now What?' model (Rolfe et al., 2001). This reflective framework encouraged Specialist Nurses to describe the observed events (What?), interpret their significance (So What?), and identify actionable insights for future practice (Now What?). These debriefs were conducted in a psychologically safe environment and served both as a data collection tool and a developmental opportunity for participants.

3.8.15. Pseudo-anonymity and Ethical Data Handling

All data collected during the study were handled in accordance with the General Data Protection Regulation (GDPR), the Data Protection Act (2018), and the University of Birmingham's Research Data Management Policy. Prior to any observation, Specialist Nurses obtained verbal consent from potential donor families for my presence. No patient-identifiable information was recorded. Instead, contextual details, such as age range, cause of death, and family composition, were pseudo-anonymised to preserve confidentiality while allowing for meaningful thematic analysis. Specialist Nurses were fully informed about the nature of data collection and how their contributions would be used. Data were stored securely on a password-protected NHS laptop, and all project outputs, including quotes and thematic summaries, were anonymised.

The Nursing and Midwifery Council's Code of Conduct (2024) guided all aspects of confidentiality, professional behaviour, and respect for participants, ensuring that both donor families and healthcare professionals were protected throughout the research process. Clear communication about data processing was prioritised, in line with GDPR requirements. Participant Information Sheets included standardised HRA wording to clarify that data could not be altered or accessed once anonymised, thereby maintaining the reliability and integrity of the research. These measures ensured that the study was conducted lawfully, ethically, and with full transparency, reinforcing trust among participants and stakeholders.

3.9. Positionality, Reflexivity and Limitations

My positionality, shaped by my worldview, professional background, and relationship to the social, political, and organisational context of this study, influenced every stage of the research process, from the formulation of research questions to the interpretation of findings (Rowe, 2014). I recognise that positionality is not a fixed declaration but an evolving stance requiring continuous self-reflection to ensure transparency, credibility, and trustworthiness (Cohen et al., 2005). Rather than viewing it as a limitation, I embraced it as a valuable lens that enriched understanding and deepened engagement with the data. Ignoring this influence would risk undermining the integrity of the study and the validity of its conclusions. As the researcher evaluating an education and training programme, I co-designed with the Legislation Change Team (LCT), I occupied a dual role: both insider and evaluator. My background as a former Specialist Nurse in Organ Donation, and currently as one of two Heads of Education and Professional Development within the national organisation, provided extensive contextual knowledge and privileged access to participants. This insider status offered distinct advantages, such as established rapport, shared language, and a nuanced understanding of organisational dynamics (Fleming, 2018), yet also required careful management of potential bias and ethical complexity (Naples, 2003). To navigate these tensions, I adopted a reflexive stance throughout the study, using a reflective journal as a central tool for documenting assumptions, interpretations, and emotional responses over time. As Ortlipp, (2008) suggests, reflective journaling is not merely a methodological add-on but a vital mechanism for enhancing transparency and making decision-making processes visible.

Throughout the study, I remained alert to the risks of professional conflict inherent in my dual role. I actively interrogated my tacit assumptions and challenged preconceived ideas, using the journal as a space for accountability and insight. I was explicit with Specialist Nurses that the purpose of the study was to explore the effectiveness of the training and identify areas for improvement, not to critique individual practice. Anonymity and honest feedback were prioritised to develop trust and encourage open dialogue. I also recognised the importance of maintaining critical distance, as Moore et al, (2015) caution, to avoid overidentification with the intervention and ensure clarity in observation and reporting.

Rather than striving for detached objectivity, I used my insider perspective to ask relevant questions, interpret findings within context, and contribute meaningfully to practice improvement. My involvement in regional organ and tissue donation collaboratives, recipient coordinator webinars, and national and international conferences provided opportunities to test emerging insights and engage in reciprocal learning (Attia & Edge, 2017).

This iterative reflexivity helped ensure the evaluation remained grounded in the lived realities of Specialist Nurses while maintaining analytical rigour. Being embedded in the clinical and educational context during the implementation of the deemed consent legislation offered a rare opportunity to reflect on how positionality shaped data collection, interpretation, and representation (Greene, 2014). Upon reflection, the observational process yielded more than anticipated, including several unexpected findings. However, the method is inherently time-consuming and introduces the risk of observer bias. I acknowledge that my presence may have influenced participant behaviour, a phenomenon known as the Hawthorne effect (McCarney et al, 2007). While such behavioural changes may be seen as distortions, they can also affirm good practice and offer developmental feedback. Observation, therefore, should be considered not only as a research tool but also as a mechanism for reflective learning and continuous improvement. This situational perspective also highlighted that consent is not a discrete event, but a complex process shaped by contextual factors before and after the point of approach. The emotional, relational, and legislative dimensions of these conversations demand a high level of skill, empathy, and adaptability from Specialist Nurses, qualities that were richly evident through participant observation. Ultimately, by situating the research within its ethical complexity and acknowledging the influence of my positionality, I aimed to produce a credible, contextually rich account of training implementation. This reflexive approach enabled the evaluation to offer both practical recommendations for improving Specialist Nurse education and theoretical contributions to the ethics and epistemology of insider research within a complex health system.

While this mixed-methods evaluation offers a comprehensive and contextually rich account of training implementation, it is important to acknowledge certain limitations. The observational component, though limited to 13 deemed consent approaches, yielded valuable insights that were effectively triangulated with other robust data sources. This integration of methods provided a well-rounded, 360-degree perspective on the training programme. The use of convenience sampling in field-based activities may limit representativeness; however, the inclusion of highly skilled Specialist Nurses ensured the relevance and depth of the data collected. My dual role as insider and evaluator introduced potential for observer bias and ethical complexity, yet this was actively managed through reflexive journaling and critical self-awareness. Desk-based surveys relied on self-reported data, which may be influenced by social desirability bias, though anonymity and clarity of purpose helped mitigate this.

Finally, the study was conducted during a period of legislative transition, which may have shaped participant responses in ways that are difficult to separate from the training's impact. These limitations are not viewed as weaknesses, but as contextual factors that were transparently addressed and thoughtfully considered in the interpretation of findings, as discussed further in the conclusion.

3.10. Research Strength and Quality

Traditionally, research strength and quality have been defined in terms of reliability and validity, with reliability referring to the consistency and dependability of research processes (Robson, 2011) and validity concerning the accuracy and appropriateness of methods in measuring what they intend to measure (Cohen, Manion & Morrison, 2018). While these concepts remain essential building blocks, particularly for ensuring systematic and transparent methodological procedures, they are not sufficient to capture the complexity inherent in qualitative evaluations situated within dynamic healthcare environments. For studies such as this, which explore interpersonal processes, emotional labour, and clinical judgment within the context of deemed consent, research quality is better understood through the broader framework of trustworthiness (Guba & Lincoln, 1985). Trustworthiness comprises four interconnected dimensions of credibility, transferability, dependability, and confirmability, each contributing to a holistic assessment of methodological rigour.

Credibility, the extent to which findings authentically reflect participants' experiences, was strengthened through triangulation across observations, debriefs, interviews, and surveys (Denzin, 1978), alongside member checking during Specialist Nurse debriefs (Birt et al., 2016). My reflexive field notes provided a further credibility layer by capturing real-time interpretations, emotional tone, contextual cues, and emergent analytical questions, enabling sustained interrogation of assumptions and supporting interpretations grounded in the data. Transferability was enhanced through thick descriptive accounts of organisational context, legislative influences, communication practices, and emotional climates. Reflexive field notes enriched these descriptions by documenting fine-grained detail such as interpersonal dynamics, pacing of conversations, and Specialist Nurse decision-making strategies, allowing readers to judge applicability to other settings.

Dependability, which is closely aligned with reliability in qualitative research, was supported through a transparent audit trail documenting methodological decisions, coding development, and procedural adaptations across the study. Standardised observational and debrief procedures ensured consistency in data generation, while reflective field notes and analytic memos provided a record of how interpretations evolved over time. Confirmability, referring to the extent to which findings are shaped by participants rather than researcher bias, was strengthened through reflexive journaling and explicit engagement with my insider positionality.

NVivo was used as a structured data-management tool to maintain an auditable record of coding activity, memo-writing, and theme development. Importantly, the use of NVivo did not constitute analysis in itself; rather, it supported the rigorous application of Braun and Clarke's (2006; 2021) reflexive thematic analysis by enabling systematic organisation while the interpretive work remained firmly researcher led. To support the overall quality and trustworthiness of the study, I also used recognised tools commonly applied in health research. The Critical Appraisal Skills Programme (CASP) qualitative checklist (CASP, 2018) helped guide the study design by encouraging clear aims, appropriate methods, and careful attention to ethical issues and transparency. In addition, the study's reporting was informed by the Consolidated Criteria for Reporting Qualitative Research (COREQ), a 32-item checklist that helps researchers describe their qualitative work more clearly, especially in relation to researcher roles, participant context, and how the analysis was carried out (Tong, Sainsbury & Craig, 2007). Using these practical frameworks, supported throughout by my ongoing reflections and field notes, helped ensure the study was carried out and reported in a clear, honest, and structured way, without overstating its claims and in line with accepted standards for qualitative research.

3.11. Summary of Methodological Approach

This study used a mixed-methods, complex systems evaluation to examine the implementation and early impact of the deemed consent education and training programme within NHS clinical practice. The approach was designed to reflect the layered and evolving nature of legislative change, capturing how the intervention functioned across varied clinical environments and practitioner experiences. Quantitative methods included training needs analysis, operational temperature checks, modular course evaluations, and a validating survey, providing measurable insights into reach, fidelity, and perceived effectiveness. Qualitative methods added depth through participant observations, semi-structured interviews, and debriefs, offering rich perspectives on how training translated into practice, especially during sensitive donation conversations. Together, these methods formed a comprehensive evaluation strategy that went beyond outcome measurement to explore delivery (process evaluation), behavioural influence (outcome evaluation), and potential for system-level change (impact evaluation). This design was well-suited to the NHS context, where legal, emotional, and relational factors converge. By triangulating diverse data sources, the study offers a nuanced and ethically informed understanding of how training can support the practical application of deemed consent legislation.

Chapter 4. Findings: Organisational Readiness and Clinical Practice

This chapter presents the findings of the evaluation by drawing together evidence generated across two complementary workstreams, one desk-based and one field-based. As outlined in the methodology, these workstreams provided a structured and comprehensive approach to understanding organisational readiness for deemed consent and how Specialist Nurses applied training and policy guidance in practice. Workstream 1 examined organisational preparation and training quality. The Training Needs Analysis identified baseline knowledge and support requirements, while Operational Survey Temperature Checks assessed early confidence and concerns within the workforce ahead of the legislative change. Post-course Training Evaluations provided feedback on the relevance and delivery of the educational content, and the Critical Friend Pilot Evaluation offered an independent developmental review of how well the training design aligned with real-world clinical needs.

Workstream 2 explored how this preparation translated into day-to-day clinical behaviours. A Comparison of Online Training Footage with Real-world Observations assessed the alignment between taught communication models and actual practice. Through Participant Observations, the study documented Specialist Nurses' approaches to donation conversations, including communication strategies, decision-making processes, and contextual influences. These observations were followed by structured Debriefs with Observed Nurses, which captured reflective insights, emotional processing, and ethical reasoning. Semi-structured Interviews further explored Specialist Nurses' understanding, attitudes, and interpretations of deemed consent, while a Workforce-wide Survey enabled comparison of experiences across the broader cohort working under the new legislation.

The chapter concludes with Post-Implementation Perspectives, drawing on the Workforce Survey to examine how confidence, attitudes, and preparedness changed once the law came into effect. This final section brings earlier findings together, illustrating how Specialist Nurses' views evolved over time and enabling comparison between the study region and the wider workforce. It highlights where results align, diverge, or offer additional insight into the lived experience of implementing deemed consent. Taken together, these sections provide a clear, connected account, from the organisational level down to individual Specialist Nurses' experiences. This layered structure demonstrates how policy is enacted in real-world settings, pointing to both areas of strength and opportunities for further development.

4.1. Organisational Preparedness: Training Needs Analysis Findings

As explained in the methodology chapter (Section Training Needs Analysis: Workstream 1.1 p.50), the development and design of the Training Needs Analysis (TNA) survey are detailed there.

Prior to developing the education programme for implementing the deemed consent legislation, the TNA survey (Appendix 5) was circulated to Specialist Nurses across the UK, using Microsoft Forms. A total of 117 responses were received, offering valuable insight into preferred learning formats and the content areas considered most important. The majority of respondents (97 participants; 85%) indicated a preference for face-to-face training, and 101 respondents (88%) emphasised the importance of understanding the deemed consent legislation, particularly its practical implications for clinical practice. Participants also identified the value of case studies (84 respondents; 73%), learning from the Welsh experience (73 respondents; 63%), and specific guidance on completing consent forms (73 respondents; 63%).

With regard to training delivery methods, respondents expressed a stronger preference for practising conversations with professional actors (mean rating 3.6 out of 5.0) compared with practising without actors (mean rating 3.1 out of 5.0). Additional suggestions included the use of video logs demonstrating potential deemed consent cases, opportunities for shared practice within teams (50 respondents; 44%), access to e-learning and online resources (49 respondents; 43%), and practical tools such as aide-memoire cards, flow charts, and simple leaflets (48 respondents; 42%).These findings, along with the subsequent ‘temperature checks’ described below, which were used to monitor engagement and identify emerging learning needs, directly informed the development of the blended training programme. The final programme incorporated professional actors to enhance realism, video logs and SharePoint-hosted resources to improve accessibility, credit-card-sized aide-memoire cards to support everyday practice, and a streamlined consent manual to replace multiple policies and procedures. Together, these elements aligned the training with the preferences and needs expressed by the Specialist Nurse workforce prior to the programme’s development.

4.2. Operational Workforce Readiness for Deemed Consent Survey

To evaluate the Specialist Nurse workforce’s preparedness for the introduction of deemed consent legislation, regular ‘temperature checks’; were conducted between Autumn 2019 and Winter 2020 using Microsoft Forms (Appendix 28). These surveys targeted Specialist Nurses/Requesters directly responsible for leading deemed consent conversations, as their comprehension of the law and its practical application was vital for effective implementation. The checks provided real-time feedback, which served both to inform the design of training and public awareness strategies and to address emerging concerns promptly. Findings demonstrated a progressive increase in confidence regarding the delivery of key messages, with respondents reporting high levels of trust in the training’s effectiveness. Despite distribution during peak holiday periods, engagement levels remained consistent, indicating sustained commitment to the process. Respondents expressed a clear appetite for debriefing sessions, which were subsequently recognised as effective mechanisms for reflection and peer support.

The data identified areas requiring further development, with some respondents reporting lower confidence in discussing deemed consent with families and emphasising the need for continued group work and practice in challenging scenarios. Additional training was requested on pre-formal consent procedures, particularly regarding blood sampling. Specifically, participants sought clearer guidance on what is ethically and legally permissible under deemed consent legislation, versus actions that require explicit family discussion and permission, for example, whether blood samples can be taken and processed based on deemed consent (similar to organ donor registration), or if verbal consent from the family is required.

While some anticipated minimal changes to practice, others emphasised the need for positive communication, including the sharing of good-news stories and emotive examples, to ensure that increased public awareness did not lead to misinformation. Without proactive education, long-standing myths, such as concerns about organs being taken without consent, could resurface and would need to be actively dispelled. The six-month operational temperature check reinforced the value of debriefing sessions and highlighted the importance of ongoing training, communication, and support. Collectively, these insights captured the workforce's level of readiness for the legislative change, illustrating both areas of confidence and domains requiring targeted development to ensure effective implementation of deemed consent.

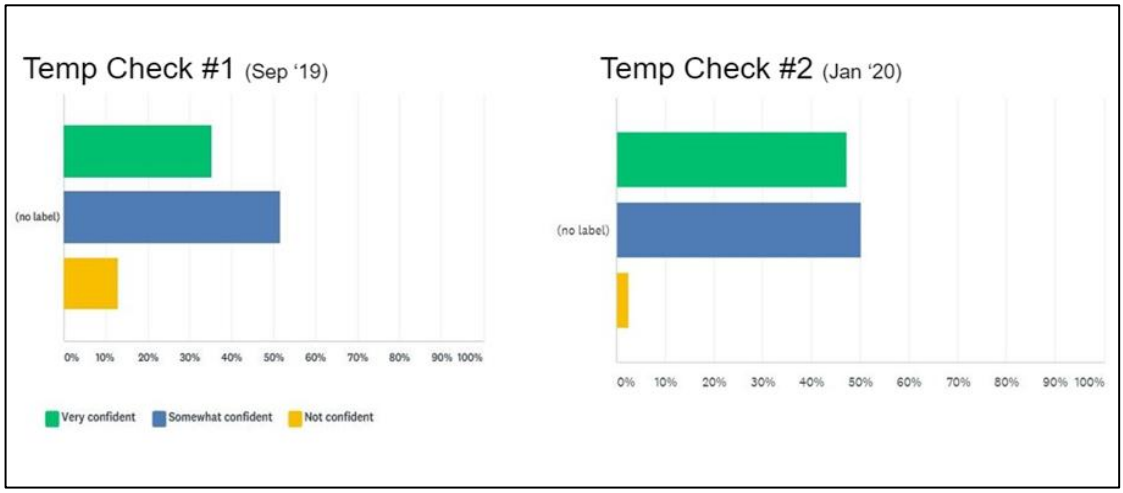

Figure 29 - Confidence in the Key Messages Increased between temperature check one (Autumn 2019) and two (Winter 2020).

4.3. Analysis of tri-modular Opt-Out Education Programme (OOEP) evaluation questionnaires

As seen in the methodology chapter, the Opt-Out Education Programme (OOEP) was designed to ensure that 100% of Specialist Nurses participating in the on-call rota received training, in accordance with the target set by the Department of Health and Social Care (DHSC).

The programme comprised three modules:

Module 1: Legislative Framework

Module 2: Conversational Practice

Module 3: Integration of Theory and Practice

4.3.1. Module 1 - Legislation Theory

Feedback from 298 Specialist Nurses who completed Module 1 provided significant insights into its effectiveness. In the Microsoft Forms evaluation, participants were asked to rate the module on a scale from 0 to 10, and module 1 received a strong mean score of 8.7, with respondents affirming that the course materials and associated media were highly effective in meeting their learning needs. Training demonstrably enhanced understanding of the legislative changes, with 205 participants (69%) rating this statement as 'extremely true.' Furthermore, 280 respondents (94%) indicated that they would recommend the training to colleagues. Positive comments highlighted the innovative use of the 'car park board' for collating questions requiring further discussion and praised educators for addressing complex queries. Participants noted that Module 1 was particularly beneficial for those unfamiliar with deemed consent legislation. Interactive elements, such as quizzes and video logs (vlogs), were regarded as engaging and informative, reinforcing theoretical concepts. Trainers were commended for their expertise and delivery style, with the pacing considered appropriate. Areas for improvement included the need for greater clarity regarding evolving Human Tissue Authority (HTA) Code of Practice F guidelines, as some questions remained unresolved due to ongoing updates. Technical issues, such as occasional audio difficulties when streaming vlogs, were also reported. Overall, Module 1 was well-received, with recommendations focusing on enhancing clarity and addressing minor technical challenges.

4.3.2. Critical friends' evaluation of Module 2 Pilot

Experts from palliative care were invited to act as 'critical friends' in reviewing Module 2. Their feedback was overwhelmingly positive, commending the Legislation Change Team (LCT) for their transparency and collaborative approach. An evaluation of this module has been published (Miller et al, 2020)

> *'It is clear that you are very good communicators … there are no hidden agendas … only that you want to be successful and are working as a team to ensure that the project is successful. I will be using forum theatre in my own teaching.'*
>
> *Professor in palliative care.*

The use of forum theatre as a pedagogical tool was strongly endorsed, and the compassionate handling of complex scenarios by facilitators was acknowledged:

'Complex situations being dealt with compassionately… by experts.'

Consultant nurse in palliative care 2.

Inclusive facilitation and effective media use were also highlighted. A consultant nurse 1 emphasised the enduring importance of empathy and rapport:

'Be human, be kind; the story is changing, but humans are not, connect and influence.'

Additionally, a donor family representative expressed reassurance regarding the safeguarding of donor families:

'It was good to be involved and to know that donor families are in safe hands.'

This evaluation confirmed the appropriateness and quality of the educational materials and delivery methods.

4.3.3. Module 2 - Conversational Practice

Module 2, launched in January 2020, aimed to develop communication skills for implementing deemed consent legislation. Initially planned as face-to-face training, delivery was disrupted by the COVID-19 pandemic and transitioned from face to face to virtual platforms over an eight-week period to ensure workforce safety. The module applied Malcolm Knowles' adult learning principles, recognising that adult learners are self-directed, bring valuable prior experience, and respond best to learning that is relevant, problem-centred, and immediately applicable to practice., articulated in The Adult Learner (Knowles, Holton & Swanson, 2020). Building on Module 1's theoretical foundation and incorporating inclusion/exclusion criteria for applying deemed consent. Participants practiced deemed consent approach conversations with professional actors in a controlled and psychologically safe environment.

A total of 303 Specialist Nurses completed the training, with 228 participants (75%) attending face-to-face sessions and 75 (25%) completing the virtual option. Evaluation completion rates were high for face-to-face delivery with 223 respondents (98%) submitting evaluations but were notably lower for virtual training with 41 respondents (55%) completing them. The Department of Health and Social Care's objective of training all Specialist Nurses on the on-call rota was met, supported by the availability of recorded training content made available for those who had been redeployed. Face-to-face training received an average rating of 9.1 out of 10, compared with 8.3 out of 10 for virtual delivery. Course materials were rated very positively across both formats: 221 participants (97%) from the face-to-face cohort and 71 participants (95%) from the virtual cohort agreed that the materials were effective.

Understanding of deemed consent legislation improved significantly, reported by 216 face-to-face participants (95%) and all 75 virtual participants (100%). Recommendations for the training were similarly strong, with 214 face-to-face participants (94%) and 70 virtual participants (93%) indicating that they would recommend the training to others. Qualitative feedback identified forum theatre, videos, and vlogs as particularly impactful during face-to-face sessions, complemented by theory refreshers and personal narratives (e.g., Professor Frost's prior experience as an ICU clinician implementing deemed consent in Wales). Suggested improvements included increasing engagement in forum theatre, allowing more discussion time, providing printed resources, and adding further examples of communication strategies.

> '*More engagement from the attendees in forum theatre, but that wasn't anything that the PDSs could have improved as it was very engaging.*'

Overall, Module 2 was well received, with only minor enhancements identified.

4.3.4. Module 3 Consolidation

Module 3 was designed to strengthen Specialist Nurses' competence in applying deemed consent legislation by supporting critical analysis, informed decision-making, and effective communication with donor families. It addressed queries related to HTA Code of Practice F, promoted consistency in clinical application, and incorporated simulation scenarios reflecting England's cultural and faith diversity. Time was allocated for shared learning and consent form completion. Originally designed for face-to-face delivery, the module was adapted to virtual delivery via Zoom due to COVID-19 restrictions and implemented regionally over eight weeks. Of the 333 Specialist Nurses requiring training, 311 participants (93%%) on the on-call rota completed the module, while 22 (7%) were unable to attend due to sickness, maternity leave or sabbatical. Evaluation responses were received from 215 participants (69%). In the Microsoft Forms evaluation, the module received an average rating of 8.6 out of 10. A total of respondents 217 (70%) agreed the training enhanced knowledge and understanding of the legislation, while 80 participants 26% found this 'somewhat true' and 12 (4%) considered it 'slightly true'. Recommendation rates were high, with 286 respondents (92% stating they would recommend the module. Interaction was also rated positively rated 261 participants (84%) reporting excellent opportunities for questions and engagement. Confidence scores averaged 8.53 out of 10 for applying deemed consent criteria and 8.2 out of 10 for planning conversations with clinicians.

Qualitative feedback highlighted the value of case studies, facilitator expertise, and the virtual format's convenience. Participants appreciated the recap of Module 1, use of videos and vlogs, and demonstrations of integrating opt-out discussions into end-of-life care.

> '*Really well delivered, clear content explained really well, I feel so much more prepared and confident*.'

Suggested improvements included longer discussion time, provision of printed resources, pre-training quizzes, and use of breakout rooms. While some preferred face-to-face delivery for role-play, overall feedback indicated strong engagement and preparedness for clinical application. they would endorse the programme. Qualitative feedback consistently described the sessions as 'interactive' and 'well-paced,' with facilitators praised for their clarity and engaging delivery style. In contrast, virtual participants highlighted limitations linked to the pandemic-driven shift to online delivery, noting that the absence of forum theatre reduced opportunities for communication practice and interaction. Some participants expressed a preference for face-to-face formats, emphasising the value of being able to ask questions and role-play scenarios directly:

> '*Maybe use break-out rooms for discussion points to encourage more people to get involved. Delivery was good but I prefer face-to-face for asking questions, acting out scenarios*.'

However, others noted advantages of the virtual format, particularly the reduced need for travel:

> *'So much better doing it as Zoom than travelling to meetings*.'

Together, these comments show a clear contrast between appreciation for the quality of facilitation and the mixed views on the virtual delivery format.

Table 3 - Participant's overall star rating for tri-modular deemed consent legislation training

Participant Evaluation of the Tri-Modular Programme		
Module	**Mode of Delivery**	**Star Rating**
Module1: Legislation (Theory)	Face to face	8.7/10
Module2: Conversation (Simulation/Practice)	Face to face	9.1/10
	Virtual	8.3/10
Module3: Consolidation	Virtual	8.6/10

4.4. Expert Panel Review of Digital Training Footage

In the methodology section, I described the design of the panel review of the digital training footage (p81 section 3.6.4).

The purpose of this review was to examine how effectively the digital training environment reflected real-world practice and to support refinement of the observation tool. An expert panel assessed recordings from the Continuing Professional Practice Course, which delivers annual consent and authorisation training for Specialist Nurses. By comparing the online learning setting with actual critical care environments, the panel helped validate and shape the observational criteria. Analysis of the recordings showed that participants demonstrated strong competency in applying inclusion and exclusion criteria for deemed consent, including in complex cases involving mental health considerations. They also displayed a clear understanding of residency requirements (ordinarily and voluntarily resident) and the relevant mental capacity legislation. Communication strategies emphasised rapport-building and framing the donor as a 'hero' leaving a legacy, using positive language to convey that non-registration implies willingness to help others. Professional actors provided real-time feedback, reinforcing the need to avoid assumptions and second-guessing. Notable observations included analogies to financial decision-making and responses that balanced family autonomy with legislative requirements, e.g., *'This decision must be right for your family; saying 'no' is as significant as saying 'yes'.*

Feedback further highlighted subtle differences in how the legislation was framed within the virtual training environment compared with how it was enacted in clinical practice. Some panel members noted that digital scenarios tended to present more structured and linear discussions, whereas in real-world settings conversations were often more fluid, emotionally charged, and influenced by the dynamics within the family unit. The review also drew attention to variances in how confidently participants articulated the shift from an opt-in to a deemed consent system, particularly when explaining exceptions or circumstances requiring explicit consent. These desk-based insights directly informed the subsequent field-based evaluations. The refined observation tool was then applied in real clinical settings, allowing for a more detailed examination of how Specialist Nurses navigated family conversations about organ and tissue donation. Observations, debriefs, and interviews conducted in practice helped test whether the competencies demonstrated in digital simulations translated into genuine clinical decision-making and communication behaviours, enabling ongoing triangulation between virtual learning, observed practice, and practitioner reflections.

4.5. Insights from Real-World Practice: Participant Observations

As outlined in the methodology section in Chapter 3, participant observation formed a central component of the study's data collection. The overall pool of potential participants comprised 28 Specialist Nurses in Organ Donation and Specialist Requesters, whose geographic proximity enabled real-time shadowing of deemed-consent approaches in ICU. Although all 28 were eligible, only 13 were involved in on-call activity during periods when the researcher was available, reflecting the practical constraints of coordinating donation referrals with researcher capacity alongside full-time employment.

Of these 13 call-outs, 10 progressed to full shadowed observations, with three classified as non-proceeding, due to clinical contraindications or delays in family arrival, which extended activity into the following day. Despite these limitations, the observations generated substantial, practice-based data that underpin several of the thesis's core findings and provide essential insight into how deemed consent operates in real clinical settings. Within this sample, thirteen real-time shadowing sessions were conducted in ICU settings, focusing on interactions with potential donor families and with medical and nursing staff. Ten of these encounters developed into formal deemed-consent discussions (see Appendix 29), undertaken by three Specialist Nurses-Organ Donation and seven Specialist Requesters. Each case was systematically labelled (Case 1–10) and attributed to the relevant professional role, providing a clear and consistent referencing structure for the findings and discussion chapters. This immersive, field-based component represented the most substantial source of qualitative data in the study, offering access to a rarely observed area of clinical practice and enabling close examination of the relational, emotional, and procedural dynamics that shape family consent discussions under deemed-consent legislation. These aspects of practice, particularly the unfolding interpersonal dynamics, environmental pressures, and moment-to-moment decision-making, are not easily captured through interviews or document review alone, making the observational field notes an essential layer of contextual understanding.

The data include both structured observations guided by the observation tool (Appendix 9) and unanticipated contextual details captured through meticulous note-taking and a reflective research diary. This systematic and reflexive approach aligns with Braun and Clarke's (2013) principles for generating rigorous qualitative evidence and strengthens the credibility of the findings presented. The following section sets out the observation findings and accompanying field notes, beginning with the three approaches that could not be observed directly, followed by detailed accounts of the ten deemed-consent family approach discussions.

4.5.1. Unobserved Approaches: Contextual Factors and Limitations

Three of the thirteen deemed consent approaches were not observed due to specific contextual factors detailed below.

Medically Unsuitable Donor:

In one case, the potential donor's organs were deemed clinically unsuitable for transplantation due to multiple comorbidities, leading to discontinuation of the process.

Logistical Constraints:

In another case, observation was precluded as the Specialist Requester had already commenced the discussion with the family prior to my arrival. Furthermore, the approach was subsequently deferred until the following day to accommodate the presence of additional family members.

Delayed Family Attendance:

A third approach was postponed due to the anticipated arrival of key relatives. The donor's mother, who had tested positive for COVID-19, was traveling from Nigeria, while other family members were journeying from London. The process was deliberately slowed to allow the family sufficient time to comprehend and accept the gravity of the situation.

4.5.2. Findings from the Ten Observed Deemed Consent Discussions

As has already been established within the wider legislative context, the deemed consent framework requires that organ and tissue donation be considered whenever clinically appropriate, with adults presumed to have consented unless they have explicitly opted out. It is clear from previous discussion that under the deemed consent legislation, organ and tissue donation is expected to be considered whenever clinically appropriate, with adults presumed to have consented unless they have explicitly opted out. Best practice recommends a structured, collaborative approach to family discussions, typically involving three key professionals: the Specialist Nurse or Requester, the Consultant or Clinical Lead for Organ Donation (CLOD), and the bedside nurse (Donation Actions Framework, 2022). Analysis of the ten observed deemed consent approaches revealed three distinct outcomes.

Four cases resulted in supported deemed consent, where donation and transplantation were successfully completed. In contrast, three cases represented unsupported deemed consent, with the process not progressing to donation. The remaining three cases involved families who explicitly declined donation, indicating known decisions not to donate. Observational data indicated that Specialist Nurses/Requesters consistently engaged in planning conversations with the Consultant or CLOD, with or without the bedside nurse. In nine of the ten cases (90%), a Consultant/CLOD was involved in planning. Among supported deemed consent cases, 75% adhered to the recommended inclusion of all three roles. In unsupported cases, the guidance was followed in all instances (100%). For cases involving known decisions not to donate, two out of three (66%) achieved a triumvirate approach during planning. The triumvirate approach improves outcomes by ensuring that family discussions are conducted in a structured, collaborative manner, drawing on the complementary expertise of three key professionals. This model facilitates clear communication, consistency in messaging, and emotional support for families, while also enabling timely clinical decision-making.

By drawing together clinical expertise, specialist knowledge, and a consistent relational approach, this model fosters trust and confidence among families. In practice, these elements help to positively shape consent decisions, reduce fears or uncertainties, and address common misconceptions. Evidence from the observed cases indicates that following this model is associated with more effective consent conversations and, ultimately, higher rates of successful donation outcomes.

To ensure clarity and consistency within the analysis, each of the ten observed discussions was assigned a numerical case label (Case 1–10) (Fig. 30 below) in chronological order, reflecting the date on which each discussion occurred. Each case was then categorised according to the professional role involved, either a Specialist Nurse in Organ Donation (SN) or a Specialist Requester (SR). This system provides a clear reference framework throughout the findings and discussion, enabling each observation to be easily linked to the Specialist Nurse/Requester involved and the clinical context in which it took place. The figure (30) below also presents the outcome categories in the same chronological sequence, beginning with cases where families expressed a known decision, followed by those where the decision was unsupported, and finally those where the decision was supported.

Case No	Specialist Nurse	Specialist Requester	Clinical Lead Organ Donation	Consultant in Planning	Consultant in Approach	Bedside Nurse	DBD/DCD	Trio	Outcome	Reason
2							DCD		Expressed Known Decision	Buried Whole
3							DCD		Expressed Known Decision	Did not want donation for his father
6							DBD		Expressed Known Decision	Spiritual belief
4							DCD		Unsupported Deemed	Buried Whole
7							DBD		Unsupported Deemed	Against religion
9							DBD		Unsupported Deemed	Been through enough
1							DCD		Supported Deemed	Aware of legislation
5							DBD		Supported Deemed	Supported of donation – HCP
8							DCD		Supported Deemed	Unaware of legislation
10							DBD		Supported Deemed	Did not know what they would have wanted

Case Number	Professional Identifier
Case 1	SR1
Case 2	SR2
Case 3	SN3
Case 4	SR4
Case 5	SR5
Case 6	SN6
Case 7	SN7
Case 8	SR8
Case 9	SR9
Case 10	SR10

Figure 30 - Outcomes and personnel involved in planning the deemed approach conversation (cases presented in order of outcome rather than chronological sequence).

One case progressed as a supported deemed consent for tissue donation rather than organ donation. The family opted for tissue donation as a means of achieving closure, perceiving the organ donation process as too lengthy and uncertain, describing it as involving 'too many ifs and buts.' The Specialist Requester referred to this outcome as a 'half-way house,' reflecting a compromise between full organ donation and complete refusal. Across all four supported deemed consent cases, the approach was led by a Specialist Requester. Two of these cases (50%) involved a full triumvirate approach, while one was conducted as a two-stage telephone discussion. In supported cases, two families demonstrated awareness of and support for the legislation, and in two instances, Specialist Requesters displayed empathy, for example, acknowledging the family's loss, gently asking what was most important to them at that moment, and responding to subtle non-verbal cues, while also providing clear, tangible information about the benefits of donation and explicitly referencing the legislation. The observed cases offer valuable insights into the dynamics of deemed consent discussions. Notably, four of the ten approaches did not involve a consultant, with two conducted via telephone. Of these, two resulted in supported outcomes, one in an expressed decision not to donate, and one in an unsupported deemed consent.

In the latter, although the consultant participated in planning, the family declined donation, citing that the patient had 'suffered enough.' All three known decisions not to donate were associated with themes of suffering, religious considerations, or a desire for the body to remain intact for burial. Similarly, in unsupported deemed consent cases, suffering and religious reasons were recurring factors influencing refusal. Overall, these observations demonstrate the complexity and individuality of decision-making within the consent process, even under a legislative framework designed to normalise donation. They highlight that while policy provides structure, outcomes are shaped by nuanced family values, beliefs, and emotional responses. The following section provides a detailed breakdown of each observation, including insights from post-observation debriefs.

4.5.3. Telephone Approaches in Deemed Consent Conversations

The observed telephone approaches (n=2) provided valuable findings into the dynamics of deemed consent conversations. Below are summaries of two cases, each highlighting different outcomes and contexts. In the telephone approach case, which resulted in a supported deemed consent (SR1), the patient was a male in his 60s who died from an intracranial haemorrhage (ICH) following a fall. The approach to discuss organ donation was made over the telephone to the patient's brother, with his wife present. Both were aware of the new law change and believed donation was something the patient would have wanted. The conversation took place in two calls: the Consultant first broke the bad news, followed by the Specialist Requester (SR1) discussing organ donation. SR1 discovered that the family had already been informed about organ donation by the Emergency Department doctor, making the introduction of the legislation unnecessary as the family had already agreed.

SR1 highlighted the importance of consulting the family and seeking their support, describing the balance of the conversation as a ‘fine line’ to avoid overemphasis while ensuring clarity. Gentle humour was used by SR1 to build rapport and ensure the family understood the process. This demonstrates SR1's subtle skill in reading the family's emotions, adopting a curious mindset and using open ended questioning to carefully navigate the conversation. In the case of Unsupported Deemed Consent (SR9), the patient, a male in his 50s, also died from an ICH and lived in sheltered accommodation. His niece, the closest relative, conveyed the information to her mother. The approach was conducted over the telephone, with the bedside nurse delivering the news using the phrase ‘passed away’ to soften its impact. The patient's death was declared following Neurological Death Testing (NDT), and the family could not attend the hospital due to caregiving responsibilities. SR9 felt unable to push the legislation due to the estranged family relationship and sensed the family's guilt for not visiting the patient. When SR9 introduced the topic of donation by explaining the legislation, the niece remained non-committal and deferred the decision. She later declined, citing the family’s emotional burden and the belief that the patient had already endured enough suffering.

During the debrief, it was suggested that using the Information Digital Link (IDL) might have helped the niece explain organ donation to her mother. Overall, the findings from both cases highlight the uniqueness of each family situation and individual decisions surrounding the organ donation process, emphasising the importance of sensitivity, clarity, and rapport-building in telephone approaches.

4.5.4. Face-to-face Supported Deemed Consent (SR5)

All three face-to-face supported deemed consent approaches were conducted by Specialist Requesters (SRs). Two cases resulted in organ donation, with both donors declared dead using Neurological Death Testing (NDT). The third case proceeded as a tissue donation, with the patient declared dead following circulatory death. Below are the details for each approach. In Case SR5, the patient was a young man in his mid-20s who died by suicide through hanging, resulting in cardiac arrest and hypoxic brain injury. He left behind a partner and three children under six years old. His partner, mother, partner’s father, and seven other family members were present at the hospital. The Consultant was responsible for breaking the bad news and conducting Neurological Death Tests (NDTs) to confirm death. Before arriving at the hospital, SR5 unexpectedly encountered armed police. Both she and the taxi driver were ordered out of the vehicle, with the driver handcuffed and taken away due to a suspected firearms incident. SR5 then walked to the hospital alone and did not disclose this experience until after delivering the bad news conversation to the family. The resilience and professionalism displayed by SR5 were commendable, highlighting that what SR5 considered routine,

> ‘It’s what we do…’

is not the norm for everyone.

Reflective field note

Before arriving at the hospital, SR5 unexpectedly encountered armed police. Both she and the taxi driver were ordered out of the vehicle, with the driver handcuffed and taken away due to a suspected firearms incident. SR5 then walked to the hospital alone and did not disclose this experience until after delivering the bad news conversation to the family. This moment struck me profoundly, it highlighted the extraordinary resilience and professionalism required in this role.

What SR5 described as routine, saying 'It's what we do,' is far from normal for most people. The ability to compartmentalise such a stressful event and immediately shift into the mindset needed to approach a grieving family demonstrates a genuine commitment to putting others before self. It also raises important questions about psychological support and self-care in these roles to prevent burnout. These experiences highlight the emotional weight and complexity of organ donation work, and the need for robust psychological support systems to safeguard staff wellbeing.

During the conversation, SR5 explained the legislation, noting that the law assumes consent unless there is a clear objection. She provided information about the children visiting the ICU and emphasised honesty when discussing death. SR5 involved all family members, ensuring everyone felt included and understood. The family appreciated SR5's approach, and she used her experience to pick up on the family's emotions and pace the conversation, giving the family time to process the information. Support services from the hospital chaplaincy were offered and accepted. SR5 also provided memory boxes, handprints, child bereavement books, and information about bereavement charities.

4.5.5. Face-to-face - Supported Deemed Consent Summary (SR8)

In this case, the patient experienced a cardiac arrest while walking with his wife and was admitted to the ICU for treatment that was ultimately deemed futile, leading to a plan for withdrawal of life-sustaining treatment (WLST). The family comprised the wife, son, daughter, her fiancé, and a close friend who was an ICU nurse. Prior to the formal approach, the Consultant had remarked that it was 'kinder to let him go,' setting the tone for end-of-life discussions. The wife expressed strong reservations about organ donation, stating that her husband, like herself, had never considered deemed consent. She reflected,

'It's hard because we just don't know what his decision would be.'

SR8 reassured the family that the decision should feel right for them collectively, but when SR8 explained the legislative framework, the wife reiterated,

'Like me, he hasn't thought about it, he's not made a decision.'

SR8 responded by clarifying,

> ‘Because he hasn’t opted out, it suggests he had no objection.’

Despite this, the family perceived the Donation after Circulatory Death (DCD) process as unnecessarily prolonging matters, describing it as involving,

> ‘Too many ifs and buts.’

Their concerns centred on the uncertainty of whether the patient’s heart would stop within the required timeframe for donation to proceed without causing ischaemic damage to transplantable organs. This unpredictability, coupled with anxiety about whether they could say goodbye and let go once circulation ceased, ultimately influenced their decision. The family opted for tissue donation instead, a choice SR8 described as a,

> ‘Half-way house.’

SR8 demonstrated exceptional sensitivity in end-of-life care, going beyond the clinical requirements to create a deeply personal gesture, a soundbite recording of the patient’s heartbeat for the daughter to wear in a locket on her wedding day. This act highlighted the uniqueness of each family’s circumstances and the profound human dimension of organ donation work. During the debrief, SR8 reflected candidly on the challenges of timing, describing the experience as feeling ‘sailed down a river without a paddle.’ The Consultant had broken the bad news without prior planning and did not engage collaboratively in the donation approach, leaving SR8 to navigate a complex and emotionally charged situation alone. Despite this, SR8 maintained a strong presence in the ICU, working closely with the bedside nurse to build rapport before the formal discussion. After I prompted the SR by asking,

> ‘I’m curious, what additional resources do you have in your toolkit that could further support the family*?’*

The family, who were notably tech-savvy, were later provided with a QR code from SR8, giving them access to the Information Digital Link (IDL), a short, engaging, and easy-to-understand video explaining the donation pathway, after being prompted. This case illustrates the adaptability and resourcefulness required in these roles, as well as the emotional labour involved in balancing sensitivity, timing, and procedural obligations, as reflected in the journal entry below. It also demonstrates how the Specialist Requester’s skill and flexibility enabled tissue donation to proceed despite the family’s reluctance toward organ donation, an opportunity that might otherwise have been lost. The case reinforces the importance of collaborative planning among healthcare professionals and the need for sensitive, family-centred approaches to donation discussions.

Reflective Journal Entry

I observed a clear difference in Donation after Circulatory Death (DCD) cases compared to Donation after Brain Death (DBD). In DCD, death has not yet been formally diagnosed, and phrases such as 'it's kinder to let him go' highlight the challenging transition for clinicians delivering bad news and for Specialist Requesters/Nurses introducing the possibility of donation when death is imminent but not yet confirmed, and the likelihood of donation remains uncertain. This family described the process as having 'too many ifs and buts,' reflecting the unpredictability of whether the heart would stop within the timeframe needed to prevent ischaemia and preserve organs. By contrast, neurological death provides certainty; death is formally declared through neurological death testing, making donation discussions more definitive. This clarity may explain why three out of four, deemed consent cases that proceeded to donation in this study were DBD cases.

This observation highlights the need for targeted training and communication strategies in DCD cases, equipping Specialist Requesters/Nurses and doctors, to manage uncertainty effectively and support families through complex, emotionally driven decisions.

4.5.6. Face-to-face - Supported Deemed Consent Summary (SR10)

In this case, the patient was a woman in her 60s who suffered an intracranial haemorrhage. Her family included her partner, his two children, and her two sisters. SR10 demonstrated proactive engagement by making early contact and maintaining a presence in the ICU prior to the formal approach. She built rapport with the partner to ensure emotional support and collaborated with the Clinical Lead for Organ Donation (CLOD) to plan the conversation. Due to social distancing requirements, both the breaking of bad news and the donation discussion took place outdoors in the hospital garden. SR10 took time to learn about the patient's life, her love for singing, playing the piano, and seamstress work, and discovered that her brother-in-law had previously received a kidney transplant. This personal connection helped frame the conversation sensitively. SR10 identified family members who needed additional support and addressed the partner's concerns about the donation process, including fears that his partner would be 'butchered' or left in a 'debilitated state.' Through compassionate listening and clear explanations, SR10 kept the discussion on track and empowered the patient's sisters to communicate with their brothers, emphasising the importance of family consensus. SR10 explained the legislation change, stating that the patient's lack of objection suggested consent. This firm yet compassionate explanation helped the family support the decision. When the partner expressed uncertainty, SR10 clarified that the patient had not opted out of the Organ Donor Register, and under the new law, lack of objection implied consent. SR10 explained that this decision was made to avoid burdening family members.

This approach worked for this family, though SR10 noted that in training, some families, like solicitors, might challenge this reasoning. During the debrief, SR10 reflected on the importance of handling the situation with care and sensitivity, considering both emotional and legal aspects. SR10's initial interaction-built trust and rapport with the family. She adapted her approach based on the family's response, informing them about the law change early in the conversation to reduce uncertainty. SR10 engaged all family members, including the stepdaughters, and reiterated the importance of their support. She discussed the benefits of organ donation, sensing a positive shift in the family's attitude. SR10 highlighted the value of introducing the legal context early, using appropriate language to make it easier for the family to understand and accept the situation. Insights from SR10's debrief emphasise the importance of finding out about the potential donor as a person, and how showing a genuine and curious interest, builds trust and rapport. By reframing the legislation as a means of alleviating the family's decision-making burden and addressing their concerns through clear, factual information, SR10 was able to lead and respond in a bespoke way to meet the family's needs during the donation conversation effectively.

> ***Reflective Journal Entry***
>
> *This case reinforced the critical role of presence, both physical and relational, in donation discussions. Being visibly present on the unit and emotionally present with the family positioned the Specialist Requester (SR) as a familiar, supportive figure rather than a stranger entering an emotive conversation. Building rapport with nursing staff and leveraging an established relationship with the CLOD created psychological safety and signalled collaboration, helping normalise the donation process and reduce barriers. The Specialist Requester's proactive engagement, connection and emotional intelligence, demonstrated by taking time to learn about the patient as a person, understanding what mattered most to the family, and providing clear, tailored information, enabled the family to feel confident when explaining the situation to the patient's brothers.*

At the time, I recognised that what I was observing was grounded in presence, empathy, and relational warmth, the emotional intelligence and advanced communication skills that build trust by genuinely connecting with a family and tailoring the conversation to their needs. In later reflection with my supervisor, after observing these conversations, I found myself wanting to bottle and replicate this level of communication skill, it felt like witnessing an art form in practice. I realised that although I could instantly recognise 'good practice when I saw it,' it was not something that could be fully taught in a classroom; it was a deeply human skill. This is where the concept of *phronesis*, practical wisdom, became visible: ethical, intuitive judgement applied in real time. While not explicitly taught, these skills *can* be nurtured through experiential learning, such as simulated conversations with professional actors, which provide a safe space to practise, make mistakes, and refine one's approach.

Phronesis complements technical expertise, procedural knowledge, and the legislative framework. It reflects not only an understanding of the clinical and legal requirements of the organ donation pathway, but also the ability to build authentic human connection grounded in compassion, sensitivity, and respect.

4.5.7. Face-to-face - Unsupported Deemed Consents

Two face-to-face approaches resulted in unsupported deemed consent cases, one by SR4 and the other by SN7. In SR4's case, the patient was a woman in her 40s who suffered an intracranial haemorrhage. Treatment was deemed futile, and withdrawal of life-sustaining treatment was planned. Her family included her mother, partner, daughter, brother, and sister-in-law. SR4 established early contact, building trust with the staff and family. During the approach conversation, SR4 presented the opportunity for organ donation. The family initially responded negatively, unable to consider donation. SR4 emphasised practices in line with other countries (deemed consent). The patient's mother, brother, and partner all objected to organ donation, with the partner vividly describing not wanting the patient to be 'in pieces like a jigsaw'. SR4 redirected the conversation to the importance of helping others through donation.

The family had prior conversations about the gravity of the situation, so the futility of treatment was not a surprise. The Consultant showed the family CT scans to prepare them for discussing next steps. SR4 offered religious and spiritual support, which the family declined, and explained the change in legislation regarding deemed consent. Despite addressing objections, the partner remained firm in wanting the patient to remain 'whole'. SR4 attempted to shift perspective by asking the partner to consider what the patient herself, would have wanted, but the partner could not get past the visual concept. When the partner asked about a brain transplant, SR4 tried to turn the conversation around by asking if they would want another family to say yes to donation if it could save their loved one. Despite this, the partner's mind was not changed. Donation conversations are inherently sensitive and emotionally charged, and SR4 managed this case with professionalism and care. She noticed the brother attempting to close the discussion and, despite using deemed consent to ease decision-making, encountered persistent resistance.

In the debrief, SR4 acknowledged she may have,

> '*…pressed the issue a bit but did not regret it…*'

emphasising her commitment to ensuring an informed decision. The family's firm stance highlighted that legislation had little influence, as each member had personal reasons for declining donation. Reflecting on this, I noted my own uncertainty about whether I would have explored as much in her position and commended SR4 for maintaining clarity and avoiding ambiguity. This moment represented a particularly poignant part of the research study (as expanded in the reflective journal entry below). It was here that I realised every Specialist Requester/Specialist Nurse, has a personal boundary, a point they are unwilling to cross, when sensing discomfort in others and intuitively recognising when to stop.

SR4's intuition was central in navigating this threshold, demonstrating the delicate balance between advocating for donation and respecting family vulnerability. Despite the discomfort, clarity remained essential; ambiguity was avoided to ensure decisions were informed and definitive. SR4 emphasised the opportunity to save lives through donation. While the family could not see past the current circumstance, SR4 wanted the partner to consider the future impact of the decision. SR4's approach inquiring about the patient as a person highlights the importance of rapport-building. The genuine 'no' elicited from the family was well-informed and respectful. SR4 acknowledged the value of having another person present (me) for feedback and reflective discussion. This presence provided a sounding board for processing the emotional complexity of the interaction and offered an opportunity to validate her approach. It reinforced how collaborative reflection can enhance professional practice, support decision-making in ethically sensitive situations, and mitigate feelings of isolation often experienced in high-pressure conversations.

Reflective Field Notes

This case was a turning point in my research, where I experienced a disconnect between what is written in the regulation (HTA CoP F) and taught in the classroom regards exploring a known decision, not to be a donor, and the reality of practice. In theory, we teach to follow and apply legislation confidently, but in this moment, I realised that human emotion and context often override legislative and regulatory approaches. What stood out was the Specialist Requester's handling of the situation. They emphasised what was taught in the classroom and how a refusal should be based on clear, informed understanding rather than ambiguity, ensuring the family gives a definite 'no' to avoid later regret. However, my discomfort arose when the partner used a striking metaphor, saying he did not want his loved one 'cut up into little pieces like a jigsaw.' The Specialist Requester gently reframed this by asking, 'what if she could be saved by a transplant, would you want that?' The partner responded, 'Can she? Can she have a brain transplant?' This exchange revealed lingering hope and a lack of acceptance of death, alongside a strong desire to avoid any disfigurement of the body. Ultimately, the family expressed a very definite and pluralistic view not to donate.

In that moment, I realised that every Specialist Requester or Specialist Nurse has a threshold, a line they cannot cross when they sense distress in families who are struggling and unable to support donation. Of all the requests I observed, this was the only occasion where I felt that, even as an educator and former Specialist Nurse, I would not have been able to move beyond that discomfort had I been in the SR's position. It highlighted a gap between policy and practice and reinforced the importance of education in helping Specialist Nurses make sense of, and integrate, both for real-world application. This experience also challenged my ability to practise what I teach, reminding me that some families hold firm, polarised views about donation regardless of legislation or the Specialist Nurse/Requester's skill.

This experience highlighted that, despite best-practice guidance, donation conversations remain profoundly human and ethically complex. SR4 also reinforced the value of shared reflection, not only for immediate learning but for building resilience and wellbeing in emotionally demanding roles. It also exposed a gap: our current peer review process feels subjective, lacking a clear benchmark or aspiration. Feedback often depends on personal interpretation rather than evidence. I realised that although the observation tool and best practice guide developed for my research are comprehensive, they are potentially, too lengthy and impractical for use beyond the study. Using this insight, I set out to develop a more effective approach by creating an evidence-based tool grounded in observed best practice and supported by literature, with my thesis as its foundation. I began by analysing patterns from real-world observations and aligning them with Bloom's taxonomy to ensure the tool promoted progressive learning. I integrated principles of *phronesis*, translating them into practical measures such as sensing the atmosphere in the room and interpreting what remains unsaid, skills that are vital yet often overlooked. These insights were designed to feed into the curriculum, providing clarity and consistency. To move beyond subjective judgments, I documented a measurable framework of *what good looks like*, transforming peer review from isolated opinions into a structured continuum of best practice. By embedding guided debriefing as a core component, making it a powerful mechanism for learning from successes and refining approaches with confidence.

4.5.8. Face-to-face - Unsupported Deemed Consent (SN7)

SN7 approached the case with sensitivity, cultural awareness, and a strong focus on building rapport. The CLOD role-modelled best practice by introducing SN7 as the Specialist Nurse supporting end-of-life decisions. The patient, a young woman with a brain tumour, had treatment deemed futile. Her family, a group of ten from the Islamic community, had accepted that death was imminent and were making arrangements for the release of her body. The family were in contact with the bereavement office, to expedite the Medical Certificate of Cause of Death, which was partially completed and clipped to the observation chart when we arrived. SN7 recognised the family's preference for a rapid release of the body and noted tensions were high due to an ongoing grievance from another family about WLST, and staff had as a result been issued with personal attack alarms for safety.

SN7 noticed that not all family members were ready to move on and allowed time at the patient's bedside. SN7 approached the conversation with care, prioritising sensitivity and cultural awareness to maintain trust with the family. Before meeting them, she refreshed her understanding of Islamic beliefs, watching a resource on organ donation in Islam and arranged for the hospital Imam to attend. SN7 built rapport by learning about the patient's love for housework, especially hoovering, and sharing that she too came from a large family, creating a sense of commonality. She demonstrated excellent communication by pausing when the family asked about next steps.

When the brother strongly objected to organ donation on religious grounds, SN7 chose not to mention the legislation change. His firm response, 'no!', was followed by an explanation that organ donation contradicts their faith:

> *'If you take organs out of the body, they don't go whole to God.'*

SN7 explored this objection respectfully, asking about their religion's view on helping others through donation, but the brother reiterated their refusal. SN7's handling of this unsupported deemed consent case illustrates the delicate balance healthcare professionals must strike. Despite the objection, she respected the family's stance and shifted the focus to what mattered most to them rituals, keepsakes, and pain relief. SN7 reflected on the importance of meeting the family before breaking bad news and involving a faith representative only if the family wishes, as they were not receptive to the hospital Imam. Their preference for their own Imam was unexpected. SN7 considered whether emphasising the benefits of donation might have opened further discussion, but ultimately her decision not to mention the legislation change was guided by the need to preserve a positive relationship.

One family member was very concerned about a post-mortem and surgery to the body. Despite the Islamic faith supporting donation, the family wanted the body buried whole. SN7 felt the legislation was irrelevant to this family due to their dynamics and beliefs. She noted that pushing the issue could have damaged her relationship with them. The family was firm in their decision, with no indication of disagreement among them. SN7's professionalism, empathy, and commitment to respecting the family's wishes demonstrate the challenging of each unique donation discussion. Her approach highlights the importance of cultural sensitivity, clear communication, and respecting family dynamics in such sensitive situations. During the debrief, the findings reflect what SN7 might do if faced with a similar situation again. I shared insights from a Team Manager (TM) spoken during a shared practice session. The TM explained the organ donation system to a family from the Islamic community, then highlighted the benefits of organ donation by stating,

> '*People within your community are dying every day waiting for a transplant, and more people in your community die because people of the same blood group and tissue type aren't donating organs*.'

The TM provided a statistic,

> '*People from Black, Asian, and Minority Ethnic communities represented 7% of all deceased donors last year, compared with 32% of those on the transplant waiting list'*.

To which a younger family member responded positively, expressing a desire to change that statistic. SN7 found this approach inspiring and noted it down. This case illustrates the boundary SN7 would not cross. Based on the rapport built with the family, SN7 chose not to mention the legislation.

Although reported as an ‘unsupported deemed’ case, the legislation was not discussed (as discussed in reflective note below). The family's refusal was primarily due to fears about the surgical procedure and a strong desire for their loved one to be buried whole. In practice, the use of such community-specific statistics requires careful professional judgement. While highlighting disparities in donation and transplantation can be powerful, there are circumstances in which this approach may be inappropriate or even counterproductive. Some families might feel that drawing attention to community-level inequalities places an unfair burden of responsibility on them as individuals, particularly when those inequalities stem from wider systemic issues such as discrimination or inequitable access to healthcare.

Exercising *phronesis*, the practical wisdom that enables Specialist Nurses to discern what is appropriate for a particular family at a particular moment, is therefore essential. The synergy between SN7 and the CLOD was also discussed. SN7 was reflective and driven to learn from this case, consulting with the Equality, Diversity, and Inclusion (EDI) leads to understand why the family seemed offended by the presence of an Imam that she had sourced through the hospital. The EDI lead suggested it might be because the family were waiting until their loved one had died, as it would attract unwanted visitors. Understanding post-mortem rituals in the Islamic faith will influence SN7's future discussions. For example, female family members asked the men to leave the room. SN7 will now consider the gender of the patient and its implications for the family. SN7 has enlisted the support of the EDI lead to facilitate meetings with Imams and develop a training package for Specialist Nurses. SN7 noted that not everyone understands different rituals and might be reluctant to ask about them. The family did not want locks of hair, as hair is sacred in their religion. SN7 highlighted how knowing more about these rituals makes conversations easier and how she would be more comfortable next time. SN7 showed humility, compassion, and a willingness to reflect and learn. The findings illustrate SN7’s compassionate and respectful approach and demonstrate her curiosity to learn from the TM’s perspective. However, while not mentioning the legislation might seem sensitive, it raises the question of how to measure its impact or effectiveness.

> ***Reflective Journal Entry:***
>
> *This case raised an important issue: if deemed consent is neither introduced nor meaningfully used within the conversation, it becomes difficult to determine whether the legislation is genuinely influencing family decision-making. In this instance, although the case was recorded as an ‘unsupported deemed’ outcome, the legislation itself was never mentioned. The family’s decision not to proceed was driven by religious beliefs, concerns about bodily integrity, and a wish for their loved one to be buried whole, factors unrelated to the deemed consent framework.*

This illustrates the challenge of accurately categorising such cases. Without explicitly drawing on the legislation, we cannot reliably assess whether deemed consent is functioning as intended or whether it could have had any impact at all.

It also highlights the need for clearer definitions and reporting criteria that distinguish between refusals arising from fundamental beliefs and those in which the legislative framework was actively considered yet ultimately not supported.

4.5.9. Face-to-face expressed known decisions

Under the deemed consent legislation, individuals are considered potential donors unless they have made an explicit decision otherwise. However, the law also recognises that an *expressed known decision*, whether to donate or not, can be communicated verbally and is legally valid. This creates what could be seen as a practical loophole: even without a formal written record, a verbal expression of intent is sufficient to override deemed consent. The following section will examine each of the three expressed known decisions in turn.

Face to face expressed known decision summary (SR2)

This case concerned a middle-aged woman who experienced a sudden cardiac event. Despite intensive efforts, treatment was deemed futile, and a plan for Withdrawal of Life-Sustaining Treatment (WLST) was agreed upon. Her immediate family included her adult daughter and her partner, as well as the patient's ex-husband and his two teenage children from a subsequent marriage. The approach to the family was carefully and collaboratively planned by Specialist Requester 2 (SR2), the Consultant, and the bedside nurse to ensure consistency and compassion. During the initial conversation, the family demonstrated understanding that WLST was in their loved one's best interests. Palliation was also discussed to reassure them that comfort measures would be prioritised if death did not occur as quickly as anticipated. SR2 paused after delivering the difficult news, acknowledging the family's visible distress. She reassured them of her role in supporting both the patient and the family and sensitively explored any personal or religious needs. The patient, identified as Roman Catholic, received the sacrament of the last rites from a priest, honouring her faith. Recognising that the family remained overwhelmed, SR2 gently introduced the next topic by saying she had 'important information' to share.

She explained:

> *'There's nothing more we can do to save X's life. However, she is in a rare situation where she could save up to five other lives after her own death, by that, I'm talking about organ donation*.'

This phrasing framed organ donation as an opportunity for legacy and hope, delivered with empathy and clarity at a profoundly difficult time. SR2 went on to say:

> *'The situation now is that we want people to tell us if they don't want to donate, they can opt-out via GP, Boots advantage card, on-line or by telling their family.'*

Then SR2 asked,

> *'Have you had any conversations with x about organ donation, something she would have had opinions on?'*

The patient's ex-husband immediately said,

> '*I'm ok with that'*.

The daughter responded in turn, to say,

> '*No…we've talked about organ donation and Mom specifically said she wanted to be buried intact.'*

SR2's approach was like that of most (n86%) of the respondents in the *whole workforce survey* who ascertain the patient's last known decision early in the conversation. Those who did not use this approach cited, their reason for not choosing this approach, is that it sometimes leads to an immediate negative response, as seen in this case. During the debrief, SR2 reflected on how the family had already envisioned a particular pathway before organ donation was introduced. She paused after the bad news conversation, noting the daughter's additional worry about a hereditary risk to her mother's cardiac event. SR2 was professional, articulate, and supportive of the family's decision. She shared, how typically, she does not mention the legislation and has an 88% (22/26) consent rate. After discussing the pros and cons of using the legislation, SR2 reflected and considered exploring the *known decision* to be *buried intact*, to ensure it was an informed decision, potentially avoiding later regret. Keepsakes were also discussed during the debrief. SR2 felt that offering keepsakes is *subjective* and how she does not routinely offer keepsakes, unless there are children, or she has spent a prolonged time with the family. SR2 noted that,

> '*It feels strange that keepsakes are not standardised care and not routinely given in every ICU'*.

although her colleagues routinely offer them regardless of the outcome. The findings show that organ donation is a critical decision, and respectful communication is essential during moments of heightened emotion. SR2's approach highlights the delicate balance between compassion, informed consent, and family dynamics, illustrating that in cases of disunity, the decision is often made to not proceed with donation as reflected upon in the field note below.

Reflective Journal Entry:

A key moment in this research was recognising the complexity of exploring an expressed known decision regarding organ donation. While intended to clarify the patient's most recent wishes, this step can unintentionally trigger a knee-jerk response rooted in acute grief. Families may react with a premature 'no', not necessarily reflecting the patient's true intent but rather their own emotional state in that moment. Interviews also highlighted that this process can sometimes feel like offering families a 'get-out clause', an unintended loophole within the deemed consent legislation. Instead of reinforcing the patient's autonomy, it risks shifting the decision-making burden onto relatives during a time of profound distress. This insight emphasises the need for sensitive timing, language, and support when exploring expressed decisions, ensuring that the law's intent, to honour the individual's wishes, is upheld without inadvertently creating space for reactive refusals.

Face to face expressed known decision summary (Specialist Nurse Organ Donation (SN3)

This case involved a man in his 40s who was found at work following an accidental hanging in a warehouse. Planning took place between SN3 and the Consultant, with the family initially not accepting the patient's impending death. The plan was to discuss WLST and end-of-life care, with SN3 pausing the conversation if the family remained in denial. However, the plan was not followed, and SN3 felt 'thrown into the donation conversation' when the Consultant introduced her to the family as they asked,

'*What happens next?'*

SN3 began explaining WLST, but the family expressed a desire for 24 more hours, to which the Consultant responded that additional time would not change the outcome and emphasised,

'*preserving the patient's dignity*'.

SN3 resumed the conversation, explaining WLST and leading into the benefits of organ donation. She mentioned the opt-out system and asked if the patient had ever expressed his wishes. The family unanimously agreed that the patient wanted to be buried whole, as he had expressed when his own father died. During the debrief, SN3 reflected on the planning discussion, recalling that she and the Consultant had agreed donation would only be raised if the family first accepted the patient's death. However, when the Consultant introduced SN3 as the Specialist Nurse in front of a large family gathered in a small, confined space, the situation felt particularly daunting for SN3.

The Consultant's explanation of the patient's situation lacked clarity, and his mention of,

'...putting him through the mill'

implied prolonged suffering, which SN3 felt influenced the family's decision. SN3 described feeling unprepared when the Consultant unexpectedly introduced organ donation into the conversation. Although the family ultimately gave a unanimous decision against donation, SN3 sensed that not all members were fully aligned or ready to accept that death was imminent, some still held hope and needed more time and information. During the debrief, SN3 acknowledged that, in hindsight, she would have paced the conversation more carefully, creating space to explore the patient's wishes in greater depth. She also reflected on the complexity of interpreting expressed decisions, noting that a person's preferences for others may differ from their own. In this case, while the patient had previously stated he did not want donation for his father, the fact that he had not opted out for himself could indicate he did not object to being a donor. This observation highlights the individualised nature of consent and the importance of sensitive, tailored discussions. Arguably, this scenario could have been interpreted as an unsupported deemed consent case.

Face to face expressed known decision summary (SN6)

In this memorable case involving a woman in her 60s of Vietnamese origin, the patient suffered an Intracerebral Haemorrhage (ICH) and was declared dead following Neurological Death Tests (NDTs). Her son and daughter were present, the latter being a pharmacist in Intensive Care. Specialist Nurse (SN6) faced a challenging moment when approaching the family about organ donation. Her mind went blank, and she forgot the patient's name. When she tried to recall it, the name sounded similar to an animal (kangaroo), and not wanting to cause offence, she referred to the patient simply as 'their mother.' This case highlights the critical importance of remembering patient names, a challenge I had previously observed during the online training comparison as part of workstream 2.1, when a Specialist Nurse faced a similar issue. At the time, I was comparing classroom learning with real-world practice as part of testing the participant observation tool. Interestingly, I also noted an experienced Specialist Requester writing down the patient's name in her notebook during planning with the Consultant and family, demonstrating a practical strategy to avoid such situations. Although SN6 had achieved competency on the rota in March 2021, she had not conducted a formal approach since then. Seeking exposure, she proactively volunteered for a Specialist Requester shift. Planning took place between SN6 and the Consultant, and the family fully understood the gravity of the situation. When SN6 spoke to them for the first time, she personalised the conversation by referring to the patient as 'their mother.' Despite not having made early contact, she quickly built rapport by learning about the patient's love for growing food and her kindness and independence.

During the approach, SN6 explained:

> *'Unfortunately, we were unable to save your mother, but through organ donation, she could save the lives of others.'*

The daughter explained that her mother had frowned upon organ donation due to spiritual beliefs when she herself signed up for a donor card at age 16. Although the family had previously declined religious support offered by SN6, she chose not to reference legislation, accepting the daughter's reasoning as an expressed known decision not to donate. This response was based on the daughter's account of her mother's disapproval and, upon further exploration by SN6, confirmation that these views were rooted in spiritual beliefs. In the debrief, SN6 reflected on the importance of remembering patient names. To mitigate this, one Specialist Requester noted they write down family names as a prompt. SN6 also acknowledged that expressing condolences earlier would have been appropriate. The Consultant had initially discussed futility, end-of-life care, and NDTs before handing over the organ donation conversation to SN6. SN6 expressed her own discomfort with the term 'law,' which she felt implied *obligation* and *force*, preferring 'legislation' as a softer alternative. Her nervousness stemmed from limited recent experience, aligning with workforce survey findings that exposure strongly influences Specialist Nurse confidence and competence. Looking ahead, SN6 resolved to review all documentation before meeting families to ensure clarity on names, ages, and case details. Even if the patient's decision was an 'expressed known wish,' she would reference legislation to provide legal context, acknowledging the law change, even when the decision against donation was clear. SN6's use of the term 'wish' rather than 'decision' reflects abstract legacy language, contrasting with the concrete terminology taught in training. While some respondents find this distinction memorable, it did not resonate with SN6 in this case. This case highlights how exposure impacts confidence and competence, and the significance of understanding a patient's last known decision. It reinforces the need for Specialist Nurses to adhere to legislation and provide families with sufficient information to understand the patient's views, gathering enough evidence to reasonably conclude whether they wished to donate. To enrich these observations, semi-structured interviews were conducted to triangulate findings. These interviews added depth and nuance, corroborating and expanding the insights presented here. The results of these interviews will be discussed in the following section.

Reflective Journal Entry:

This case illustrates how what is taught in the classroom requires deliberate practice to translate effectively into real-world application. Limited exposure can lead to reliance on a 'comfort blanket' of familiar habits, rather than adapting to the latest evidence-based training. One example is the persistence of legacy language, using the term 'wish' instead of the more concrete and precise term 'decision'. While classroom training emphasises clarity and legal accuracy, the absence of regular practice can result in reverting to softer, abstract language that feels safer but lacks the definitive tone required in professional conversations. This highlights the need for ongoing experiential learning and reflective practice to embed new approaches and ensure confidence in applying legislation and best-practice communication strategies.

These observational insights highlight how Specialist Nurses draw on *practical wisdom* to interpret the emotional considerations present in real-time interactions. To extend and triangulate these findings, the next section draws on data from the semi-structured interviews, where participants describe how they recognise, interpret, and respond to emotional cues in practice. The interview narratives not only reinforce the patterns observed, they, also provide reflective accounts of the reasoning behind their actions, offering a richer understanding of how emotional context is incorporated into decision-making and professional judgement.

4.6. Debriefs Post Shadowing Participant Observations in Clinical Practice

As outlined earlier in the Methodology chapter (Debrief Post Observation (Workstream 2.3): p. 38–39) the debriefs formed the second stage of the participant-observation data collection process. They were intentionally designed to capture Specialist Nurses immediate reflections *in the moment*, before experiences were diluted by time, documentation, or retrospective rationalisation. This method was selected for its unique capacity to access the tacit knowledge and clinical reasoning that Specialist Nurses draw upon during family approach conversations. It captures the subtle, often unspoken aspects of practice, the intuitive judgements, relational sensitivities, and moment-to-moment adaptations, that are rarely articulated in interviews or formal documentation.

In many respects, this dataset represents the most insightful and revealing material in the study, providing crucial triangulation across data sources and offering a direct window into how Specialist Nurses and Specialist Requesters interpret, apply, and navigate the deemed consent legislation within real-world encounters. The ten debriefs were conducted in clinical practice immediately following periods of shadowing, with Specialist Nurses and Specialist Requesters reflecting on the real family approaches observed that day. Debriefs were recorded either in writing, via Microsoft Teams, or using a digital voice recorder. Each conversation was then transcribed verbatim and uploaded into NVivo for analysis.

Following Braun and Clarke's Reflexive Thematic Analysis, I systematically coded and interpreted the transcripts to identify patterned insights across cases. Across these ten debriefs, a vivid and coherent picture emerged of *practical wisdom* (phronesis) in action. Specialist Nurses described pacing conversations according to families' emotional readiness, adapting language to prevent feelings of pressure, and using the deemed-consent framework as a supportive, clarifying structure rather than an authoritative mandate. Timing emerged as a key theme: nurses repeatedly framed it not as a procedural requirement but as a matter of professional judgement and ethical sensitivity.

Specialist Nurses spoke of intentionally pausing after breaking bad news or following neurological death testing, stepping away to,

> '*let it land'*

and only returning,

> '*when you feel ready*.'

These pauses were described not as delays but as protective acts, spaces that safeguarded families from overload. Conversely, when timings were accelerated by others,

> '*…the consultant threw me into what happens next'*.

Specialist Nurses reflected that this disrupted their ability to stage conversations in a way that supported emotional safety and understanding (Transcripts 1; 5; 7). These debrief reflections provide essential contextual insight into the observation findings that follow. They illuminate the reasoning behind actions later described in field-note excerpts and offer a deeper understanding of how Specialist Nurses make sense of their role within the deemed consent system. Together with the shadowing observations, they form a detailed and deeply textured evidence base for the later analysis and overall conclusions of the thesis.

4.6.1. Language Choices

Language choices were framed as ethical work in their own right. Specialist Nurses moved away from potentially coercive phrasing such as *assume/deem* toward threat-reducing wording like 'consider willing,' and many preferred *legislation* or *system* to the word *law*, which some felt could imply obligation. One debrief summarised the principle simply, it is about 'the right words at the right time,' avoiding technical terms that distance families from meaning. This linguistic care was especially visible in phone calls, where rapport must be built without visual cues; as one observer noted admiringly, 'gentle humour' and 'warning shots' helped avoid sounding 'like a robot.' (Transcripts 3;5;10). In this context, deemed consent was introduced to normalise the pathway, not to close down discussion. Specialist Nurses commonly led with the benefits of organ donation and human meaning of donation, bringing the law in earlier only when the family's response suggested it would 'add credence' rather than pressure.

Conversely, Specialist Nurses withheld the law where it risked harm, 'the law was irrelevant to them… pressing it could have damaged the relationship', or where families were already clear: 'the law didn't make a jot of difference.' The most effective frame was to ask families to support a decision already made by the absence of an opt-out, which could reduce burden while preserving voluntariness. (Transcripts 2;10).

4.6.2. Cultural and faith meaning-making

Cultural and faith meaning-making featured strongly, particularly concerns about bodily integrity ('the body should remain whole'). Specialist Nurses demonstrated the importance of *phronetic* sensitivity, exploring gently to discern whether refusals were doctrinal, familial, or personal, while learning from missteps (e.g., an unsolicited offer of an Imam felt intrusive in context). Follow-up with EDI leads helped translate these moments into practical adjustments (privacy expectations, gendered space, ritual timing), highlighting that cultural competence is situational rather than generic. (Transcript 7).

4.6.3. Interprofessional context

The interprofessional context also played a significant role. The way consultants framed the situation shaped how families understood their choices; for example, the word choice to suggest that it was 'kinder to let him go', lingered and influenced how relatives weighed prolongation of treatment against donation. Role clarity was an ethical issue when juniors (bed side nurse) were left to deliver the outcome of neurological death testing by phone, which the Specialist Requester judged inappropriate. Conversely, well-planned staging (plan, test and regroup) and clean handovers allowed Specialist Nurses to maintain pace and tone, and to keep donation within an end-of-life care frame rather than as a bolt-on request. Transcripts 2;10).

4.6.4. Telephone-only approaches

Telephone-only approaches revealed a different set of constraints. Without non-verbal cues, uncertainty about who was deciding and how much they understood was common (one relative 'sounded about 12… actually 32'). The Specialist Requester highlighted the need to establish clear timeframes and, following prompting, acknowledged that providing a short Information Digital Link (IDL) could help support the family's understanding prior to further contact. These structured moves attempted to compensate for the thinner relational bandwidth of the medium and the logistical barriers to attending in person. (Transcript 7).

4.6.5. Decision-classification challenges for the Potential Donor Audit

Debriefs also surfaced decision-classification challenges. Teams reflected on the difference between an expressed known decision and an unsupported deemed outcome, especially when the law was never mentioned or when a refusal rested on beliefs rather than an explicit personal decision. One practical suggestion was to code whether legislation was raised (and by whom), alongside the *basis* of refusal, so potential donor audit labels better reflect what actually happened in the room. Importantly, when refusals were accepted, Specialist Nurses worked to ensure they were informed, 'a genuine *no*… no ambiguity', rather than knee-jerk responses in acute grief. (Transcript 1;7).

4.6.6. Exceptional End of life Care

Across cases, whole-family end-of-life care continued irrespective of the donation decision. Specialist Nurses offered chaplaincy, memory boxes, child bereavement guidance, rapid release where possible and a soundbite recording of a father's heartbeat for the daughter to wear in her locket on her wedding day; they also supported how parents might tell children and whether to bring them in to say goodbye, integrating donation into a broader care narrative. These compassionate acts of kindness were not mere add-ons but an integral part of the Specialist Nurses role, that sustained trust and dignity at the bedside. (transcript 3;5). Running through the debriefs is the thread of emotional labour and resilience.

Specialist Nurses described 'parking' their own shock, including one Specialist Requester who had been stopped by armed police on the way to the hospital and was still able to compartmentalise the experience because,

'…*there was a family waiting*.'

Others noted the strain of crowded rooms and competing clinical pressures. Debriefs gave language to this invisible work and, importantly, generated *immediate* practice changes, using,

'*consider willing'***,**

instead of

'*assume*,'

bringing legislation in earlier when it helps to normalise (but never to coerce), setting timeframes and sending the IDL in phone cases, and recapping names/details before entering the room. In this way, debriefs operated not merely as reflection but as a means of practice improvement, turning tacit judgement into shared, teachable practice. Transcripts 5;10;7). The table below presents an overview of all ten debriefs, outlining the clinical setting, key initial codes (RTA Phase 2), the final theme generated (RTA Phase 5), a short illustrative quote, and the associated practice implication derived from Braun and Clarke's Reflexive Thematic Analysis (Braun and Clarke, 2021).

Table 4 - Analysis of ten debriefs using Braun & Clarke's Reflexive Thematic Analysis, including the clinical setting, early codes (Phase 2), final themes (Phase 5), quotations, and implications.

Debrief (source)	**Setting**	**Initial codes (RTA Phase 2)**	**Final theme (RTA Phase 5)**	**Short quote**	**Practice implication**
Debrief 1 (Transcript 1)	Telephone; family already supportive	Phone rapport; 'warning shots'; gentle humour; avoid robotic tone; minimal law; anchor in context.	Telephone context; Language as ethical practice.	'Gentle humour… warning shots… you don't want to come across as a kind of robot… anchor it in some sort of context.'	Build deliberate phone rapport; keep law minimal when support is clear; still document deemed basis.
Debrief 2 (Deemed Transcript 2)	Reflective learning after shadowing	High-consent practice not law-first; weigh pros/cons of legislation after benefits; NMC Code links to reflective practice.	Practice learning; Benefits-first framing.	'Usual practice was not focused on the legislation… useful discussion of pros and cons.'	Reinforce benefits-first pedagogy; channel reflective outputs into revalidation and training.
Debrief 3 (Transcript 3)	Face-to-face; crowded room; DCD.	Timing forced by consultant; would have paused; closed question gave an easy out; consider IDL; set timeframes.	Timing & pacing; Question design.	'I would have liked to pause… but the consultant threw me into what happens next… next time avoid the closed question.'	If pacing is disrupted, slow and revisit; use open questions; consider IDL to support understanding.
Debrief 4 (Transcript 4)	Face-to-face; refusal with strong imagery.	'Jigsaw' metaphor; ensure clarity; law made no difference; aim for informed no; value of debrief.	Genuine, informed 'no'; When law won't help.	'You elicited a genuine 'no'… no ambiguity, not a knee-jerk refusal… the law didn't make a jot of difference.'	Prioritise decision quality over conversion; document basis of refusal for audit/learning.
Debrief 5 (Transcript 5)	Face-to-face; staged NDT; EoL care	Plan, then test, then regroup; SR slowed down; involve children; memory boxes; emotional labour (parked own shock).	Timing & pacing; Whole-family EoL care; Emotional labour.	'When you feel ready…' / 'I parked it—there was a family waiting.'	Stage BBN, NDT, donation; integrate keepsakes/child guidance; support staff wellbeing (PNA, debriefs).
Debrief 6 (Transcript 6)	Face-to-face; known decision	Prefer legislation/system over law; right words; forgot	Language as ethical practice; Legislation acknowledgement	'I feel more comfortable with legislation than law… right	Use threat-reducing language; pre-brief

		name, pre-brief details; optional system acknowledgement.		words at the right time.'	names/details; acknowledge system change for clarity where appropriate.
Debrief 7 (Transcript 7)	Face-to-face; large Muslim family	Bodily integrity (remain whole); law irrelevant; avoid pressing; EDI learning; add who-raised-law to audit.	Cultural/faith meaning making; Classification fidelity.	'We just don't want it… law was irrelevant… offer of an Imam felt intrusive.'	Explore beliefs sensitively; consult EDI; record who mentioned law and basis of refusal; consider IDL.
Debrief 8 (Transcript 8)	Face-to-face; WLST; tissue pathway.	Too many ifs and buts; tissue as half-way house; consultant phrasing lingered; heartbeat soundbite keepsake.	Consultant framing; Tissue donation option	'Kinder to let him go… too many ifs and buts.'	Align messaging with consultants; offer tissue when organ timelines feel burdensome; use meaningful keepsakes.
Debrief 9 (Transcript 9)	Telephone; distant relatives.	Caller sounded 12 (was 32); set timeframes; send IDL; junior left to deliver brain-death outcome by phone.	Telephone constraints; Role clarity.	'Set a timeframe and send the IDL… junior left to deliver brain death by phone, not appropriate.'	Structure remote cases (timeframes and IDL); ensure senior clinician delivers death notification.
Debrief 10 (Donor Transcript 10)	Face-to-face; early law (appropriate)	Benefits-first; early law can add credence; support, not consent; right words, right time.	Legislation as supportive frame; Benefits of donation first.	'Bringing it in earlier gave credence… we weren't asking for consent, but for support of a decision already made.'	Introduce law earlier (not first) when it normalises; frame as family support for no-opt-out decision.

4.7. Semi-Structured Interviews

All Specialist Nurses, Specialist Requesters, and the Professional Development Specialist within the study region were invited to participate in interviews, and all 28 agreed. However, due to sickness and capacity constraints, 24 interviews were completed (1 Professional Development Specialist, 8 Specialist Requesters, and 15 Specialist Nurses). The design and structure of the interviews are detailed in the methodology section (Chapter 3.67, p.86).

The interviews captured participants' reflective interpretations of their practice, providing insight into values, judgements, and emotional responses that could not be fully accessed through observation alone. These data complemented the observational findings and supported analytic triangulation, strengthening the study's credibility.

During interviews, information was gathered on participants' roles, length of time in post, prior professional background, and any lead responsibilities. The findings presented in this chapter draw on these 24 semi-structured interviews, with anonymised identifiers (e.g., I10) used to preserve confidentiality while reflecting participants' voices and illustrating how deemed consent is enacted in practice. All Specialist Nurses, Specialist Requesters, and the Professional Development Specialist working within the study region were invited to participate in interviews, and all agreed. In total, 24 out of 28 interviews were conducted (comprising 1 Professional Development Specialist, 8 Specialist Requesters, and 15 Specialist Nurses).

The design and structure of the interviews are discussed in detail in the methodology section (Chapter 3.67, p.86). The role of the interviews was to capture participants' reflective interpretations of their practice, enabling exploration of underlying values, judgements and emotional responses that could not be fully accessed through observation alone. These interview data complemented observational findings and supported analytic triangulation, thereby strengthening the credibility of the study. Four interviews could not be completed due to capacity constraints or sickness. During the interviews, data were gathered on participants' roles (Specialist Nurse, Specialist Requester, or Professional Development Specialist), length of time in post, prior professional background, and any lead roles they held. This chapter presents the findings as a narrative drawn from these 24 semi-structured interviews with Specialist Nurses/Specialist Requesters. All quotations are linked to anonymised interview identifiers (e.g., I10) to preserve authenticity while ensuring confidentiality. The aim is to reflect participants' voices and illustrate how deemed consent is enacted in real-world practice.

Before writing the interview narratives, I carried out a structured process of Reflexive Thematic Analysis (RTA) based on Braun and Clarke's six phases. This involved first spending time reading and re-reading the transcripts to become fully familiar with the data, then coding the narrative line by line to identify key points. I grouped these initial codes into early theme ideas and repeatedly reviewed them against the dataset to check their relevance and clarity. I then refined and named the themes by identifying the central idea that held each one together, as recommended in RTA. Throughout the process, I understood coding and theme development to be an active and interpretative task rather than a matter of simply 'finding; themes in the data, which aligns with Braun and Clarke's guidance on reflexivity and researcher judgement (Braun & Clarke, 2021) I subsequently revisited, adjusted, and reorganised my codes, merging those that overlapped, separating those that were too broad, and clarifying their wording. to make sure each code accurately reflected the data and was clearly distinct from neighbouring codes.

Through these iterative cycles, I developed a set of overarching themes and sub-themes that captured consistent patterns of meaning across the dataset, in line with quality principles for RTA (Braun & Clarke, 2019). The hierarchical relationships between these themes, sub-themes, and codes are shown in figures 31 and 32, in parts 1 and 2 below:

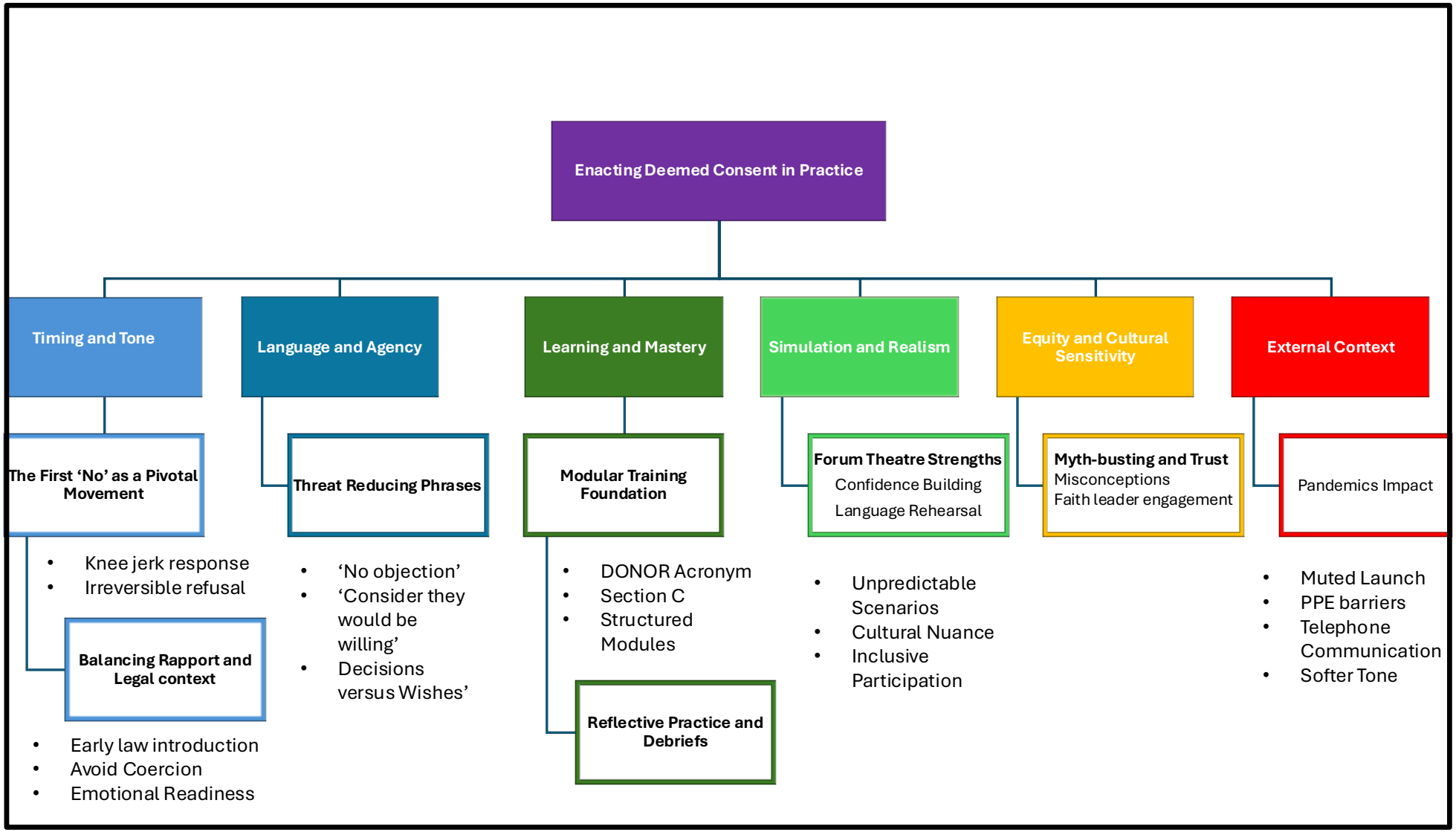

Figure 31 Part 1 - Reflective Thematic Analysis: Colour Coded Tables

Theme	Sub-theme	Codes/Nodes
Timing and Tone	First 'No' as pivotal moment	Knee jerk response, Irreversible refusal
Timing and Tone	Balancing rapport and legal context	Avoid Coercion, Emotional Readiness, Softer Tone, Telephone Communication
Language and Agency	Threat-reducing phrases	'No objection', 'Consider they would be willing', Decisions versus Wishes
Language and Agency	Policy/structured language supports	DONOR Acronym, Section C
Learning and Mastery	Modular training foundation	Structured Modules
Learning and Mastery	Reflective practice and debriefs	Reflective Practice and Debriefs
Learning and Mastery	Embedded frameworks in practice	DONOR Acronym, Section C
Simulation and Realism	Forum theatre strengths	Forum Theatre Strengths
Simulation and Realism	Confidence building	Confidence Building
Simulation and Realism	Language rehearsal	Language Rehearsal, Telephone Communication
Equity and Cultural Sensitivity	Building trust & correcting myths	Myth-busting and Trust, Misconceptions
Equity and Cultural Sensitivity	Community and faith engagement	Faith leader engagement
Equity and Cultural Sensitivity	Inclusive practice	Inclusive Participation, Cultural Nuance
External Context	Pandemic impact on practice	PPE barriers, Telephone Communication, Muted Launch
External Context	Policy timing	Early law introduction

Figure 32 Part 2 - Reflective Thematic Analysis: Colour Coded Tables

The following narrative draws on the semi-structured interviews to provide a detailed, practice-based understanding of how Specialist Nurses and Specialist Requesters adopt deemed consent in their everyday work. These accounts offer insight into the reasoning, judgement, and communication strategies that shape their decision-making and extend the patterns observed in clinical settings. The following sections explore each theme in turn Language and Agency, Timing, Tone, and the First 'No'; Language that Lowers Threat and Preserves Agency; From Modules to Mastery: Exposure, Feedback, and Debriefs; Simulation and realism: Dial-Up/Dial-Down Complexity; Equity, Culture, and Myth-Busting; The Pandemic's Shadow; and Illustrative Case Examples, showing what these findings mean in practice. Each theme is supported with participants' own words, allowing their experiences, challenges, and reflections to guide and ground the analysis.

4.7.1. Language and Agency

Across the interviews, Specialist Nurses consistently described the law as something that supports the donation conversation rather than drives it. The legislation offered clarity, but staff emphasised that in the absence of a recorded decision, families' memories, values, and stories remained central. In effect, the law functioned as a supportive cue, the *carrot*, not the *stick*, rather than a force dictating how Specialist Nurses should proceed. Several participants reflected on how their practice had shifted with experience. One Specialist Requester described how their early cases prompted them to refine the order in which they structured their deemed-approach conversations.

> *'I now bring the law in early… framed softly (it would suggest no objections).'* (I10)

This approach aimed to introduce the legal context in a neutral, non-pressurising way. Others cautioned that leaving it too late could undermine trust:

> *'If you come in at the last minute with it, it appears coercive… so I get to it sooner rather than later, if appropriate.'* (I17)

These reflections highlight the theme of Timing and Tone, showing how the placement and framing of legal references shape perceptions of autonomy and openness. Participants also described being cautious with legalistic terminology, noting its potential to either open or close dialogue. As one Specialist Nurse explained:

> *'I prefer 'no objection'… families worry we'll just take organs now, so we have to bust myths gently.'* (I24)

This aligns with the sub-theme of Threat-Reducing Phrases under *Language and Agency*, where softer, more collaborative language helps reduce anxiety and encourages families to engage in the decision-making process.

4.7.2. Timing, Tone, and the First 'No'

Timing emerged as a central theme across interviews, shaping both the progression and outcomes of consent conversations. Specialist Nurses described a delicate balance between introducing the legal framework early and allowing sufficient space for rapport to develop, with some expressing uncertainty about how best to achieve this in practice. As one participant reflected,

> *'Something I do struggle with is how and when to bring the legislation in and… what's going to work best for that family in that conversation?'* (I19).

Central to this challenge was the notion of the 'first no', often a reflex response, which participants viewed as important due to its tendency to become a fixed endpoint, rather than a moment of hesitation open to further discussion. Interviewees highlighted the difficulty of revisiting this initial refusal once expressed, reinforcing the importance of careful timing in how and when the law is introduced. As another participant noted,

> *"Families are often polarised yes/no; once 'no' is voiced, it's hard to recover, so a soft law frame early can help"* (I18).

This insight highlights the importance of timing and tone in framing the conversation. Specialist Nurses noted that introducing the law too abruptly can feel coercive yet delaying it too long may allow misconceptions to harden. Strategies varied: some advocated for embedding the legal context early in a gentle, non-threatening way, while others preferred to first establish emotional connection before referencing legislation. For many, the goal was not to override a family's position but to keep the dialogue open, transforming a knee-jerk refusal into an opportunity for reflection rather than a definitive conclusion.

4.7.3. Language that Lowers Threat and Preserves Agency

Across interviews, participants consistently emphasised the power of language in shaping family perceptions and maintaining a sense of control during consent conversations. Certain phrases were identified as particularly effective in reducing perceived threat while clarifying the legal position. Examples included: *'no objection,' 'we can consider they would be willing,'* and reframing *'wishes'* as *'decisions.'* These linguistic choices were not merely semantic; they were strategic tools for the Specialist Nurses to uphold family agency and avoid coercion. One interviewee explained the rationale behind favouring *'no objection'* language:

> *'We always involve families, soft opt-out still includes a family conversation'.* (I24).

This approach reflects a deliberate effort to counteract assumptions that deemed consent removes family involvement.

By using language that signalled support and collaboration rather than *assumption* or *presumption*, Specialist Nurses aimed to preserve trust and minimise defensiveness' The shift from *'wishes'* to *'decisions'* was also significant. Specialist Nurses showed awareness of how *'wishes'* could feel abstract or uncertain, whereas *'decisions'* conveyed was more concrete and tangible, providing clarity and respect for autonomy.

Similarly, phrases like,

'...we can consider they would be willing'

were seen as gentle bridges between the legal framework and the family's emotional reality, avoiding stark binaries of compliance versus refusal. These were described as gentle ways of linking the law to the family's situation, rather than forcing a clear 'yes or no' decision. They show that how something is said matters, as soft, careful language helps families feel respected, supported, and in control. Participant I17 reinforces this by explaining that timing is key, noting that,

'if you come in at last minute with it, it appears coercive',

meaning that introducing the law too late can feel pressurising instead of supportive. Underlying these choices was a shared understanding that tone and phrasing are not incidental but central to compassionate practice. Language that reduces perceived threat does more than soften the conversation; it signals respect, reinforces voluntariness, and helps maintain the family's sense of agency within a legally structured process.

4.7.4. From Modules to Mastery: Exposure, Feedback, and Debriefs

Participants contrasted the clunky, legalistic feel of the language practiced in early deemed-consent training with the more fluent and comfortable vocabulary they were accustomed to when using a presumptive approach with patients on the ODR. Over time, however, practising the deemed-consent approach enabled them to develop a smoother, more natural, and authentic communication style, essentially allowing them to 'find their own way' in these conversations. The modular training provided what many called,

'*the bones'*,

a structured foundation of criteria, the DONOR acronym (pictured below), and procedural elements such as completing Section C on the consent form (Appendix 30).

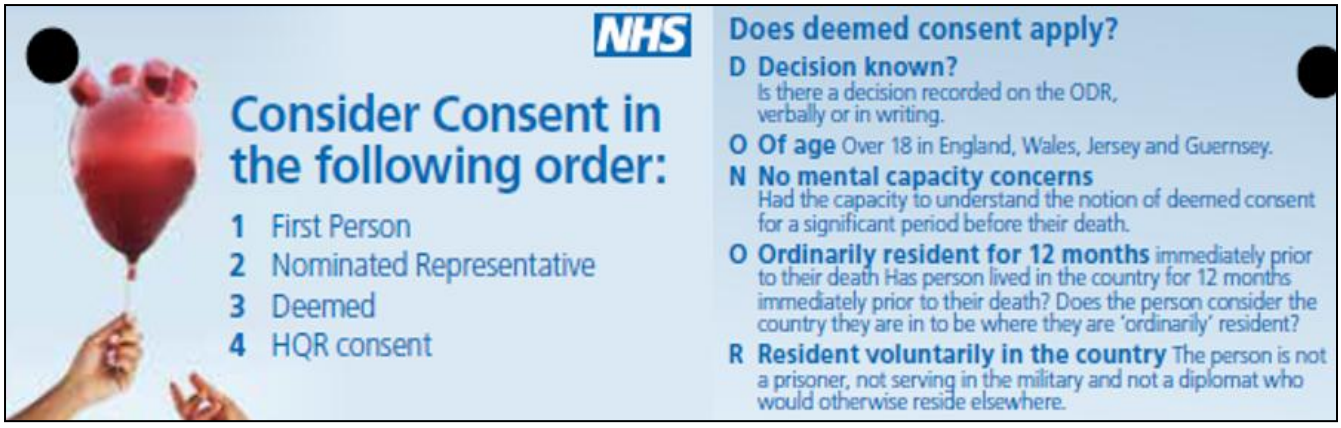

Figure 33 - DONOR acronym card (a credit card size card worn on the back of the Specialist Nurses/Requesters lanyard as a reminder of deemed consent criteria).

While these modules were essential for orientation, participants emphasised that competence deepened through repeated exposure, practice, and reflective feedback. Several interviewees acknowledged the strengths and limitations of the formal training:

'Training was well structured but overwhelming, over-egged at times,'

one participant reflected, adding that,

'Spacing and practice made the difference for me.' (I1).

This sentiment was highlighted by other participants (I15 and I23) that the cognitive load associated with initial learning and illustrates the benefit of a tri-modular approach in which theory, practice, and consolidation are spaced out over time to strengthen skills. For many, mastery was not achieved in the classroom but through iterative cycles of real-world application, practice and reflection. Importantly, participants pointed to the role of psychologically safe spaces for debriefing. Rather than large, formal debriefs, small and trusted groups were preferred for processing complex cases:

'Small trusted debrief groups consider the whole context; big calls can be fatiguing.' (I21, I24)

These smaller debriefs allowed Specialist Nurses to explore nuances, tone, timing, and emotional dynamics, without fear of judgment. They were described as vital for transforming procedural knowledge into adaptive expertise, enabling Specialist Nurses to fine-tune their approach in ethically sensitive conversations. In summary, while modular training laid the groundwork, mastery was developed through lived experience, reflective dialogue, and constructive feedback. This progression highlights the importance of embedding continuous learning opportunities within practice, ensuring that technical competence evolves into relational fluency.

4.7.5. Simulation and realism

Forum theatre emerged as a valued training method, offering Specialist Nurses the opportunity to 'try out' language in a safe, simulated environment. Many participants described these sessions as instrumental in building confidence and experimenting with tone, phrasing, and timing. The interactive nature of role-play allowed for immediate feedback and iterative learning, which participants saw as essential, for preparing for real-world conversations. However, over time, some scenarios were perceived as overly predictable, limiting their developmental impact. One Specialist Nurse reflected:

'*Actors get predictable… we need dial-up/dial-down difficulty and twists' (I16).*

This participant emphasised the need for scenarios that introduce conflicting relatives, cultural sensitivities, and legal complexities to genuinely test judgement and adaptability. This call for greater complexity highlights a need for training that better mirrors the unpredictability of real practice. Participants suggested incorporating layered challenges, such as family disagreements and disunity, time pressures, or ethical dilemmas, to help Specialist Nurses prepare for the emotional and cognitive demands of consent conversations. While many welcomed the increased realism, others raised an additional concern regards participation equity. Even in actor-led sessions, they noted that the same voices often dominated unless the structure explicitly ensured that everyone had opportunities to participate.

'Even with actors, it's better when everyone has a go at least once, otherwise the same voices dominate.' (I22)

Reflective Journal Entry:

This interview prompted me to think more critically about the structure and inclusivity of deliberate practice with professional actors. Although actor-led scenarios are valuable, participants noticed that participation is not always equitable; the same individuals often take the lead while others remain observers. To create a more balanced learning environment, it feels important to design these sessions so that everyone has the opportunity to participate meaningfully.I also reflected on the need for scenarios that can be flexibly dialled up or down in complexity, depending on learners' developmental stage and confidence. The ability to adjust the emotional intensity, relational dynamics, or legal complexity in real time would allow the practice to better meet individual learning needs. Finally, I am increasingly aware that learner preferences and neurodiversity must be considered when designing these sessions. Not all learners thrive in high-pressure, performative environments, and some may require alternative ways of engaging or processing information. A more intentional approach to structuring and differentiating actor-based practice would help ensure that it is both equitable and genuinely supportive of diverse learning needs.

This insight points to the importance of inclusive facilitation, ensuring that all Specialist Nurses experience the discomfort and learning that comes from active participation rather than passive observation. So, while forum theatre remains a positive of experiential learning, participants advocated for evolution, moving beyond static scripts toward dynamic, context-rich scenarios that challenge judgment, cultural competence, and ethical reasoning. Coupled with equitable participation, these enhancements could transform role-play from a rehearsal into a robust simulation of real-world complexity.

4.7.6. Equity, Culture, and Myth-Busting

Issues of mistrust and misconception surfaced repeatedly across different settings, often rooted in cultural narratives and historical sensitivities. Participants described encountering persistent myths, such as the belief that under deemed consent, organs would be taken without family involvement, which required careful reassurance and transparent explanation. One participant captured this challenge succinctly:

> *'People think you'll 'just take organs now'; you have to reassure, explain, and sometimes partner with community leaders,'*

referencing collaborative work with local mosques and the use of culturally resonant stories to build trust (I16).

These accounts highlight that consent conversations do not occur in isolation, they are shaped by broader social and cultural contexts. Specialist Nurses emphasised the importance of myth-busting through proactive engagement, often extending beyond the hospital setting. Building relationships with faith leaders and community advocates was seen as critical for dismantling misconceptions and reinforcing the principle that families remain central to decision-making under soft opt-out legislation. Specialist Nurses also noted that equity in practice requires sensitivity to diverse cultural frameworks and communication styles. This includes adapting language, acknowledging spiritual beliefs, and creating space for dialogue rather than imposing a legal narrative. For some, this meant drawing on real-life stories that resonate within specific communities, helping to humanise the process and counteract fear or mistrust. Ultimately, these reflections show that achieving equity is not simply about applying policy uniformly, it demands cultural competence, relational trust, and sustained efforts to challenge myths that undermine confidence in the system.

4.7.7. The Pandemic's Shadow

Participants repeatedly reflected on how the timing of the deemed consent legislation coincided with the COVID-19 pandemic, shaping both public perception and clinical practice. Several interviewees felt the launch of the law 'snuck in under the radar,' overshadowed by dominant messaging around COVID safety and the operational realities of working in a pandemic environment.

> *'It was drowned out by COVID—people were focused on PPE, masks, and survival, not new legislation,'* (I17).

One participant explained, highlighting how the context muted awareness both inside and outside the hospital. Another respondent captured this sentiment vividly, using an analogy to describe the anticlimactic nature of the launch:

> *'…like you know them, party blowers that you go (party blower inflating) and then they go (party blower deflating).'* (I16)

The practical constraints of the pandemic, wearing face masks, maintaining physical distance, and relying heavily on telephone communication, added layers of complexity to consent conversations. These conditions disrupted the usual reliance on non-verbal cues and rapport-building, requiring Specialist Nurses to adapt their tone and approach to maintain trust in a more impersonal setting. Others described how this muted awareness influenced bedside interactions, shaping a softer tone and a more explanatory style. With families often unaware of the legislative change, Specialist Nurses found themselves myth-busting more frequently, offering additional reassurance, and exercising greater patience with uncertainty:

> *'We had to slow down, explain more, and really check understanding, people were anxious and distracted,'* (I20).

This period highlighted the fragility of public engagement during times of crisis. While the law introduced a new framework, its implementation was tempered by competing priorities and heightened emotional strain. For many Specialist Nurses, the pandemic required not only technical adjustments but also a renewed emphasis on empathy and adaptive communication strategies to sustain trust in an environment of unprecedented uncertainty.

4.7.8. Illustrating the Themes in Practice

To deepen and contextualise the thematic findings presented above, the following integrated accounts drawn directly from the semi-structured interviews, illustrate how participants described applying these approaches in real clinical discussions. As outlined in the methodology chapter (3.67) these narratives were generated through in-depth interviews with Specialist Nurses and Specialist Requesters, and they are woven into the findings here to show how the themes were enacted in everyday practice. A recurring strategy described by participants involved what several referred to as 'front-pocket legislation.' Rather than delaying statutory references until later in the discussion, some Specialist Nurses introduced relevant guidance earlier and in a gentler, more conversational way.

One Specialist Requester explained,

> *'it would suggest no objections.'* (I10).

A colleague reflected on the benefit of this shift in timing, noting that it helped,

> *'avoid the late coercive feel.'* (I17).

These accounts show that the law was never positioned as the basis on which consent depended; instead, its earlier, lighter introduction reduced the risk of appearing to invoke legislation suddenly or forcefully later in the interaction. Participants also emphasised the importance of providing clarity without overstating authority. Even when a family had already agreed to proceed, Specialist Nurses described briefly revisiting elements such as Section C of the consent form to maintain transparency and prevent misconceptions.

As one participant explained,

> *'I explain it briefly, so there's no myth of 'automatic' donation and the record is clear.'* (I18)

This practice highlighted a commitment to openness and ensured that deemed consent was not misinterpreted as automatic removal. Cultural preferences and relational trust were likewise central to many accounts. One participant described a sensitive discussion with a large Muslim family in which reassurance, rather than immediate consent, became the primary outcome,

> *'We addressed fears and set expectations; later, we followed up through mosque outreach.'* (I16).

This example illustrates how meaningful engagement may unfold over time and that trust-building often extends beyond a single encounter. Across these narratives, a shared message emerged: deemed consent enables a conversation; it does not replace one. The law provided the framework, but the timing, tone, and clarity of communication, and the practitioner's ability to reduce perceived threat and document discussions transparently, were described as decisive. Mastery of this approach was most evident among Specialist Nurses who engaged fully in the learning cycle of observing, practising, debriefing, and reflecting. These Specialist Nurses also played a key role in maintaining public and clinical understanding of the law, particularly considering the muted impact of the COVID-19 *Pass It On* campaign. Their experiences demonstrated that successful implementation of deemed consent relies not only on statutory change but on sustained professional skill, ethical sensitivity, and ongoing reflective practice.

4.7.9. What this Means in Practice

Participants' stories converge on a simple proposition: deemed consent enables a conversation; it does not replace one. Bringing the law in at the right moment, in the right way, using threat-reducing language, and documenting clearly were the practice that mattered most to the participants. Mastery was most evident in Specialist Nurses who completed the full learning cycle, observing, practising, debriefing, and reflecting, and who continued to sustain public and clinician understanding of the law, particularly following the muted COVID-19 *Pass It On* campaign.

4.7.10. Semi-structured Interview Summary

Across the interviews, participants spoke with a tone that was thoughtful, practical, and compassionate. They described the law as something that provides a supportive framework, rather than a driving force, with families and their values remaining at the heart of every decision. When timing, tone, and language respect that reality, conversations progress smoothly; when they do not, they stall. The real skill, participants suggested, lies in recognising that difference and documenting it clearly.

4.8. Whole Specialist Nurse Workforce Survey

To explore whether the patterns identified in the focal cohort were reflected more widely, a cross-regional workforce survey was undertaken with Specialist Nurses working under deemed consent legislation across England and Wales. As discussed in the methodology chapter (3.8), where the survey design, distribution strategy, and rationale are outlined in detail. The purpose of this quantitative component was to test the transferability of the qualitative themes and to examine whether similar practice norms, confidence levels, and conversational behaviours appeared across the wider workforce. The survey was issued on 4 January 2022, approximately eighteen months after the law came into effect, and distributed to 232 members of the Specialist Nurse workforce. A total of 115 Specialist Nurses responded, producing a 50% response rate. This compares favourably with recognised benchmarks in organisational research, where clinical workload pressures and survey fatigue often reduce participation (Fincham, 2008) and aligns with methodological guidance suggesting that response rates of 50–60% are typically considered acceptable to high for professional groups (Holtom et al, 2022). Industry sources similarly note that workplace surveys circulated without prior relational contact may return as little as 5–30% (SmartSurvey, 2022). Against this backdrop, the achieved response rate provides a robust dataset for triangulating the earlier observational and interview findings. The respondents, shown in Figure 4.7.0.1, comprised 70 Specialist Nurses in Organ Donation (60.9%), 43 Specialist Requesters (37.4%), and 2 individuals (1.7%) who did not specify their role. These data extend the qualitative insights by enabling cross-checking of practice norms, confidence levels, and language choices across a broader professional population.

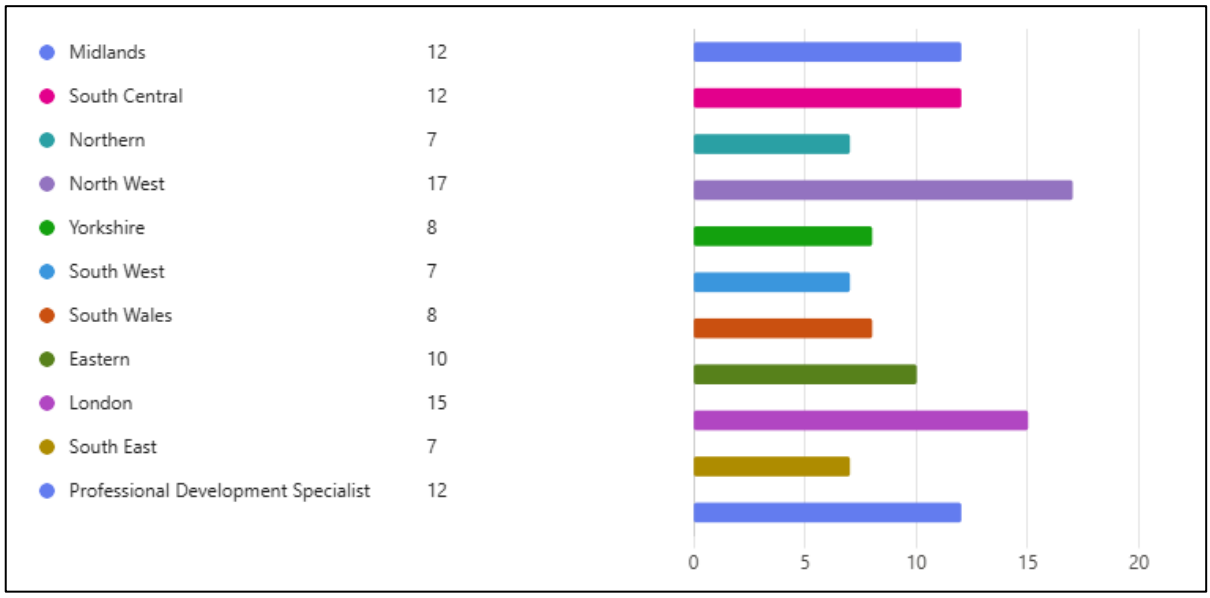

Figure 34 - Survey response rates from each of the ten organ donation service teams and the professional development team across England and Wales

The findings show that deemed consent is not usually placed at the forefront of approach conversations. Most respondents, 87 of 115 (75.7%), said that the legislation is not a prominent part of their discussion with families. Instead, Specialist Nurses tend to focus first on the patient's values and the benefits of organ donation. This is reflected in the fact that 102 respondents (88.7%) said they usually introduce the legislation after discussing donation, while only 10 (8.7%) lead with it, and 3 (2.6%) do not mention it at all. This pattern fits with the strong emphasis placed on confirming the patient's last known decision early in the conversation: 99 respondents (86.1%) reported doing so at the start, 15 (13.0%) later on, and only one person (0.9%) did not explore it. Taken together, these results point to a consistent preference for a patient-centred, relational approach in which the legislation is used to support, rather than direct, the conversation. Confidence in raising deemed consent was reported as high across the workforce. 110 out of 115 respondents (95.7%) felt at least somewhat confident in raising the legislation, with 46 respondents (40.0%) identifying themselves as *extremely* confident. Notably, a role-based distinction emerged: 24 out of 43 Specialist Requesters (55.8%) reported being extremely confident, compared with 21 out of 70 Specialist Nurses (30.0%), suggesting that SRs, who more frequently lead donation conversations, may experience greater familiarity or comfort with the legal framing. This distinction is reflected in conversational strategy: 8 Specialist Requesters (18.6%) reported leading with the legislation when clinically appropriate, compared with only 2 Specialist Nurses (2.9%).

Respondents used a range of terminology when talking to families about the legislative change. While some chose the term 'law' because it aligned with public messaging, others avoided it to prevent families feeling that they lacked choice. Survey data showed similar variation: 'legislation' was the most frequently used descriptor (48 respondents; 41.7%), followed by 'law' (26 respondents; 22.6%) and 'system for donation' (24 respondents; 20.9%), with 17 respondents (14.8%) using alternative phrasing. This diversity reflects Specialist Nurses' efforts to remain accurate yet approachable, selecting language that feels non-pressuring, accessible, and sensitive to families' emotional and informational needs.

Free-text responses further demonstrated how Specialist Nurses adapted their communication in real time, drawing on professional judgement to decide how and when to introduce the legislation in a way that best supported each family. Their ability to tailor explanations to individual situations, aligned with higher-order cognitive processes outlined in Bloom's taxonomy, enabled them to guide families through the deemed consent framework thoughtfully and person-centrically. Figure 35 illustrates this diversity of approach, highlighting the different ways Specialist Nurses integrated the legislation into family conversation. In summary, the survey data reinforces the broader findings generated through the qualitative components of the study. Specialist Nurses across England and Wales tend to ground organ donation conversations primarily in the patient's wishes and the potential therapeutic value of donation, drawing on the deemed consent legislation judiciously to clarify the consent pathway. Overall, the workforce appears to have internalised a shared model of practice, benefits first, patient decision next, legislation when helpful, that is both relationally attuned and procedurally aligned with the ethical intent

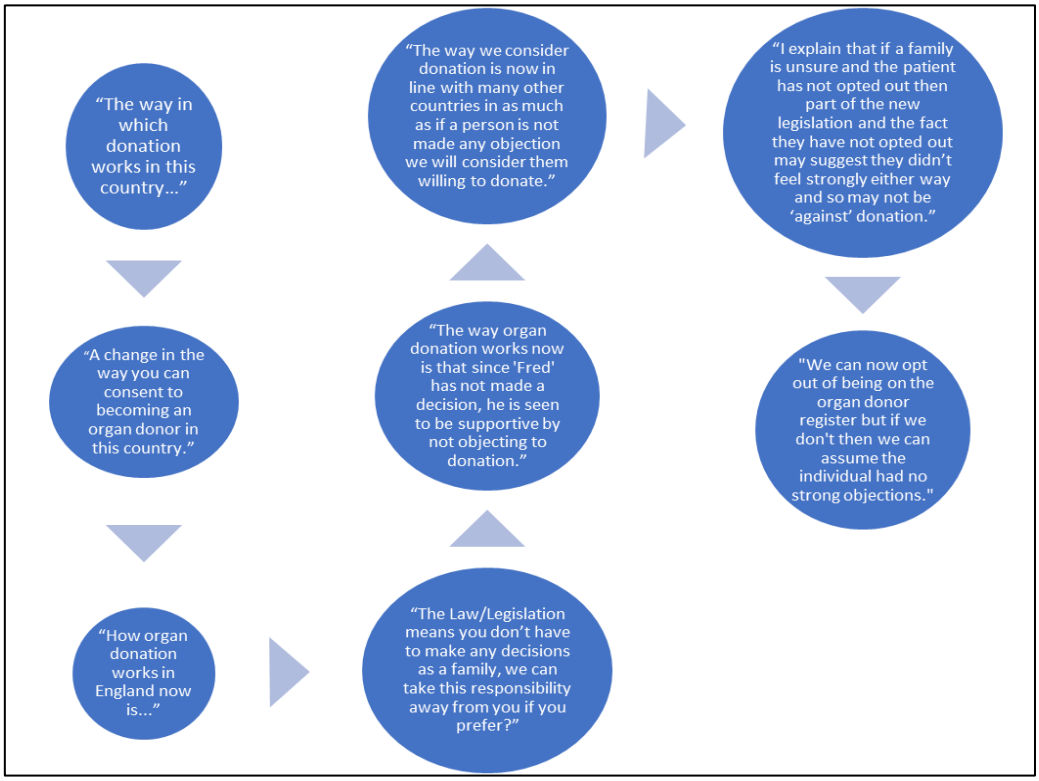

Figure 35 - Respondents' alternate ways of discussing the deemed legislation with family members

of the deemed consent framework.

4.8.1. Structuring the Deemed Approach

Responses showed wide variation in how Specialist Nurses structure a deemed consent approach. Some began by exploring the family's understanding of the situation before introducing the legislation, while others clarified the patient's views first and referred to the law only if needed. Many Specialist Nurses focused early on whether the patient had expressed any wishes about organ donation, and several noted that if families were already supportive, they tended not to mention deemed consent until completing the formal consent documentation.

Conversely, where families were unsure or unsupportive, Specialist Nurses were more likely to draw on the legislation to aid decision-making. Specialist Nurses in Wales frequently encountered families who were already aware of the law change and raised it themselves. Some respondents described keeping the legislation 'in their back pocket,' introducing it only when uncertainty remained. Exposure to Deemed Deliberate Practice also influenced practice, with some respondents reporting increased confidence in integrating references to Max & Kiera's Law into conversations. Most respondents (99; 86%) confirmed the patient's views at the start of the discussion, routinely using open questions to reduce the risk of families shaping their answers to fit their own preferences. Several described asking broad end-of-life questions (e.g., 'Has your loved one ever expressed any decisions we should be aware of?') to give families space to disclose verbally expressed objections. Some deliberately avoided direct questions about organ donation for fear of inadvertently prompting biased responses. Overall, the findings indicate that Specialist Nurses value flexibility, sensitivity, and early clarification of the patient's wishes, adapting the conversation to the family's emotional state and the information available.

4.8.2. Information Digital Link (IDL)

Only a small number of respondents (n = 3) reported using the Information Digital Link (IDL), a short explanatory video about the benefits of organ donation. For these Specialist Nurses, the IDL provided families with time to reflect on donation and consider how it aligned with the patient's character and values. One respondent described using the legislation to explore a patient's potential willingness rather than seeking an immediate yes or no. Another recommended developing an IDL specifically tailored for deemed consent discussions.

4.8.3. Lack of Exposure

Several Specialist Nurses highlighted limited exposure to deemed approaches, often due to the Specialist Requester role taking the lead on most donation conversations. Some felt this reduced their confidence and risked creating skills gaps within the Specialist Nurse workforce. Newly appointed Specialist Nurses particularly noted the challenge of finding the right language and expressed a need for more practical examples. Despite this, some respondents took proactive steps, such as shadowing Specialist Requesters, to maintain competence and confidence.

4.8.4. Change in Practice

Views on whether deemed consent had changed practice were mixed. Some respondents felt it had become 'business as usual,' naturally integrated into conversations. Others described it as an additional tool available when needed. A few noted minimal changes to their approach, despite the legislative shift. One Specialist Nurse recalled initial scepticism among colleagues during the roll-out yet personally felt that the legislation meaningfully shaped how families are now approached.

4.8.5. Necessity of Mentioning the Legislation

There were diverse views on when, or whether, the legislation should be raised. Some Specialist Nurses felt it was not always necessary, preferring instead to focus on supporting families and preserving a sense of dignity for the patient. Many avoided mentioning deemed consent when families already supported donation, to ensure families felt ownership of the decision. Others introduced the legislation only when families were uncertain, divided, or did not know the patient's wishes. A number of respondents emphasised that families may not be emotionally ready to process legal information and that raising it prematurely could feel coercive. Conversely, legislation was described as helpful in clarifying the patient's lack of objection and reducing perceived pressure or burden on families. Some respondents highlighted its value in navigating disagreements within families. Specialist Nurses also noted challenges when consultants raised donation without the Specialist Nurse present, risking conversations that did not incorporate the nuance of deemed consent. A small number reported that, in rare cases, mention of the legislation caused families to feel pressured, requiring sensitive follow-up. Overall, respondents highlighted the importance of professional judgement, ensuring legislation is used only when it meaningfully supports the family and aligns with the patient's values.

4.8.6. Structure of Deemed Consent Conversations

The structure of deemed consent conversations varied depending on the needs and expectations of each family. Some Specialist Nurses avoided rigid scripts, adjusting the conversation flow in response to family cues. While a small number introduced the legislation early, most respondents (102; 89%) prioritised discussing the benefits of organ donation first and brought in the legislation later if appropriate. Many described using it only as needed to help families weigh up the patient's likely wishes. Earlier awareness of the law among families, particularly since the introduction of deemed consent, was frequently noted. Where families were unaware, Specialist Nurses emphasised reassuring them that the legislation exists to support rather than pressure them and reiterated their commitment to avoiding coercive language.

4.8.7. Human Touch

Some respondents highlighted the importance of simplicity and human connection, often referring to 'Max and Keira's Law' to frame the legislation in accessible terms. They stressed the need to focus on the patient as a person before introducing legal aspects, ensuring that the meaning and value of organ donation are not overshadowed by procedural or legal details. These reflections align with broader palliative care principles emphasising relational influence and emotional sensitivity.

4.8.8. Debriefing and Shared Practice

Debriefing and shared practice were commonly identified as valuable, particularly the Deemed Deliberate Practice sessions. Respondents noted that these sessions supported confidence, encouraged reflective learning, and assisted in navigating complex or unsupported deemed cases. Shared practice was viewed as essential for professional growth and maintaining high-quality communication within donation conversations.

4.8.9. Public Awareness

Regarding public awareness of the opt-out system, respondents reported that although many families had heard about the law, their understanding was often partial or inaccurate. A recurring misconception was that organ donation was automatic unless a person had explicitly opted out, leading some patients, families, and even healthcare professionals to believe that donation was mandatory. This misunderstanding frequently surfaced in practice, with families expressing a verbal 'known wish not to donate,' despite the absence of a formally recorded objection.

NHS Blood and Transplant audit data for the 13-month period between April 2023 and May 2024 show a similar pattern. Of 1,375 eligible donors, only 73 individuals (5%) had formally opted out, while 293 cases (21%) involved families reporting a verbal opt-out. This discrepancy suggests a notable gap between legally recorded decisions and family declarations. A further 173 families (13%) were unsure of their loved one's wishes, highlighting circumstances in which the legislative framework may appropriately be used to guide decision-making based on the principle that, in the absence of an opt-out, an individual is presumed willing to donate.

Reasons why family did not give consent/authorisation or support a decision to donate

NHS Blood and Transplant

This report includes all cases where a donation decision conversation occurred.

*PDA criteria: Deaths in critical or emergency care in patients ≤ 80 years (before their 81st birthday).

Reasons why the family did not give consent/ authorisation for organ donation	Eligible donors after brain death	Eligible donors after circulatory death	Total eligible donors	Total inclusive of donors that are not eligible
10 Patient had registered a decision to Opt Out	23	50	73	75
20 Patient had previously expressed a wish not to donate	109	184	293	305
30 Family were not sure whether the patient would have agreed to donation	50	123	173	178
40 Family did not believe in donation	6	13	19	19
50 Family felt it was against their religious/cultural beliefs	56	34	90	91
60 Family divided over the decision	12	28	40	43
70 Family felt patient had suffered enough	27	84	111	112
80 Family did not want surgery to the body	47	69	116	122
90 Family wanted to stay with the patient after death	6	17	23	24
100 Family had difficulty understanding/accepting neurological testing	3	0	3	3
110 Family felt the length of time for the donation process was too long	30	186	216	225
140 Family concerned other people may disapprove/be offended	3	4	7	7
150 Family felt that the body should be buried whole (unrelated to religious/cultural reasons)	16	19	35	37
160 Family believe patient's treatment may have been limited to facilitate organ donation	0	1	1	1
170 Family concerned that organs may not be transplantable	3	9	12	12
200 Strong refusal - probing not appropriate	27	43	70	72
210 Other	27	66	93	108
NULL Not Reported	0	0	0	2
Total	**445**	**930**	**1375**	**1436**

Figure 36 - Why families do not support donation - potential donor audit data (1st April 2023 - end of May 2024).

Respondents also noted that more families are now initiating conversations about organ donation themselves, sometimes even before the Specialist Nurse raises the topic, reflecting increased general awareness following the introduction of the law and its associated publicity campaigns.

However, the persistence of misconceptions indicates that public understanding remains uneven, and that verbal opt-outs may at times reflect family preferences rather than the donor's actual view.

4.8.10. Advice or Guidance on the Deemed Consent Approach

When seeking guidance, most respondents (34; 30%) turned to colleagues as their primary source of support. Additional advice was drawn from PDS and Specialist Requester colleagues, valued for their skill in sensitive communication. Shared practice forums and tools such as the Post Approach Analysis Tool (PAAT), along with resources on SharePoint (e.g., HTA Code of Practice F), also played a key role in supporting practice.

Figure 37 - Survey Responses who the Specialist Nurses access for support and advice about the deemed consent approach.

4.8.11. Educational Support

When asked what additional support they would find helpful, respondents overwhelmingly requested more practical opportunities, including simulation, debriefing, and shared practice sessions.

Specialist Nurses valued these formats for enabling deeper reflection and skill development within real-world contexts. Some noted the increasing complexity of donation conversations, particularly where multiple organ, tissue, and research requests intersect, and expressed concern that this could shift focus away from families' needs. Respondents recommended greater distribution of approach opportunities across the workforce to prevent skills erosion, and several suggested additional guidance on language and phrasing for deemed consent discussions. Some felt that referencing 'Max and Keira's Law' could encourage earlier or clearer explanation of the legislation. Others requested support in managing conversations with clinicians less familiar with deemed consent. While some Specialist Nurses felt current training was sufficient, others expressed a need for refreshed or extended learning opportunities.

4.9. Synthesis and Conclusion of Findings Chapter

Across the participant observations, semi-structured interviews, debriefs, and the workforce survey, a consistent and realistic picture emerges of how deemed consent is put into practice and shaped by the judgement and experience of those delivering it in the real-world clinical setting.

The participant observations the richest dataset in this study show the profound *professional wisdom* and *situational judgement* (phronesis) that Specialist Nurses and Specialist Requesters draw upon when holding emotionally charged, ethically complex donation conversations. These observations reveal what is often missing from policy documents: the advanced communication skills and emotional intelligence required to judge the right timing, tone, and pace of the conversation, alongside sensitivity to family cues, awareness of the emotional dynamics at play, and the ethical care needed to ensure families feel supported rather than overwhelmed or coerced. The semi-structured interviews reinforce and extend these practice-based insights, revealing how Specialist Nurses consciously adapt their language, sequence information, and shape their conversational strategies in response to family dynamics, cultural context, emotional cues, and the shifting complexities of DCD and DBD pathways. Debriefs add a distinctive layer by revealing the *reasoning-in-action* behind bedside decisions and turning tacit know-how into shared practice. They surface the advanced communication of ethical communication, protective pauses, slowing the flow after rushed handovers, and using open prompts to evidence a genuine, informed decision, while showing how wording (e.g., 'consider willing' vs. 'assume') and judicious law placement normalise the pathway without pressure. Conducting debriefs immediately after the clinical encounter provides a psychologically safe space to clarify *what happened*, *why it mattered*, and *what should happen next*, effectively applying Rolfe's 'What? So what? Now what?' reflective cycle in routine practice and aligning with NMC expectations for reflective learning and revalidation (Rolfe, Freshwater and Jasper, 2001; NMC, 2019).

In this study, near real-time reflection generated concrete 'what could be done differently' for subsequent cases, such as earlier but non-coercive law placement, threat-reducing wording (e.g., *consider willing*), clearer sequencing, explicit phone timeframes with an IDL link, and pre-briefing key details, turning tacit judgement into teachable practice. Debriefs also highlighted contextual factors often absent from policy documents, including cultural and faith considerations, interprofessional dynamics, telephone-specific constraints, decision-classification nuances, whole-family end-of-life needs, and the emotional labour required of Specialist Nurses. Together, these insights supported subtle but important refinements in language, sequencing, and remote-case approaches, while providing targeted learning aims for future family conversations (Rolfe, Freshwater and Jasper, 2001; NMC, 2019). Finally, the whole-workforce survey shows that these patterns extend beyond the study cohort. Across England and Wales, Specialist Nurses consistently describe using the legislation as a supportive guide rather than a directive force, keeping the focus on patient values, human connection, and the overall purpose of helping others. Collectively, these combined data sources show that successful implementation of deemed consent depends far more on *professional judgement, emotional intelligence, and reflective practice* than on legislation alone. They highlight how Specialist Nurses blend structured training with embodied phronesis to navigate the fine balance between clarity and compassion, legal accuracy and psychological safety, policy intent and human need.

This synthesis provides the foundation for the discussion chapter 5, where I examine how these findings align with the existing literature, build on current understandings, and, in some areas, offer alternative perspectives on soft opt-out systems, ethical communication, and the enactment of legislation in end-of-life care. The discussion will consider where the evidence reinforces established knowledge, where it contributes new insights that move the field forward, and where it challenges or complicates prevailing assumptions.

Chapter 5. Discussion: Interpreting Policy, Practice, and Professional Judgement Under Deemed Consent

This chapter interprets the study's findings in relation to the Organ Donation (Deemed Consent) Act 2019 and the Opt-Out Education Programme (OOEP), connecting the intentions behind the legislation with the realities observed in clinical practice. Building on the methodological foundations outlined in chapter 3 where the design and rationale of the training evaluations, ICU observations, debriefs, interviews, and workforce survey were described, the discussion integrates these datasets to address all four research questions. The chapter is organised thematically to reflect how the evidence converges across methods.

The opening section (5.1) examines the system-level purpose of deemed consent and evaluates the OOEP's design and implementation, directly addressing Research Question 1. Here, the analysis shows that while the OOEP was thoughtfully developed and delivered to a high standard, success in classroom environments did not always translate into effective practice at the bedside. Section 5.2 explores how these trained behaviours were enacted in donation conversations, drawing on observational, debrief and interview evidence to address Research Question 2 and extend Research Question 3. This section identifies a clear theory–practice gap, particularly in emotionally complex or fast-paced situations, and highlights the significance of timing, sequencing, and trust when supporting families under a soft opt-out system. Section 5.3 focuses on the exercise of professional judgement in conditions of uncertainty. It demonstrates that while legislation assisted with some hesitant families, it carried less influence where strong cultural, religious, or emotional concerns were present. In line with HTA Code of Practice F, Specialist Nurses found that sensitively exploring the donor's last known decision was often more impactful than referencing the law. This section shows how *phronesis*, practical wisdom, underpins skilled, context-responsive application of deemed consent in practice. Section 5.4 addresses Research Question 4 by setting out practical implications for strengthening training and professional development. Recommendations include the use of more complex simulation, structured SEDA-based scenarios, enhanced debriefing, expanded cultural and faith-based learning, emotional-cue coaching, and opportunities for shared practice. A new **Phronesis-Based Assessment Framework, Grounded in Bloom's Taxonomy** (Fig.41), is introduced to support measurable skill development in deemed consent approaches and to make expert judgement more visible and teachable. Collectively, the chapter argues that the success of England's soft opt-out system rests not on legislation alone but on high-quality communication, reflective practice, and the *phronetic* judgement of Specialist Nurses and Specialist Requesters. It explains why early outcomes have not met expectations, identifies where the OOEP is functioning well, and proposes clear, evidence-based recommendations for strengthening training, policy, and everyday practice.

The discussion now turns to Section 5.1, beginning with an examination of why organ supply remains limited, an essential context for understanding the policy drivers behind deemed consent and the rationale for targeted education.

5.1. Interpreting the Findings in Context

5.1.1. Why Organs are Still in Short Supply

The persistent shortage of transplantable organs is best understood as the cumulative outcome of clinical scarcity, organisational capacity constraints, legal ethical framing, and the emotionally sensitive dynamics of end-of-life decision making. As set out in Chapter 2.2, Reasons for the Organ Shortage, donation-compatible deaths are both rare and concentrated within critical care settings requiring ventilatory support. When the window for potential donation is so narrow, even small process failures, such as late referrals, delays in coordination, or poorly timed or unclear conversations, can quickly translate into missed opportunities and extended waiting times for patients. International experience reinforces this point. Spain, for example, did not see an increase in deceased donation rates following the introduction of opt-out legislation alone. Sustainable improvements only emerged once substantial operational infrastructure was introduced, including a national transplant network, early identification of potential donors, and the deployment of specially trained transplant coordinators to support families at the bedside (see discussion in Chapter 2.54, at p.25). Likewise, in the UK, the establishment of the Potential Donor Audit created a reliable, systematic mechanism for identifying missed donation opportunities and driving quality improvement through data-led performance monitoring, making donation processes more consistent across hospitals (Chapter 3.2.2, pp.51). Together, these examples demonstrate that positive and sustainable gains depend far more on early identification, reliable potential donor audit, and professionalised coordination than on the legislation change alone.

At the bedside, families make decisions under conditions of acute shock and grief, often while processing either neurological death or impending circulatory death following withdrawal of life-sustaining treatment (WLST). These moments are further shaped by religious and cultural beliefs (Chapter 2.2.2, p.16), concerns about body integrity and fears of bodily mutilation (Chapter 2.2.6, p20), and varying levels of trust in the healthcare system, all of which may outweigh previously expressed support for donation. As detailed in Chapter 2.2.3, p.17), these pressures frequently push families toward caution, especially when they feel unprepared, overwhelmed, or emotionally destabilised. Consistent with this, Chapter 4 shows that the moments immediately after bad news is communicated are critical. The importance of timing identified in this study aligns with established transplant literature, which emphasises that poorly timed requests can be perceived as pressurising and negatively impact consent (Siminoff et al, 2001).

Throughout my observations and post-conversation interviews, I found that poor sequencing in these early interactions can lock families into an initial ‘knee-jerk no’, a response that Specialist Nurses described as difficult to recover from once voiced (Chapter 4.6.5, p133). This reflects existing evidence that donation decisions are shaped less by factual information alone and more by the quality and style of communication (Simpkin et al, 2009; Hulme et al, 2016). The observations and interviews consistently indicate that a structured conversational sequence, beginning with a clear clinical explanation of neurological death or impending circulatory death after WLST, followed by presenting the tangible and relatable benefits of donation, and only then introducing the legislation where it constructively supports those in the ‘moveable middle’, before exploring any expressed known decision, helps reduce reflex and uninformed refusals and the likelihood of later regret (see the discussion at Chapter 5.13,p.164). Importantly, throughout my data gathering it became clear that legislation may set the legal framework, however, it cannot determine successful donation outcomes all on its own. While the soft opt-out policy adopted under the ODDC Act 2019 establishes a default expectation of donation and signals societal support for donation, its real-world impact still depends on the context and infrastructure in which it is embedded, as well as on the human interactions between Specialist Nurses and families during the donation conversation. As outlined in Chapter 2.25, (pp.19-20), the real effects of opt-out systems are mixed once registry design, the nature of family involvement, and system capacity are considered. Spain’s sustained improvements arose from hospital-level coordination, early donor identification, and professionalisation, rather than legislation in isolation; Wales similarly saw gradual shifts that aligned with broader system-wide change rather than the legislative switch alone.

The empirical findings presented in Chapter 4 further support and refine the literature by demonstrating how opt-out legislation functions in practice. Consistent with previous evidence, Specialist Nurses and Specialist Requesters described the law not as a directive or coercive tool, but as a form of conversational support that could facilitate discussion with families. This aligns with earlier research emphasising the importance of communication skill, relational practice, and family-centred approaches in shaping consent outcomes (McLaughlin et al, 2021). In particular, the findings reinforce the argument that legislation alone does not determine behaviour at the bedside; rather, its influence is mediated through professional judgement and interpersonal interaction. This strongly agrees with the broader literature reviewed in Chapter 2, which highlights that family involvement and clinical practice remain central, even within opt-out systems (McLaughlin et al, 2024). At the same time, this research extends existing knowledge by providing detailed empirical insight into how the law is operationalised in real-world conversations. Specialist Nurses/Requesters consistently reported that the way the legislation was introduced, particularly its timing and tone, was important. Early, sensitive framing of ‘no objection’ was perceived to support trust and facilitate decision-making among undecided families, whereas late or heavy-handed introduction risked being seen as coercive and damaging to rapport.

This extends the literature by moving beyond abstract discussions of consent systems to show how implementation is enacted at the micro-level of communication practice. It also deepens understanding of why legislative change alone produces variable outcomes, highlighting the relational and emotional dimensions that shape how policy is received in practice. Furthermore, the research adds to and partially challenges assumptions within the literature by illustrating how external contextual factors can disrupt the intended effects of opt-out systems. In England, the implementation of the Organ Donation (Deemed Consent) Act 2019 coincided with the COVID-19 pandemic, which significantly constrained key mechanisms through which the policy was expected to operate. Public awareness campaigns were suspended, communication with families was often conducted remotely, and non-verbal rapport was limited by the use of personal protective equipment. In addition, redeploying Specialist Nurses and members of the Legislation Change Team, who were responsible for delivering the training programme, back to Intensive Care Units to support colleagues limited opportunities for experiential learning and reflective practice. These findings extend previous studies by showing how implementation conditions can undermine the embedding of opt-out systems as a social norm, and by highlighting the dependency of legislative impact on stable organisational and social environments.

These conditions made it harder for the new default to embed as a social norm and further highlight the language choices and value of introducing the law early and clearly rather than as a late attempt to pressure families (see findings in 4.6.1, p.132). In Chapter 2, we were already introduced to the influence of **'**hot–cold' empathy gaps, in which the intensity of immediate emotional distress after bad news leads people to respond more defensively than they would in calmer circumstances. This dynamic was outlined in Chapter 2.9, p.34 above), where we saw that immediate emotional needs can override prior intentions or known preferences, highlighting the importance of clarity, sequencing, timing, and skilled communication. This supports the concept of the 'hot–cold empathy gap', where acute emotional distress can impair decision-making and increase defensive responses (Loewenstein, 1996). The findings of this research also reinforce a key argument within the literature that the effectiveness of opt-out systems cannot be understood in isolation from the wider organisational and operational context in which they are implemented. As outlined in Chapter 2, the impact of deemed consent legislation is shaped by factors such as registry design, family involvement, and overall system capacity (McLaughlin et al., 2024). This reflects evidence from the Spanish model, where sustained improvements in donation rates are attributed not to presumed consent legislation alone, but to organisational features including hospital-based coordination, early donor identification, and the professionalisation of specialist roles (Streit et al, 2023). My study supports this interpretation, demonstrating that legislation functions primarily as a supportive framework rather than a direct mechanism for increasing donation. Similarly, experiences in Wales and England indicate that any changes observed following opt-out implementation are gradual and linked to wider system developments rather than legislative change alone (McLaughlin et al, 2024).

In this respect, the research agrees strongly with the Spanish literature in emphasising the primacy of system organisation over legal reform. The findings also corroborate a consistent theme across the literature regarding the central role of families in decision-making. Despite the presence of presumed or deemed consent frameworks, families continue to exert a decisive influence over whether donation proceeds in practice. Evidence from Neades (2009) demonstrates that, even in countries operating under presumed consent, healthcare professionals routinely involve families and often defer to their wishes, highlighting a clear dissonance between legislation and its application in practice. This research reinforces that finding, showing that family agreement remains a critical determinant of outcomes at the bedside. In addition, the study aligns with process evaluation research demonstrating that consent outcomes are heavily dependent on the communication skills, experience, and relational practice of healthcare professionals (McLaughlin et al., 2020). Together, these findings confirm that opt-out systems remain, in practice, family-mediated rather than purely legally determined.

Importantly, this research extends the existing evidence by providing deeper insight into how these interactions are enacted in real time. The findings resonate strongly with Avilés' (2024) concept of 'reading the family,' which describes the skilled and relational process through which practitioners assess, interpret, and respond to families' emotional states during donation conversations. My study builds on this by demonstrating how Specialist Nurses/Requesters adapt the use of legislation within this relational process. Specifically, the law is not used as a fixed rule but is interpreted and applied flexibly, depending on the emotional readiness of the family. Early, sensitive framing of the law as 'no objection' or 'considered willing' was found to support trust and decision-making, whereas poorly timed or overly assertive use risked being perceived as coercive. In doing so, the research extends Avilés' work by showing how legal frameworks are actively mediated through emotional and relational practice of professional wisdom (*phronesis)*, rather than simply applied.

Furthermore, the study contributes to the literature by highlighting the gap between policy design and clinical reality. As identified by Neades (2009), healthcare professionals often do not apply the full extent of presumed consent legislation, instead using it as a guide while prioritising ethical and relational considerations. These findings confirm and add to this idea by demonstrating how it plays out in real-world practice, especially in the UK context. The findings therefore challenge policy assumptions that legislative change alone can drive behavioural change, demonstrating instead that its impact is dependent on how it is interpreted, communicated, and experienced in practice. Overall, this research both corroborates and extends existing evidence by demonstrating that the effectiveness of opt-out systems is highly context-dependent and mediated through clinical and relational practice. While closely aligned with the Spanish model and wider European evidence in emphasising the importance of organisational infrastructure and family involvement, it advances the literature by providing detailed empirical insight into how legislation is operationalised within emotionally complex, real-world encounters.

The findings therefore reinforce the conclusion that sustainable improvements in organ donation require coordinated, system-wide approaches that prioritise organisational capacity, workforce capability, and skilled, family-centred communication, rather than reliance on legislative reform alone. These themes are reiterated in the conclusions from the literature review, where it is emphasised that opt-out systems function effectively only when supported by training, awareness, infrastructure, and consistent professional practice (see Chapter 2.15, p.46). The Opt-Out Education Programme (OOEP) was designed to mirror these system features, integrating legislative understanding with simulation, debriefing, and deliberate practice. Although evaluation data confirmed the programme's strengths, Chapter 4 shows that meaningful impact depends on how Specialist Nurses behave and adapt in practice. Skills deepen through repetition, psychologically safe debriefs, reliable rota structures, and stable leadership that reinforces good habits. These findings emerge in the evaluation of Module 2 - Conversational Practice, which highlights how structured rehearsal and deliberate practice strengthens confidence (Chapter 4.7.4, p.142); in From Modules to Mastery, which demonstrates that refinement occurs through exposure and reflective consolidation rather than from training alone, and in Lack of Exposure, where limited opportunities to practise deemed-consent conversations are shown to constrain confidence, consistency, and legislative fluency (Chapter 4.8.3, p. 151).

Overall, these findings provide a coherent explanation for persistent donation shortfalls. Organs remain scarce because donation opportunities occur infrequently, families must make decisions during extreme emotional and cognitive strain, and organisational systems vary in their ability to translate legislation into trusted, well-sequenced practice in the clinical setting. Sustainable progress therefore requires coordinated movement across legal, clinical, infrastructural, and societal domains. This encompasses early identification and timely referral; multidisciplinary planning between the Specialist Nurse/Requester, the Consultant or CLOD, and the bedside nurse; conversational sequencing that begins with clear clinical explanation and the potential benefits of donation before gently introducing the legislative context; and the consistent use of soft, non-legalistic language, such as referring to 'no objection' or interpreting 'willingness to donate' from the absence of an opt-out, rather than invoking 'the law,' in order to preserve family agency and minimise any sense of pressure. The emphasis on soft phrasing such as 'willingness' reflects wider evidence that public and family responses are highly sensitive to how opt-out systems are framed (Shepherd & O'Carroll, 2014). Concerns about appearing coercive reflect core ethical principles of voluntariness and respect for autonomy, which emphasise that decisions must be free from undue influence (Beauchamp & Childress, 2019). It also requires sustained, faith-sensitive public engagement and strengthened potential donor audit systems capable of recording not only family awareness and prior discussions but also the order in which information was presented and, importantly, how, when, and whether the legislation was introduced, because without this data the true impact of deemed consent cannot be meaningfully evaluated.

When aligned, these mechanisms address the real bottlenecks in the system and support the conversion of rare clinical opportunities into realised donations.

5.1.2. Linking Legislative Intent, Educational Design, and Real-World Practice

This section examines the system-level purpose of deemed consent and evaluates the design and implementation of the OOEP, directly addressing Research Question 1. The analysis shows that while the OOEP was thoughtfully designed and delivered to a high standard, strong performance in classroom environments did not always translate into effective practice in the clinical context. To orient the reader, the design of the programme, a detailed description of the tri modular curriculum is provided in Chapter 1.4 (p.8). The Methods Chapter (3.4: pp.53-62) goes on to provide the detailed description of the theory underpinning the tri-modular curriculum, followed by an examination of the evaluation measures. As previously established, the programme was constructed around Malcolm Knowles' adult learning principles and Bloom's Taxonomy. The pedagogical foundation of Bloom's six-level cognitive hierarchy, and its role in structuring the incremental design of the OOEP, is elaborated in Chapter 3, Section 3.4.1 Bloom's Taxonomy (pp. 54–55) is presented alongside Knowles' theory of adult learning, which emphasises self-direction, experiential relevance, and readiness to learn. Together, these frameworks are identified as core principles underpinning the tri-modular structure and are outlined in the opening methodological overview (p.52). Each module was therefore designed to build progressively from legislative theory to structured rehearsal of deemed-consent conversations with professional actors, and finally to integrative consolidation supported by facilitated debriefs and deliberate practice sessions.

In addition to these educational foundations, the OOEP was explicitly grounded in the COM-B behavioural change model, as outlined in Chapter 3.4.2 (pp. 57–59).COM-B asserts that Capability, Opportunity, and Motivation must all be present for behavioural change to occur. Without all three domains, learning may fail to transfer into practice: Specialist Nurses may forget key elements (capability), feel unable to apply them within pressured clinical settings (opportunity), or lack motivation due to limited exposure to real deemed-approach situations. The programme's conceptual framework was further strengthened through integration of Will Thalheimer's Learning-Transfer Evaluation Model (LTEM) and its SEDA (Situational Evaluation, Decision, Action) component, both detailed in Chapter 3, LTEM and SEDA (pp. 58–60). LTEM emphasises performance-based outcomes rather than mere knowledge recall, aligning closely with Knowles' emphasis on relevance to practice and Bloom's progression from understanding to application. SEDA adds an additional evaluative lens focused on real-time decision-making under emotional and situational complexity, conditions that precisely characterise organ donation conversations under deemed consent. Taken together, these aligned models provided a coherent theoretical backbone for the OOEP, shaping its educational design, determining its behavioural objectives, and structuring its evaluation strategy.

As outlined in Chapter 3 (pp. 60–61), the integration of Bloom, COM-B, and LTEM reflects an intentional effort to build a training programme capable of supporting not only cognitive learning but the behavioural and ethical judgement required for Specialist Nurses to operationalise soft opt-out legislation in real-world clinical practice.

5.1.3. When Legislation Supports Donation Practice

Early on during the course of this research it became evident that changing the legal default to opt-out may create favourable conditions for organ donation but does not in itself deliver higher consent; outcomes depend on how teams apply the law at the bedside. In practice, Specialist Nurses and Requesters consistently used the legislation as conversational support rather than leverage, with the best results occurring when it was introduced early and gently for families who were still weighing their options. This pattern is evident in the detailed interview and thematic analysis of timing, tone, and the 'first no' (Chapter 4.7.2: p.141).

Across observed cases, the most effective sequence was:

1. Clear clinical explanation of death, through neurological death or anticipated circulatory death following WLST;
2. Tangible and relatable benefits such as legacy, comfort, and meaning-making;
3. Allowing the last known decision to surface naturally within the discussion.

This sequencing, as illustrated in Figure 35 below, reflects my recommendations for maintaining agility and adaptability to individual family needs. It emphasises the importance of gauging the family, picking up on cues and responding appropriately, while feeling confident in addressing initial concerns and gently moving beyond them to provide clear information. This approach aims to help avoid an immediate, instinctive refusal. Rather than serving as a script, it is intended as an evidence-based guide to support a compassionate, positive, and appropriately presumptive approach to organ donation.

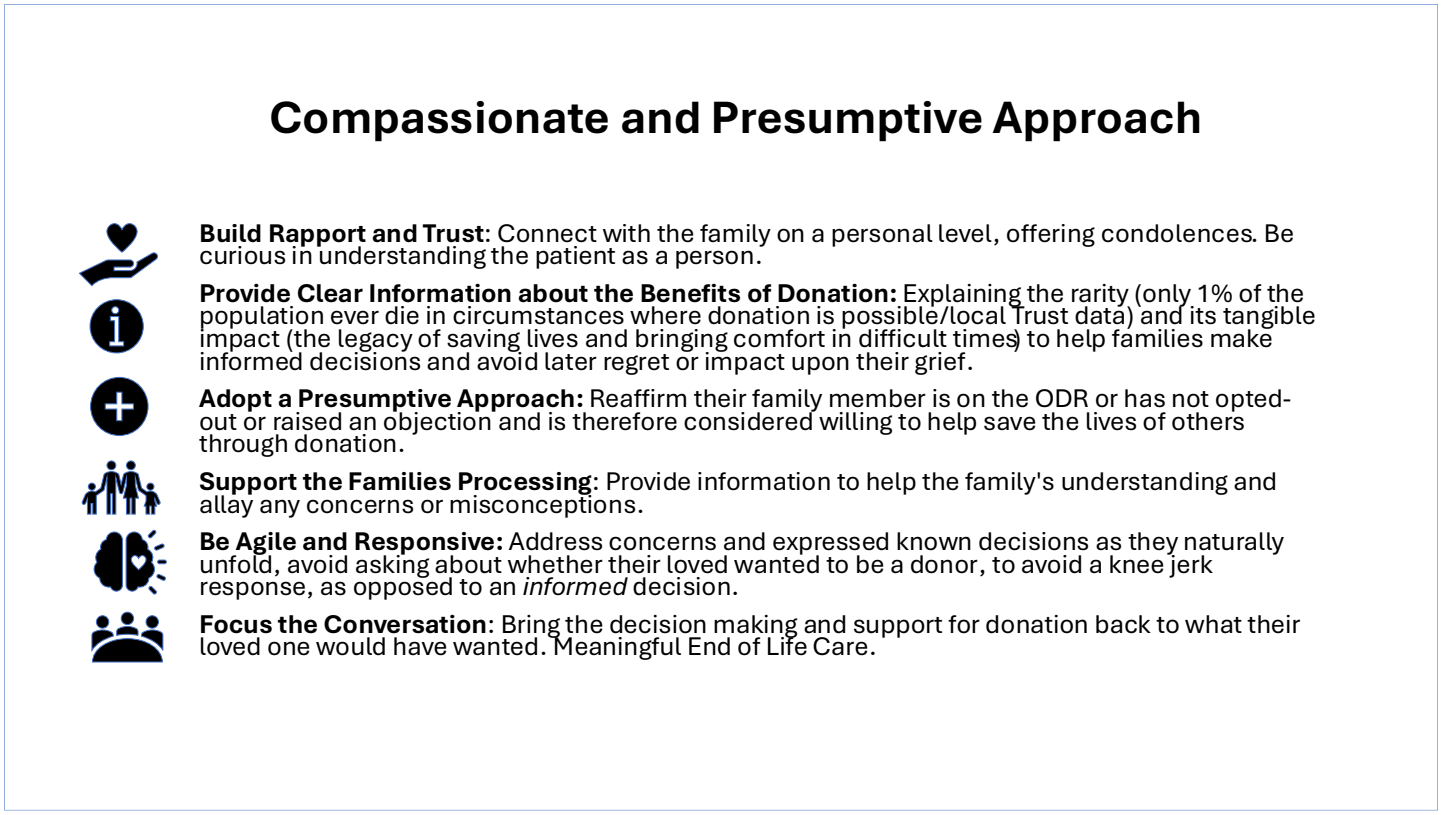

Figure 38 - Compassionate, positive and presumptive approach for organ donation sequence

The analysis also challenges more general assumptions within the literature by demonstrating that the influence of legislation is not applied evenly across all families. While opt-out systems are often linked to increased donation activity, earlier work has not fully accounted for the strength of pre-existing beliefs, such as concerns around bodily integrity or deeply held religious values, traditions, and beliefs (Neades, 2009). In these contexts, Specialist Nurses may make a conscious decision not to introduce the legislation, recognising that doing so could erode trust or be experienced as coercive. This highlights an important ethical boundary, effective practice involves not only knowing when to apply legislation, but also when it is more appropriate to hold back. Figure 39 illustrates this ethical positioning, showing how legislation can be used carefully to support decision-making in families who remain uncertain, while *phronesis* ensures it is not introduced in ways that might compromise trust or the integrity of the conversation. Consistent with prior evidence, the results support the argument that consent outcomes are shaped less by legislation itself and more by the interaction between families and skilled professionals (McLaughlin et al., 2020; Streit et al., 2023). In line with Neades (2009), the study confirms that legal frameworks are rarely applied rigidly, with healthcare professionals instead prioritising relational and ethical considerations when engaging with families.

However, this research extends the literature by more explicitly conceptualising how this mediation occurs, particularly through the identification of the 'moveable middle', families who are undecided and therefore most open to influence. While existing studies acknowledge variability in family responses, they do not clearly distinguish this group or examine how it can be ethically supported in practice.

Furthermore, the study advances understanding by introducing the role of phronesis as a mechanism through which practitioners navigate these complex interactions. Unlike previous research, which tends to focus broadly on communication skills or training (McLaughlin et al., 2020), this study demonstrates how experienced Specialist Requesters draw on practical wisdom to judge when and how legislation can be introduced in a way that supports, rather than pressures, decision-making. This finding builds on Avilés' (2024) concept of 'reading the family' by showing not only how Specialist Nurses assess emotional readiness, but also how they integrate legal knowledge into that relational judgement. In doing so, the research provides a more detailed account of how policy is enacted at the micro level, highlighting that the effectiveness of deemed consent is contingent on its sensitive and context-specific use.

In addition, this research refines existing assumptions within the literature by demonstrating that the influence of legislation is not uniform across all families. While prior studies suggest that opt-out systems may support donation behaviour, they do not fully account for the ways in which strong pre-existing beliefs, such as concerns about bodily integrity or religious beliefs, shape responses (Neades, 2009). The present findings extend this by showing that, in such cases, Specialist Nurses deliberately refrain from applying the law, recognising that doing so may undermine trust or appear coercive. This highlights an important ethical boundary in practice, demonstrating that the successful application of opt-out policy relies not only on its presence, but on the Specialist Nurses ability to withhold it when appropriate. Overall, the diagram captures this ethical movement, how the legislation could gently support decision-making for the undecided, while *phronesis* ensured that it was not applied where it would compromise relational trust or the integrity of the conversation.

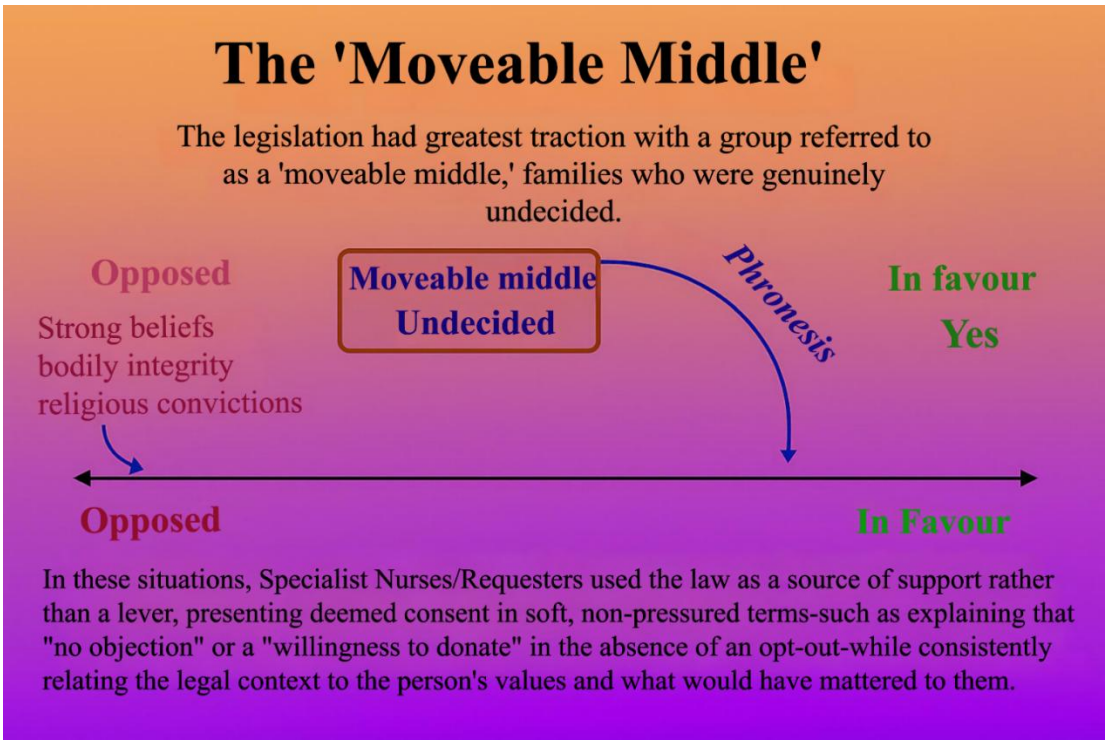

Figure 39 - The 'Moveable Middle': Illustration of where soft opt out legislation exerts most influence—among families who are genuinely undecided

5.1.4. When Legislation Does Not Deliver the Intended Outcomes

Legislation failed to deliver its intended effect where the family members lived realities of end-of-life decision-making were dominated by prognostic uncertainty, acute grief, and strong value commitments. This was most evident in Donation after Circulatory Death (DCD) pathways, where families were required to navigate both the decision to withdraw life-sustaining treatment (WLST) and the uncertainty of whether death would occur within the timeframe needed for organ viability. In the case of SR8 (4.5.5, pp. 117–118), relatives conveyed a clear sense of the complexity and uncertainty involved in the decision-making process. Despite a careful, values-led conversation, the cumulative demands of the pathway appeared to contribute to a shift towards tissue donation rather than organ donation.

By contrast, Donation after Brain Death (DBD) generally provided a clearer prognosis through neurological death testing, allowing the law to operate more reliably as a supportive enabler, as seen in the cases reported above at SR5 and SR10 (4.5.4;4.5.6, pp.115-118). Where deeply held beliefs were prominent, the relevance of legislation appeared irrelevant. In SR4 (an unsupported deemed case, 4.5.7, p. 120), refusal was shaped largely by concerns around bodily integrity and compounded by difficulty in accepting death. Similarly, in SN7, the decision-making process was influenced by religious meaning-making and a strong preference for the body to remain intact for burial. In both instances, Specialist Nurses demonstrated *phronetic* judgement, making a deliberate decision not to introduce the legislation in order to preserve trust and avoid causing additional distress.

Very importantly, my research finds that there was widespread confusion about the family's role in the soft opt-out system and that, very often, families were confused about exactly what was being asked of them. Some relatives recognised that no opt-out implies 'no objection,' but others, including actors in training, asked, 'Why are you asking me if the law presumes donation?' Inconsistent terminology used by clinicians and Specialist Nurses, shifting between the language of options, choices and decisions, sometimes intensified uncertainty about agency and responsibility. This cumulative framing risked positioning the family as active decision-makers, inadvertently reinstating the very burden the legislation was intended to reduce. Under the soft opt-out model, the absence of a recorded opt-out indicates a presumption of willingness to donate; however, inconsistent language could obscure this intent and place unnecessary decisional weight back onto families at a time of acute distress. Quantitative data indicates that four years after implementation, only 5% of eligible donors had formally recorded an opt-out (73 of 1,375). In contrast, 21% of family approaches resulted in a verbally expressed opt-out decision, and in 13% of cases families were unsure of the individual's wishes. Explicit opposition to organ donation was uncommon, accounting for just 1% of cases. Supported deemed cases remained finely balanced, resembling a *coin toss* in practice, with an overall deemed consent rate of 50% and declining (depicted in Figure 39 below).

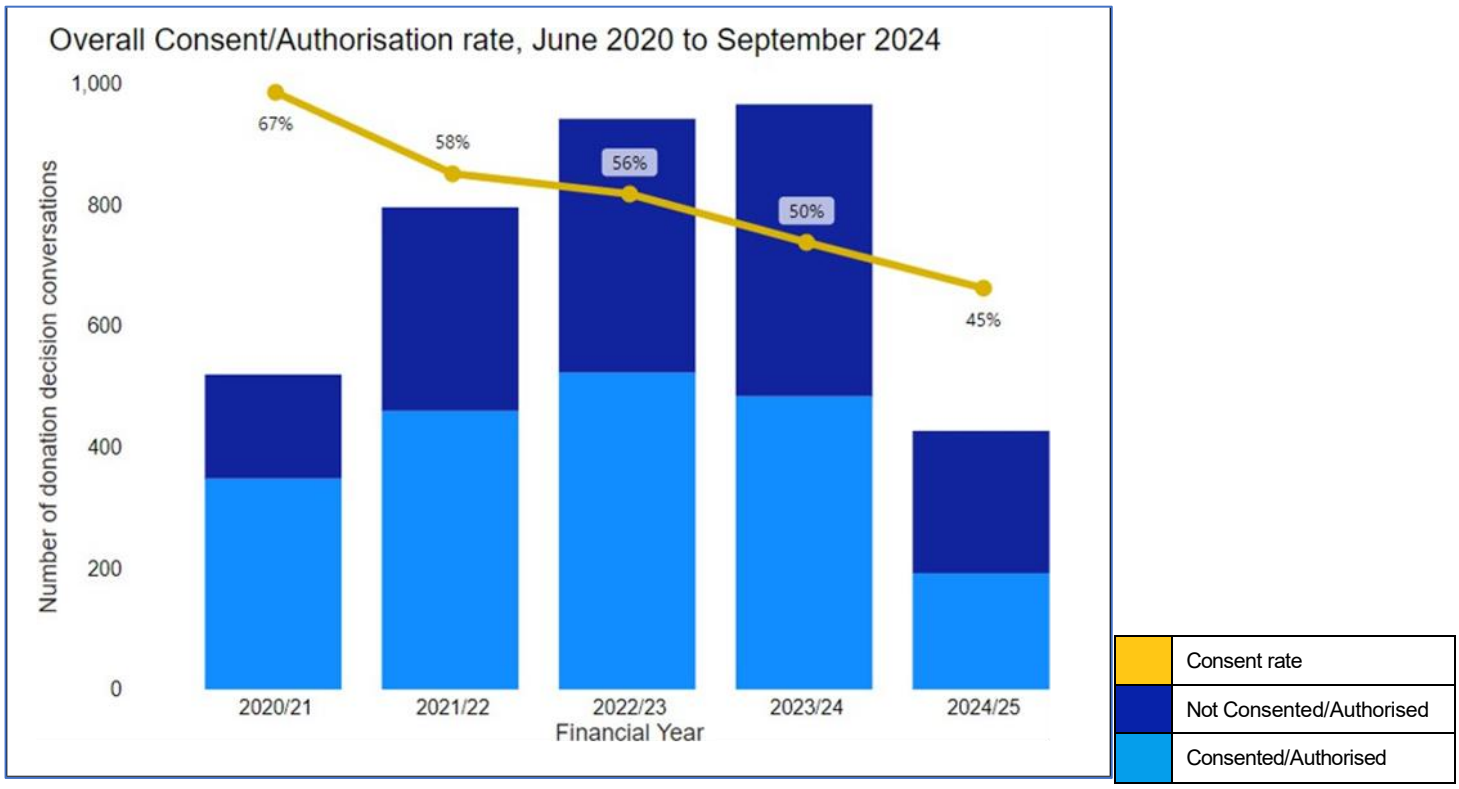

Figure 40 - Overall Consent/Authorisation rate, June 2020 to September 2024

Potential donor Audit categories, however, did not consistently record whether the legislation was mentioned, by whom, or on what basis refusal was made, limiting the system's ability to learn when the law helps and when it does not. Team coordination again emerged as an important factor. Where a deliberately planned triumvirate approach, characterised by alignment between the Consultant/Clinical Lead for Organ Donation, the Specialist Nurse/Requester, and the bedside nurse, was in place, a coherent trajectory was evident from the delivery of bad news through neurological death testing or WLST and into the donation discussion (e.g., SR10 4.5.6, pp.118-119). Effective planning enabled a seamless transition, with the 'baton of trust' passed from the Consultant to the Specialist Nurse/Requester, promoting collaboration and a shared sense of teamwork. In contrast, where alignment was disrupted, often through imprecise or clumsy language such as 'putting him through the mill' or 'preserving his dignity, the donation pathway was unintentionally closed. In these circumstances, Specialist Nurses/Requesters were required to reconstruct the donation conversation under significantly less favourable conditions, resulting in poorer outcomes. The study identifies several practical strategies, drawn from observation and debrief, that were used to mitigate these challenges. Overall, the findings suggest that outcomes were influenced less by legislation in isolation and more by how effectively teams planned, coordinated, and enacted conversations across the donation pathway. Where alignment, shared language, and an intentional handover of trust were established, discussions progressed smoothly; where coherence was lacking, opportunities narrowed and outcomes deteriorated.

Addressing these practical realities, the study identifies a set of operational levers aimed at strengthening consistency, capability, and coherence in practice. Central to this is a *phronesis*-based assessment framework, adapted from Bloom, which supports the standardisation of both competence and excellence. Routine guided debriefs convert 'what happened, so what, now what' reflections into tangible, documented improvements. Communication was further enhanced through 'benefits-first' sequencing and the early, though always gentle, introduction of the legislation, avoiding its use as a last-minute lever. Stronger ICU presence and clearer coordination and communication across the breaking of bad news, neurological/circulatory death pathway, and transition to the approach for donation phases also contributed to smoother conversations. Targeted tools, including DCD decision aids and the authentic offering of tissue donation when organ timelines felt burdensome, helped families understand complex choices. However, improvements in audit fidelity remain necessary to capture legislative awareness and how it is applied in practice. Sustaining capability requires regular OOEP refreshers, training in Deemed Modifiable Factors, balanced exposure, approach-skills logs linked to revalidation, and clearer public messaging that soft opt-out reframes rather than removes the family's role. Ultimately, legislation shapes the context in which conversations take place, it cannot however replace or override grief, beliefs, or ethical boundaries. Meaningful impact comes instead from good communication, teamwork, education, reliable data, and public awareness.

5.1.5. Practical Barriers to Putting Legislation into Practice

The findings highlight a tension within the Code that Specialist Nurses must navigate in practice. HTA guidance positions the individual's decision as primary: consent from an adult with capacity is legally sufficient to permit donation, though it does not have to be enacted, while any recorded refusal must be upheld. At the same time, Specialist Nurses are required in every case to establish whether a decision exists and, through discussion with the family, determine which decision was most recent prior to death (HTA Code of Practice F, paras. 104–107). This creates a practical and ethical ambiguity, as donation is legally enabled but not mandated, leaving Specialist Nurses to balance what is permissible in law with what is appropriate in the moment. In practice, these provisions both elevate the person's expressed wishes and create a procedural expectation to establish them early in the conversation. However, the observational and debrief data presented in Chapter 4 show that families are often in acute shock, grief, or struggling to accept death. When approached with an early, binary question about the patient's last known decision, they frequently offer an immediate, reflex response rooted more in distress than in a considered reflection of the patient's wishes (see Chapter 4.7.2, p. 138).

In the clinical setting, a form of reconciliation was evident across the supported cases, with Specialist Nurses separating legal compliance from conversational sequencing. While still establishing and recording the most recent decision, they first prioritised providing clinical clarity, whether neurological death or anticipated circulatory death following WLST, followed by introducing the tangible and relational benefits of donation, such as legacy, meaning, and helping others. The legal context was then introduced early but gently (for example, through language of 'no objection' or 'willingness'), allowing discussion of the patient's wishes to emerge more naturally. This approach, observed in cases such as SR5 and SR10 (Chapter 4.5), remained consistent with the intent of the HTA Code of Practice while reducing premature, emotionally driven refusal and enabling a more considered and defensible account of decision-making.

Although the deemed consent framework requires an 'information test', that enough evidence is available to allow a reasonable person to conclude whether the individual did or did not wish to be a donor, this relies on distinguishing between written evidence, corroborated verbal accounts, and the patient's own views. Chapter 4 demonstrates that applying this in real time is both ethically and clinically challenging. In cases involving expressed decisions and related debriefs (see Chapter 4.6), early attempts to establish this information frequently led to immediate refusals, often shaped by acute grief rather than considered reflection. Specialist Nurses described this point as inadvertently functioning as a 'get out clause', where the process, rather than protecting autonomy, shifted the burden of decision-making back onto families at a time of significant emotional and cognitive strain.

At this point, Specialist Nurses often reached a *phronetic* limit, recognising that pursuing or challenging an asserted 'decision' risked closing down the conversation altogether, as illustrated in refusals in cases such as SR4 and SN7 (Chapter 4.5.8, pp. 121–123). This helps explain why the law does not always translate effectively into practice; the expectation that a clear verbal decision can be established in the context of acute family trauma is, in many instances, unrealistic. For some families, donation was difficult to contemplate because their thinking quickly shifted to graphic and distressing images of bodily harm, which constrained their ability to consider donation in more reflective or altruistic terms. These vivid interpretations appeared to limit the cognitive space needed to reframe donation as a potentially meaningful or prosocial act. The findings also show that some families experienced a profound moral distance from the anonymous recipients awaiting transplantation. Their focus remained rooted in the immediate impact on their own family, rather than extending to future-oriented considerations about the lives that could be saved. Rodrigue et al, (2008) similarly describe how this present-focused state can lead to refusals that are later regretted, a potential pattern evident in cases within this study.

These findings both complement and challenge earlier evaluations by demonstrating that family responses to soft opt-out legislation are not formed in isolation. Decisions are shaped by shock, cultural and religious commitments, processes of meaning-making, and emotionally charged interpretations of the body. By capturing these dynamics in the moment, in the clinical setting, this study provides a more detailed, practice-based account of when soft opt-out legislation can support values-consistent agreement, and when emotional overwhelm, cultural imperatives, or embodied metaphors render the legislation less influential in shaping decision-making. Collectively, these findings complement but also challenge prior evaluations, demonstrating that families do not respond to soft opt-out legislation in a vacuum. Their decisions are filtered through shock, cultural and religious imperatives, narrative meaning-making, and emotionally provoking imagery. By capturing these dynamics in situ and in real time, this study provides detailed, practice-based evidence of when soft opt-out can support values-consistent agreement, and where cultural commitments, emotional overwhelm, or metaphorical interpretations of the body render the legislation effectively irrelevant.

5.2. Understanding Family Dynamics

Following on from the discussion above, family dynamics emerged as one of the most influential factors shaping donation outcomes under England's soft opt-out system. Although the ODDC Act 2019 sought to normalise donation as a societal default, evidence from observations, debriefs, interviews and the workforce survey indicates that families continued to play a decisive role in how donation decisions unfolded. Many encountered the legislation for the first time during sensitive end-of-life discussions, rather than through prior public understanding, placing its application within emotionally charged and unpredictable circumstances. As a result, clinical realities often diverged from the assumptions underpinning presumed consent.

Families were typically approached at moments of profound shock and grief, drawing heavily on cultural, spiritual and family members to support and make sense of events (Chapter 4.5.8, pp. 122–124). This study offers empirical insight into how these frameworks actively shaped whether deemed consent could operate as intended. For some families, particularly within Islamic contexts, deeply held beliefs about bodily integrity, the importance of burial of the body whole, and the cultural expectation for rapid burial rendered donation inconceivable. In one observed case, attention was fixed on securing timely release of the body, with formal documentation of death already underway, leaving no practical or emotional space in which donation could be meaningfully considered. Other families struggled to even contemplate donation, as their thinking quickly shifted towards graphic and distressing images of bodily harm. These kinds of metaphorical interpretations appeared to significantly narrow the cognitive and emotional space needed to consider donation as a prosocial act. The findings also suggest that some families experienced a marked sense of moral distance from potential recipients. In these situations, attention remained centred on the immediacy of their own loss and its personal meaning, making it difficult to engage with more future-oriented considerations about the impact of donation.

5.2.1. Observations: The Changing Role of Families in Opt-Out Systems

Throughout the course of my data-collection, Specialist Nurse participants in my study consistently described the introduction of deemed consent as having occurred quietly and largely unnoticed, overtaken by the scale and intensity of the COVID-19 pandemic. At a time when public attention was dominated by daily government briefings, infection rates and national restrictions, the change in organ donation law was perceived as slipping through with little public visibility. One interviewee reflected that the legislation would have benefited from a more prominent and visible launch, suggesting instead that its introduction felt muted and lacked impact. This perception points to a wider sense that a significant ethical and cultural shift was implemented without sufficient public engagement or dialogue. This limited public communication appeared to carry through into practice. Specialist Nurses described reduced confidence in drawing on the legislation, particularly as families were often encountering it for the first time within emotionally sensitive end-of-life conversations, rather than through prior awareness or understanding. In practice, many families continued to see themselves as the primary decision-makers, frequently questioning why their views were being sought if the law was *assumed* to support donation. This expectation gap required Specialist Nurses and Requesters to carefully translate the legal framework into relational language that preserved family agency, avoided perceptions of coercion and supported decisions families could live with (Chapter 4.7.1, p. 140).Across the observed cases, family positions tended to be polarised, with most families expressing either a firmly pro-donation stance or a strong opposition, and relatively few remaining spontaneously undecided (Chapter 4.5.6, pp.118-120).

What emerged was not a simple binary, but a pattern in which strong yes and strong no positions were largely immovable, while hesitancy, uncertainty or ambivalence represented a smaller but potentially *moveable* situation. Interviews repeatedly described the first verbal refusal as a reflexive, grief-driven response that, once articulated, often became fixed. This was particularly evident when donation discussions occurred before families had fully accepted neurological death or the likelihood of death following withdrawal of life-sustaining treatment, rendering early refusals protective rather than deliberative (Chapter 4.5.8, pp.122-124). These findings add to earlier literature by demonstrating that families who appear hesitant or unsure are not simply undecided by default, but often occupy a *moveable*, transitional position that can either move toward acceptance or informed decline, depending on how the conversation unfolds. Observational data show that skilled pacing, early benefit framing and rapport building by Specialist Nurses could mitigate the emergence of an early *knee jerk refusal*, while poor timing or abrupt framing risked hardening uncertainty into a definitive *no* (Chapter 4.5.2, pp.112-114). In this sense, the *moveable middle* was less about persuasion and more about creating sufficient information and emotional safety for families to think, rather than react.

5.2.2. 'Always Yes' Families: Supported Deemed Decisions

Unsupported deemed-consent cases revealed the limits of legislation. Strong cultural or religious beliefs, deep bodily-integrity concerns, or protective instincts could not be altered through legal defaults or even the most skilful communication (SR4, SN7; Chapter 4.5.7, pp. 120–125). In SR4's case, refusal centred on bodily integrity, his partner should not be 'cut up in pieces like a jigsaw', coupled with incomplete acceptance of death (SR4, Chapter 4.5.7, pp. 120-122). In SN7's case, a Muslim family emphasised the importance of burial 'whole,' rooted in faith and ritual commitments (SN7, Chapter 4.5.8: pp122-124). In both cases, Specialist Nurses demonstrated *phronetic* judgement by deliberately choosing not to introduce the legislation, recognising that doing so could escalate emotion and undermine trust within an already sensitive interaction (Chapter 4.7.1, p.140). These findings align with the evidence outlined in Chapter 2, which suggests that within soft opt-out systems, family decisions are more often shaped by emotional, religious, and cultural meanings than by legal default. This study extends that understanding by capturing how these dynamics unfold in real time. It highlights the role of communication, metaphor, misunderstanding, and emotional boundaries as they s they arise in practice, but are often less visible or simplified in retrospective accounts.

While previous evaluations (Noyes et al, 2019; McLaughlin et al, 2024) identified challenges around public awareness, my data highlights how Specialist Nurses navigate the *moment-to-moment* tensions in the clinical setting, balancing the legal requirement to explore the deceased's wishes with the ethical obligation not to distress grieving families (Chapter 4.5; 4.6). The unsupported cases show that when families hold strong religious or cultural positions, neither legal presumption nor careful explanation changes outcomes, and ethically sensitive practice requires recognising these fixed boundaries.

5.2.3. ‘Always No’ Families: Unsupported Deemed Decisions

Unsupported deemed cases clarified the limits of legislation. Strong cultural or religious beliefs or protective instincts could not be overcome by statutory defaults or careful explanation (SR4, SN7, Chapter 4.5). In SR4, refusal was shaped by concerns about bodily integrity alongside difficulty in accepting death, while in SN7, the emphasis was placed on remaining physically whole for burial, grounded in religious meaning (see Chapter 4.5; Debriefs 5 and 7). In both situations, the Specialist Nurse and Specialist Requester, drew on *phronetic* judgement, choosing not to introduce the legislation in order to maintain trust and avoid disrupting an already fragile conversation (Chapter 4.5.7, pp.120-122).

The findings show how Specialist Nurses balance the legal requirement to seek information about the deceased’s wishes with the ethical duty to avoid harm in highly emotive and sensitive moments (Chapter 4.5.10; 4.6). The findings showed that neither legal presumption nor careful explanation could overcome strong cultural, religious, or protective values. In these cases, SNs and SRs drew upon deep reserves of professional judgement, often choosing not to mention the legislation because doing so would have heightened distress or mistrust. This exemplifies the *phronetic wisdom* that emerged across my findings, an expertise not captured in the statutory framework but essential to protecting families from harm. While the London School of Hygiene and Tropical Medicine (LSHTM) evaluation included interviews with families who declined donation (McLaughlin et al., 2024), my research adds further depth by documenting the real-time language, emotions, and dynamics observed during refusal as it unfolded in clinical practice. This includes the vivid metaphors, embodied fears, spiritual commitments, and protective instincts expressed during donation conversations, elements that are often less visible in retrospective interview data. Whereas the Welsh evaluation by Noyes et al, (2019) identified challenges in public understanding of deemed consent and noted that Specialist Nurses found aspects of the system difficult to manage, it did not explore in detail how these issues play out in real time in clinical practice. My findings add further insight by showing how Specialist Nurses balance the legal requirement to seek *information* about the deceased’s wishes with the ethical need to avoid distress or perceptions of coercion during emotionally intense conversations.

This also begins to extend the LSHTM evaluation (McLaughlin et al., 2024), which identified high rates of verbal opt-outs but paid less attention to how Specialist Nurses manage the practical and emotional challenges of applying HTA requirements in real-time discussions. Taken together, these findings suggest that Specialist Nurses may be balancing the risk of appearing coercive with the need to establish clarity around decision-making, a tension that is acknowledged in existing evaluations but perhaps not fully explored in practice.

5.2.4. Helping the Hesitant: Using Soft Opt-Out to Support Uncertain Families

The legislation offered its clearest benefit with *hesitant* families, relatives who were neither firmly supportive nor strongly opposed but open to further information. In the two supported deemed-consent cases involving hesitant families, Specialist Requesters used *soft legal framing* to reinterpret uncertainty, the absence of an opt-out was explained as *no objection*, while the conversation remained grounded in the person's values and the tangible benefits of donation (SR1, SR5; Chapter 4.5, pp. 110–130). Interviews confirmed this pattern, emphasising that the law worked best when it served as a supportive conversational support rather than a directive (Chapter 47.1, p.140). Specialist Requesters consistently sequenced information in a protective order:

1. Clinical clarity (neurological death or anticipated circulatory death following WLST)
2. Tangible, relatable benefits of donation (legacy, helping others, meaning-making)
3. Gentle, early legal reference phrases such as 'no objection' or 'we can consider they would be willing'
4. Only then inviting any last known decision to surface naturally

This This sequencing appeared to protect emotional safety and reduce cognitive overload at a particularly vulnerable point (Chapter 4.6.3–4.6.5, pp. 132–133). Framing the family's role as supporting the person's likely wishes, rather than authorising donation, was especially helpful and reflected how deemed consent was enacted in practice. Donation after circulatory death (DCD) introduced additional communication challenges that were consistently evident across cases. Earlier conversations about futility and end of life often emphasised comfort, dignity, and the relief of suffering. When DCD was later introduced, with its focus on timing, uncertainty, and the possibility that donation might not proceed, families sometimes experienced this as inconsistent or as prolonging the dying process. This shift in tone, from finality to procedural uncertainty, could create unease and, at times, strain trust, particularly when the pathway felt complex or unpredictable (e.g. SR8, Chapter 4.5.5, pp. 116–118). These findings align with the Chapter 2 literature showing that decisions are shaped in highly emotional contexts, influenced by beliefs about the body, cultural and religious frameworks, and meaning-making processes that often outweigh legal defaults. They extend this evidence by showing how misalignment between WLST and DCD communication can disrupt understanding in real time. Where communication was more closely aligned from the outset, moving coherently from breaking bad news to WLST and then to donation, families were better able to follow the process and sustain trust (Chapter 4.6.3–4.6.5; Chapter 4.7.3). Within these cases, support for DCD was limited, highlighting the need for more tailored communication approaches that acknowledge uncertainty without presenting donation as a continuation of invasive treatment after a shift to comfort care.

The findings reinforce established ethical concerns about DCD, including prognostic uncertainty and the risk of process overshadowing a 'good death,' while also identifying practical ways to strengthen communication in these situations. This includes aligning language across the pathway, sequencing information carefully, and maintaining consistent multidisciplinary input. In essence, DCD required greater precision in timing, clarity, and sensitivity in communication. Compared to DBD, which offered clearer markers of death, DCD demanded more deliberate effort to maintain coherence and trust. These findings reinforce the conclusion that effective donation conversations rely not on legislation alone, but on clarity, sequencing, relational skill, and the practical wisdom needed to respond to families in the moment.

5.2.5. Trust, Mistrust, and Their Influence on Donation Decisions

Across the dataset, trust**,** far more than the law itself, emerged as the condition that shaped whether families engaged with the donation conversation. Where trust was nurtured through early presence, transparent explanations, and visible compassion, families were markedly more willing to engage.

This was illustrated in reflections such as,

> '*being visibly present on the unit and emotionally present with the family positioned me as a familiar, supportive figure rather than a stranger entering an emotive conversation.'*

(SR10, Chapter 4.5.8. pp. 122–125). Conversely, mistrust heightened when communication felt rushed, inconsistent, or culturally miscued. In one unsupported case, a relative remarked,

> *'We just don't want it… the law was irrelevant… the offer of an Imam felt intrusive'*

(Transcript 7, Chapter 4.5.8, pp. 122–123). These interactions demonstrate how fragile trust can be at the bedside, especially when cultural or spiritual expectations are misaligned. These observations strongly reflect the wider findings in Chapter 2**,** which identify trust, bodily integrity concerns, and cultural or religious meaning as major influences on family decision-making, often overriding the legal default (Chapter 2, pp.16-22).

Chapter 4 findings deepen this insight by exposing the mechanisms through which trust is either strengthened or eroded *moment-to-moment*. Specifically, the sequencing clinical clarity; benefits; soft-law framing; exploration of last known decision consistently reduced defensiveness and increased relational safety (Chapter 4.6.3–4.6.5, pp. 132–133). The workforce survey also showed that Specialist Nurses rarely lead with legislation, instead introducing it only after benefits are understood, indicating that Specialist Nurses recognise that timing, tone, and clarity preserve trust (Chapter 4.6.6, p.133). In contrast late or abrupt references to legislation were often experienced as unhelpful and could undermine

trust, particularly where they appeared disconnected from the earlier conversation (Chapter 4.7.1, pp. 140). The wider context of public awareness also shaped how families responded. Many encountered the legislation for the first time at the bedside, reflecting a broader lack of visibility during its implementation, particularly during the COVID-19 period (Chapter 4.7.7, pp. 145-146). As highlighted in Chapter 2, opt-out systems rely heavily on public understanding and trust; without this foundation, the legal framework alone has limited influence (Chapter 2, pp. 15–29).

Cultural dynamics further shaped these interactions. Established evidence points to the ongoing impact of religious beliefs, concerns about bodily integrity, and mistrust of healthcare systems on consent decisions. These factors were evident within the data, where culturally misaligned support could disrupt rapport, while approaches that were more closely attuned to family context appeared to strengthen trust and engagement (Chapter 4.5.8, pp. 116–1118). Trust was particularly sensitive in DCD pathways, where inconsistencies in communication, especially between end-of-life framing and later procedural explanations, sometimes heightened uncertainty and made the process more difficult for families to follow (Chapter 4.5.5, pp. 116–118).

These findings reinforce the importance of trust as central to decision-making. Trust was more likely to be maintained when conversations followed a clear and supportive sequence, moving from clinical understanding to potential benefits, then to the legal context, and finally to decision-making, all delivered with sensitivity and clarity (Chapters 4.6.3–4.6.5, pp.132-133). In contrast, poorly timed or inflexible use of legislation, cultural misalignment, and broader contextual factors, including reduced public awareness, could undermine confidence and engagement. Consistent with Chapter 2, this highlights that the effectiveness of soft opt-out systems depends less on the legal default itself and more on how it is communicated and enacted in practice. Specialist Nurses supported this process through *phronetic* judgement, sensitive to family cues, anticipating misunderstanding, adapting language, and maintaining emotional safety throughout the interaction.

5.2.6. Specialist Nurse Wellbeing: Psychological Support and Emotional Labour

The findings show that *phronesis*, the practical wisdom required to navigate emotionally sensitive donation conversations, is sustained not only by clinical knowledge and communication skill but also by the wellbeing and emotional capacity of Specialist Nurses. Donation discussions frequently unfold in ‘hot’ emotional states where families are processing shock, grief, bodily integrity fears, or religious meaning; unless clinicians have the emotional bandwidth to hold this complexity, even carefully sequenced conversations can unravel. Chapter 2 highlights that families often decide amidst powerful emotional, cultural, and spiritual influences, including mistrust, bodily integrity concerns, and religious convictions (2.2.3-2.2.6, pp.17-20).

The emotional intensity of this work was clearly evident within the observations. In one case (Chapter 4.5.4, pp. 115–116), a Specialist Requester encountered a highly unusual and potentially distressing situation immediately prior to a family approach, yet was able to transition into the conversation with calm professionalism. This example illustrates the level of emotional control and adaptability required in practice. Other Specialist Nurses similarly described working in challenging environments, including overcrowded clinical settings, managing additional family frustrations, or operating in units where personal safety concerns were present, all while maintaining the composure needed to support families through complex decisions (Chapter 4.5.8, pp. 122-125).

These demands were further intensified during the COVID-19 pandemic. The use of masks, restricted visiting, and reliance on remote communication reduced access to non-verbal cues, making rapport-building more difficult and increasing the explanatory demands placed on Specialist Nurses. At the same time, the introduction of the legislation occurred with limited public visibility, meaning that many families encountered the system for the first time within already heightened and emotionally constrained circumstances (Chapter 4.7.7, pp. 145–146). Several participants reflected that the emotional demands of the role could accumulate silently without supportive structures. Chapter 4 shows the value of small, trusted debriefs, where Specialist Nurses can process events, reflect on language choices, and rebuild confidence (4.7.4, pp.142-143). These findings align closely with the need for Professional Nurse Advocate (PNA) support, structured debriefing, and psychologically safe reflective spaces. Without this support, the timing, tone, and ethical judgement required for donation conversations become harder to sustain.

5.2.7. Using the Information Digital Link (IDL) Effectively

Across the findings, the Information Digital Link (IDL) emerged as a tool that when used with discernment, embodied the *phronetic* ability to judge when families required time, space, and cognitive *cooling* before continuing a donation discussion. Although used infrequently, the IDL proved particularly valuable for families who were hesitant, overwhelmed, or processing donation conversations across staged or telephone-based interactions. Chapter 4 shows that when Specialist Nurses provided the IDL, especially following an initial conversation, families were able to step back from a *hot* emotional state and re-engage in a calmer, more reflective frame of mind. This was evident in SR8's case, where relatives who were struggling with uncertainty found the DCD pathway difficult to process. The use of the IDL appeared to provide a helpful point of reference, allowing them to revisit information in their own time and away from the immediacy of the clinical setting (Chapter 4.5, pp.116-118). Interview and survey data further support this, indicating that the IDL helped families move beyond initial emotional overwhelm towards more considered, reflective thinking. It supported clearer understanding of the donation process and facilitated discussion within the family outside of the acute clinical environment (Chapter 4.9, pp.155-156).

The findings confirm three key trust-related insights, highlighting that trust is built through careful sequencing and skilled delivery. Families responded most positively when discussions progressed from clinical clarity to benefits, then to soft law, and finally to decision-making, with each stage delivered using emotional intelligence and clear communication. In contrast, trust was undermined when references to the law were introduced too early, too forcefully, or too rigidly; late legal pivots or inflexible explanations were often experienced as coercive and risked jeopardising decision-making. This finding aligns with Chapter 2's descriptions of how families often make decisions in *hot* affective states influenced by bodily integrity beliefs, religious meaning, mistrust, and shock, all of which can outweigh legal or clinical information in the moment. Allowing more processing time, supported by a simple, accessible resource, can therefore mitigate the emotional intensity that shapes early refusals.

The IDL appeared to be most effective where families were experiencing emotional overload, such as following the delivery of bad news or when trying to process the complexities of DCD alongside their grief. It was particularly helpful in telephone conversations, where opportunities to build rapport were more limited, and where families needed time and space away from the clinical environment to reflect together on values, beliefs, and the person's likely wishes. Its use also supported those who were uncertain or hesitant, enabling information to be presented more gradually and helping families feel more confident and prepared to make a decision.

In SR1's telephone case, for example, IDL availability was highlighted as a missed opportunity. In During the debrief, it was discussed how providing it earlier might have allowed the distant relative to explain donation more clearly to others and reduced uncertainty in the subsequent call (Chapter 4.5.3, pp. 115). Importantly, the IDL did not replace conversation; rather, it acted as a *phronetic* adjunct, a supplement that extended thinking time, reinforced memory, and supported comprehension without pressure. Chapter 4 demonstrates that the way Specialist Nurses timed IDL use was central to its effectiveness: it was not a universal tool but one selected with relational and contextual.

In summary, the IDL strengthened decision making when used selectively, at the right moment, and with sensitive framing. It supported families to move toward more reflective processing, especially when dealing with emotionally complex pathways such as DCD. More broadly, the IDL exemplifies how *phronesis*, the practical wisdom to judge how and when to intervene, operates not only through spoken communication but through the intentional deployment of supportive tools that extend the space for understanding and values aligned decisions.

5.2.8. Ethical Complexity: Dual Advocacy, Family Moral Distance, and Cultural Worlds

Across the dataset, Specialist Nurses described the ethical weight of *dual advocacy*, holding the potential donor's wishes in view while safeguarding the emotional wellbeing of families who were often overwhelmed, frightened, or in crisis.

This balance was particularly challenging because donation conversations routinely unfolded when families were in intensely 'hot' emotional states shaped by shock, grief, cultural or religious meaning-making, mistrust of the system, and deeply embodied beliefs about bodily integrity. As Chapter 2 shows, these factors frequently exert greater influence on decision-making than any legal default. (Chapter 2, pp.17-22). Interviews revealed that many families experienced a moral distance from organ recipients in the early stages of grief, focusing instead on the immediate meaning of dying and the care of their loved one in front of them. These findings echoed references in the literature where families ignore the deemed legislation, creating alternative narratives to override the assumption of donation (McLaughlin et al, 2024). This is consistent with Chapter 2, which highlights how decisions in the immediate aftermath of loss are often shaped more by emotional than cognitive processes (pp. 17–18), a pattern clearly evident in bedside practice. In SR4's case, the partner's use of a vivid bodily integrity metaphor signalled a firm emotional boundary. Although the Specialist Requester attempted gentle reframing, it became clear that the refusal reflected a deeply held belief that could not be negotiated within the moment.

In the debrief, SR4 reflected on having explored the issue further, valuing a clear and informed refusal over a more uncertain or ambiguous outcome (Chapter 4.5.7, p. 119). In SN7's case, involving a large Muslim family with strong commitments to maintaining bodily integrity after death, the Specialist Nurse recognised that introducing the legislation could escalate distress. The family's preference for guidance from their own faith leader, rather than a hospital-provided Imam, further highlighted the importance of culturally aligned support. In this context, the Specialist Nurse's decision not to draw on the legislation reflects careful *phronetic* judgement, prioritising trust and relational sensitivity over legal framing (Chapter 4.5.8, pp. 122–125). These cases exemplify the cultural worlds Specialist Nurses must navigate. Chapter 2 highlights how religious, spiritual, and cultural beliefs, including Islamic, Christian, and Jewish perspectives, significantly shape donation choices, especially where misunderstandings, mistrust, or concerns about body integrity are present (Chapter 2.2.2, pp.16-17).

The findings provide real-time insight into how these beliefs are expressed in practice, often through metaphor, ritual, and the establishment of clear emotional boundaries during donation conversations. Chapter 4 shows that family responses are frequently shaped by immediate emotional cues rather than legal frameworks, requiring Specialist Nurses to make ongoing ethical and relational judgements to ensure discussions remain supportive rather than coercive. This is reflected in debrief accounts, where maintaining a coherent narrative, from breaking bad news, through neurological death testing and WLST, to donation, was central to ethical practice (Chapter 4.6, pp. 130–135).Across the dataset, Specialist Nurses consistently demonstrated sensitivity to the individual family's needs by adapting their approach in response to emotional and cultural context.

This included holding back from introducing legal frameworks when distress was high, using culturally sensitive communication, responding carefully to emotional cues, recognising when refusals were grounded in non-negotiable values, and ensuring that decisions remained informed and free from pressure. These findings reinforce the Chapter 2 literature, which highlights that soft opt-out systems depend not only on legislation but on skilled communication, cultural awareness, and relational sensitivity. Without these elements, the ethical integrity of decision-making may be compromised. Taken together, the findings emphasise that ethical complexity is not theoretical but embedded in everyday practice, where Specialist Nurses continually balance respect for autonomy, family needs, cultural meaning, and legal frameworks through the application of practical wisdom.

5.2.9. Impact of the COVID-19 Pandemic on Practice

The COVID 19 pandemic profoundly affected the implementation of soft opt out legislation, reshaping the emotional, relational, and operational context in which Specialist Nurses supported families. Chapter 4 makes clear that the lockdown measures in place from March 2020, were followed only weeks later by the implementation of deemed consent in England, on the 20th May 2020. This coincidence significantly disrupted public awareness, family understanding, and clinical communication (Chapter 4.7.7, pp. 145-147). Chapter 2 outlines why these conditions were particularly challenging due to, families commonly make decisions in *hot* emotional states where bodily integrity concerns, religious meaning, mistrust, and shock strongly influence decision making. These non-cognitive factors frequently outweigh legal defaults. During the pandemic, these influences were magnified, by wearing Personal Protective Equipment (PPE), physical distancing, restricted visiting, and telephone-based communication dramatically muted non-verbal cues, lengthened explanations, and increased cognitive load for families. Specialist Nurses described needing to slow down the pace, offer more reassurance, and perform more myth busting to prevent early protective refusals (Chapter 4.7.7, pp. 145–147). Importantly, public familiarity with the new legislation was extremely limited at the time of its launch. Many relatives reported never having heard of the law change, requiring Specialist Nurses to shoulder the full explanatory burden during emotionally intense encounters (Chapter 4.8.9, pp. 153).

This concern aligns with the wider ethical analyses discussed in Chapter 2, which emphasise that opt-out systems depend on public trust, transparency, and awareness. Where families feel uninformed or encounter the legislation for the first time in moments of acute stress, the influence of legal default can be significantly diminished. The timing of implementation further compounded this issue, with limited public visibility during the COVID-19 pandemic contributing to a lack of awareness among families at the bedside. The pandemic also required Specialist Nurses to adapt how they structured conversations. With rapport more difficult to establish in telephone or masked interactions, greater emphasis was placed on sequencing, first establishing clinical clarity, then outlining tangible benefits, followed by a gentle introduction of the legal context, and only later exploring any last known decision.

This approach was consistent with patterns observed elsewhere in Chapter 4 and was supported by the use of tools such as the Information Digital Link (IDL), which enabled families to revisit information in their own time and move from immediate emotional responses towards more reflective understanding. Overall, the pandemic did not fundamentally change what constituted effective practice, but it heightened the level of skill required to deliver it. Reduced non-verbal communication, limited visiting, and lower public awareness increased the risk of misunderstanding and mistrust. In response, Specialist Nurses adapted through slower pacing, clearer explanations, early but sensitive framing of legislation, and increased reliance on cultural awareness and relational judgement. These adjustments were particularly important in DCD cases, where existing uncertainty made alignment of end-of-life and donation communication even more critical. These findings reinforce the conclusion that soft opt-out systems cannot operate effectively through legislation alone. Their success depends on trust, clarity, and relational sensitivity. In this context, it is the application of *phronetic* judgement, rather than the legal framework itself, that enables families to reach informed, values-consistent decisions.

5.2.10. Sensitivity and Societal Responsibility: Enabling Informed Decisions Without Coercion or Regret

Across the findings, it becomes clear that the primary aim of Specialist Nurse practice is to support informed, enduring decisions that families can live with, free from coercion, confusion, or later regret. As outlined in Chapter 2, this is particularly important because decisions in the immediate aftermath of loss are often shaped by intense emotional responses, where beliefs about the body, spiritual meaning, mistrust, and grief can outweigh legal frameworks. In practice, Specialist Nurses consistently prioritised these conditions over securing agreement. Ensuring that refusal, when it occurred, was clear and grounded, and carefully sequencing conversations to avoid premature or reactive responses, were central to this approach. This orientation reflects broader solidarity-based perspectives on organ donation, where relational responsibility and trust take precedence over procedural compliance. As highlighted in Chapter 2, high-performing systems are characterised less by public understanding of legislation and more by trust in healthcare systems and culturally embedded acceptance of donation.

The findings build on this by illustrating how these principles are enacted in real time. Specialist Nurses used careful pacing and sequencing, moving from clinical clarity to tangible benefits, to gentle legal framing, and only then to exploration of the person's wishes, supporting families to engage without feeling overwhelmed or pressured. The data also suggest that, particularly in early grief, families often remain focused on the immediate experience of loss, with limited capacity to engage with more abstract or future-oriented considerations. Specialist Nurses responded to this not by emphasising altruism, but by creating the conditions for understanding and emotional safety, allowing donation to be considered as part of ongoing care rather than as an additional burden. This was supported through careful language choices and by avoiding early binary questioning that might prompt protective refusals.

In practice, Specialist Nurses consistently prioritised these conditions over securing agreement. In SR4's case, there was a clear emphasis on ensuring that any refusal was informed and unambiguous, recognising that this was ethically preferable to a decision reached under pressure or uncertainty (Chapter 4.5.7, pp. 118–119). Similarly, SR2 demonstrated awareness of the risk of immediate, reflex refusals if expressed decisions were explored too early, instead structuring the conversation around clinical clarity and potential benefits before inviting families to reflect on the person's known wishes (Chapter 4.5, pp. 110–130). Overall, the findings suggest that ethical practice under soft opt-out is shaped less by legal mandate and more by how conversations are timed, framed, and delivered. Specialist Nurses consistently worked to protect emotional safety, prevent coercion, avoid premature decision points, and support families in reaching clear, values-consistent outcomes. In this context, *phronesis*, expressed through judgement, pacing, and sensitivity, emerges as the key mechanism through which ethically sound decisions are realised in practice. A recent Spanish perception study cited in Chapter 2 found very high trust in the donation system (93%) despite low awareness of the presumed-consent model (28%), concluding that family consultation norms and system trust underpin acceptance more than legislation itself (Chapter 2.2.2: p.16). Our findings build on this by showing how solidarity is enacted at the bedside. Specialist Nurses maintained a humane pacing and coherent sequencing of clinical clarity, tangible benefits, soft legal framing and allowing the last-known decision to unfold, protecting families from premature refusal while preserving autonomy (Chapter 4.7.2, pp. 141). Family moral distance from recipients was also an important factor. Interviews showed that in early grief, relatives often could not meaningfully think about people waiting for transplants; their emotional focus remained on the dying person in front of them. Chapter 2 highlights that, in some cases, families place little weight on the deemed consent framework, particularly where trust and understanding have not yet been established. The findings here show how Specialist Nurses worked to bridge this gap indirectly, not by emphasising altruism, but by ensuring that families had a clear grasp of the clinical situation, felt emotionally supported, and could begin to see donation as consistent with the person's values rather than as an added burden. This was reflected in the careful use of non-confrontational language and in avoiding early binary questioning, which could prompt protective refusals (Chapter 4.7.8, p. 146-147).

Across the dataset, Specialist Nurses consistently upheld these principles by protecting emotional safety, avoiding coercion, pacing conversations carefully, and supporting families to reach decisions that were clear, considered, and aligned with the person's values. In this sense, *phronesis*, expressed through timing, language, pacing, and cultural awareness, emerges as the key mechanism for enabling ethically sound decision-making. When applied effectively, it translates the concept of solidarity into a lived, humane practice that supports families to make decisions they can sustain without regret.

5.3. *Phronesis* as the Foundation of Practice

In this thesis, *phronesis* means the practical wisdom that helps Specialist Nurses judge how, when, and whether to act amid uncertainty, bringing together clinical facts and moral purpose for this patient and this family, in this moment. Classical accounts see phronesis as both action guiding know how and a way to balance competing aims; contemporary medical ethics shows we understand it best in real cases and communities of practice, not by rules alone (Kotzee, Paton & Conroy, 2017). This matches my findings, in that the law is clear on paper, but at the bedside outcomes turned on moment to moment judgement as Specialist Nurses and Requesters worked through grief, uncertainty, culture, and family dynamics (Chapter 4.5–4.6, pp.110-135). Chapter 2 explains why this wisdom is essential under the soft opt out system. Families often decide in 'hot' emotional states; considerations like religion, bodily integrity concerns and trust frequently outweighed families thinking about the law, and these creating dilemmas that the law itself cannot resolve but must be resolved in conversation between people. Our findings show that phronesis was visible and could be tracked in practice. More positive outcomes were associated with careful sequencing, timing, and the use of language that reduced perceived threat, preserved a sense of choice, and built trust, particularly among families within the *moveable middle*. Early attention to how the conversation was introduced following the delivery of bad news appeared to reduce the likelihood of an initial refusal becoming fixed over time, as seen in Chapter 4.6.4. Professional judgement also involved recognising when not to introduce the legislation, particularly in situations where doing so might escalate distress, prioritising trust and relational integrity over procedural consistency (Chapter 4.6.3, p.132).

Cultural intelligence was pivotal to how interactions unfolded. When offers were misaligned to the family, such as introducing a faith representative without indication of need, rapport was disrupted; by contrast, careful alignment with the family's context preserved dignity and supported more consistent outcomes (SR10; Transcript 7, Chapter 4.5). In DCD pathways, coherence between earlier futility discussions and subsequent DCD explanations emerged as essential for maintaining trust. Even where the likely outcome was tissue rather than organ donation, this alignment protected credibility and relational continuity (SR8; Debrief 5, Chapter 4.5). These findings extend the *phronesis* literature by demonstrating that effective practice depends less on rigid rule-following and more on context-sensitive professional judgement. Legal frameworks and organisational rules do not specify how Specialist Nurses should act within the fluid, emotionally sensitive reality of conversations in the clinical context. Instead, practice is guided by experience-based judgement that develops within teams through shared narratives, case-based learning, and reflective discussion (Chapter 4.5; Kotzee, Paton & Conroy, 2017). The data further show that wise action integrates epistêmê (clinical facts and prognosis) with praxis (what is best for this family at this time), which together constitute the core of practical wisdom (Chapter 4.5; Kotzee, Paton & Conroy, 2017).

Across cases, a coherent practice pattern is evident. Timing the approach to protect the immediate period following bad news and anticipating an initial negative response; sequencing conversations from clinical clarity to potential benefits before introducing a soft legal framing and, where appropriate, exploring any recorded decision; using sensitive language bespoke to the family; judging carefully if and when to refer to the legislation; maintaining cultural alignment; adapting to pathway requirements (including aligning WLST/futility narratives with DCD explanations and using the IDL where helpful); and working as a multidisciplinary team to ensure a consistent narrative from the delivery of bad news through to the donation discussion (Chapter 4.5).

Development of this capability is supported through structured debriefing and deliberate practice within psychologically safe team environments, reflecting the 'narrative community' described in virtue ethics (Chapters 4.5; 4.6.3–4.6.6; 4.7.1–4.7.3; 4.8; Kotzee, Paton & Conroy, 2017). The educational implication is a shift from compliance-focused training toward developing *phronesis*. This involves scenario-based rehearsal using real cases (e.g., SR1/SR5/SR8/SR10), short structured debriefs, and focused language practice that prioritises sensitive, family-centred communication over legalistic phrasing. In practice, although legislation provides an overarching framework, outcomes are strongly shaped by timing, sequencing, language, and particularly by the level of trust established in the minutes immediately after breaking bad news (Chapters 4.5–4.6, pp.110-135).

From these observations and debriefs, a *Phronesis*-Based Assessment Framework was developed, grounded in Bloom's taxonomy (Fig.41). This framework renders practical wisdom visible and actionable through a developmental continuum that supports self-assessment and peer review. It enables teams to identify current practice, determine progression points, and work toward expert performance. The framework focuses on core elements of timing, sequencing, communication, and judgement regarding the use of legislation and is supported by concise scenarios and prompts linked to real cases (e.g., SR1/SR5/SR8/SR10 in Chapter 4). Reflective practice underpins the framework, incorporating short structured debriefs and individual or small-group review.

Within this process, teams rehearse explaining benefits clearly, use low-threat language such as framing decisions in terms of absence of objection, ensure that cultural or spiritual support aligns with family preferences, and maintain a single, coherent narrative from breaking bad news, through clinical decision-making, to the donation discussion. Over time, this shared reflective approach enables teams to recognise, articulate, and strengthen phronesis in everyday work. Across all domains of Specialist Nurse practice, the findings position phronesis as the central mechanism through which deemed consent is enacted safely, ethically, and compassionately. While the ODDC Act 2019 establishes a structural framework, it is practical wisdom that shapes its application in real-world settings.

Specialist Nurses must interpret emotional cues, judge timing, adapt communication, and decide whether to invoke legislation within rapidly evolving and often challenging circumstances involving grief,

cultural expectations, or mistrust (Chapter 4.6). The role is therefore fundamentally relational rather than procedural. It requires integrating clinical knowledge, emotional awareness, cultural understanding, and legal context in real time. The effectiveness of a soft opt-out system depends less on statute and more on this *phronetic* practice. Through attentive presence, thoughtful sequencing, and compassionate communication, Specialist Nurses support families in reaching decisions that are informed, aligned with their values, and sustainable over time, regardless of whether the outcome is donation. In this perspective, phronesis operates as the essential link between legal framework and lived outcome: Chapter 2 establishes its necessity, and Chapter 4 demonstrates how it is enacted through repeatable, teachable practices that can be rehearsed, reflected upon, and evaluated.

5.4. Learning, Application and Professional Development

Learning transfer emerged not as a discrete event but as a gradual *phronetic* shift, moving from understanding deemed consent in the classroom to exercising judgement about when and how to introduce it within emotionally complex family conversations (Chapter 4.5, pp.110-130). Timing consistently appeared important in this transition. Specialist Nurses described moving away from introducing legislation too early, where it could feel abrupt or unempathetic, while also avoiding leaving it too late, where it might be perceived as pressurising; instead, practice was timed towards introducing the legal context at an appropriate point to support, rather than disrupt, the conversation (Chapter 4.5, pp.110-130).

Cultural responsiveness further informed this process, with some Specialist Nurses emphasising early role transparency as a means of establishing trust, particularly when working with families from communities where mistrust or strong religious norms may be present (Chapter 2, pp. 18–19). Differences in experience also shaped practice, with those more frequently exposed to real cases demonstrating greater fluency in managing timing, phrasing, and sequencing, reinforcing the importance of experiential learning in developing mastery (Chapter 4.7.4, p.142). Practical tools such as the DONOR acronym (Fig.33) and consent documentation (Appendix 30), acted as prompts, supporting clinicians to structure conversations, maintain clinical clarity, and ensure consistent, lawful practice under pressure (Chapter 4.3.1–4.3.4, pp. 106–109). Although foundational and consolidation modules were valued, scenario-based training with professional actors was described as particularly impactful in preparing Specialist Nurses for the unpredictability of real interactions, offering opportunities to rehearse pacing, respond to emotional cues, and receive immediate feedback (Chapter 4.3.1–4.3.4; Chapter 4.6.6, p. 133). Despite this, participants acknowledged occasional reversion to familiar, less precise language under pressure, highlighting the challenges of maintaining consistency in complex clinical environments. This reflects the volatile and cognitively demanding nature of ICU contexts, where real-world exposure is required to translate knowledge into judgement (Chapter 4.6.2, p. 132; Chapter 4.5.4, pp. 115–116).

Within this space, informal debriefs emerged as an important mechanism for consolidating learning, providing trusted environments in which Specialist Nurses could reflect on tone, wording, sequencing, and the emotional dimensions of their practice, thereby refining their approach over time (Chapter 4.6.6, pp. 133).Across interviews, learning transfer appeared not as a single event but as a gradual *phronetic* shift from knowing about deemed consent in the classroom to judging when and how to bring it into emotionally sensitive, real-time conversations at the bedside. Participants repeatedly emphasised timing as the hinge on which transfer turned. One practitioner explained that opening with the law felt abrupt and unempathetic, so they now introduce it only after rapport and initial clinical understanding have been established, saying:

> '*I don't bring the actual law up initially… never leave it to the end unless there's a very powerful yes*.' (Chapter 4.5).

Another interviewee described learning through reflection, recalling a case where using the legislation as a late 'backup' made a family feel pressured; this prompted a deliberate recalibration of practice so that the legal context is now raised earlier whenever appropriate to normalise the conversation while avoiding coercive timing (Chapter 4.5). Importantly, 'earlier' did not mean 'first.' Across interviews, Specialist Nurses converged on a humane sequencing pattern of rapport; acceptance of prognosis; tangible benefits; soft legislative frame, mirroring what was observed in practice and supported in training (Chapter 4.5). This pattern aligns with Chapter 2, which shows that families often decide in emotionally charged states shaped by fear of bodily mutilation, spiritual beliefs, mistrust, and cultural meaning, all of which require careful pacing and clarity (Chapter2.2.6: p20). Cultural responsiveness also shaped learning.

Some participants noted that when working with families from communities where mistrust of medical systems or strong religious norms are common, they would begin by clarifying their role early ('I'm a Specialist Nurse …') because clear role transparency built trust faster, a practice aligned with Chapter 2's findings on cultural and religious objections (pp. 18–19). Interview accounts also revealed the confidence gradient between Specialist Requesters (SRs) and Specialist Nurses. Specialist Nurses/Requesters with higher exposure to real cases consistently demonstrated greater fluency in timing, phrasing, and sequencing, consistent with Chapter 4 observations that repeated, real world exposure strengthens mastery (Chapter 4.5, pp. 115–122; Chapter 4.6.6, pp. 142–143). The DONOR acronym and Section C of the consent form were consistently experienced as practical supports that reduced cognitive load and helped structure conversations in real time. They enabled Specialist Nurses to understand and interpret the inclusion and exclusion criteria, maintain clinical clarity before moving into decision-making discussions, and ensure documentation remained consistent and legally sound (Chapter 4.3.1–4.3.4, pp. 106–109).

Although Module 1 established the legislative framework and Module 3 helped consolidate learning, it was Module 2 that participants most often returned to as the point where practice began to feel real. The use of professional actors, with space to pause, adjust, and receive immediate feedback, allowed for a level of emotional and situational realism that more closely reflected clinical uncertainty. This reinforces Chapter 4's finding that simulation supports progression beyond knowledge recall into more complex levels of performance (Chapter 4.7.5, p.144).

At the same time, Specialist Nurses described how this learning could become less stable under pressure. In live cases, some found themselves reverting to familiar but less precise language, despite training that emphasised more concrete and legally aligned terminology. This reflects the wider conditions described in Chapter 4, where practice takes place within busy ICUs, shifting team dynamics, cultural tensions, and heightened emotional distress. In these settings, knowledge alone is insufficient, and experience becomes central to moving from memory recall into confident, context-sensitive judgement (Chapter 4.6.3, pp. 132.

5.4.1. How learning transfers from training to practice

Learning transfer within the deemed consent system is best understood as a context-dependent progression from formal competence to situated, *phronetic* judgement, rather than a simple application of classroom learning. Training environments provide structure, predictability, and emotional containment, whereas clinical practice is characterised by uncertainty, emotional intensity, and competing professional narratives (Chapter 4.5.5, pp. 115-116). This contrast highlights why knowledge acquired in education settings requires adaptation when applied in the dynamic and often pressured ICU context. Within these environments, Specialist Nurses manage significant psychological demands while maintaining a composed and supportive presence for families, reinforcing the importance of experiential learning alongside formal preparation (Chapter 4.5, pp. 110–130).

The OOEP provides a necessary foundation, combining legislative knowledge with structured tools and simulated practice. Evaluation scores across modules indicate that this combination offers a credible base for practice, though early learning was sometimes experienced as comprehensive, and .9, pp.155-156.difficult to retain without reinforcement. Consolidation appeared to depend on repetition, spacing, and supported clinical exposure, particularly for those less familiar with the foundations of the Human Tissue Act (2004). In practice, learning transfer became most visible in how conversations were timed and structured. Specialist Nurses demonstrated increasing sensitivity to sequencing, integrating rapport-building, acknowledgement of prognosis, and discussion of benefits before introducing the legislative framework. This approach avoided the perception of donation being added abruptly and supported smoother, more acceptable conversations (Chapter 4, pp.155-156).

Language use further reflected this shift towards applied judgement. Participants described using terms that reduced perceived threat and maintained family involvement, ensuring that discussions remained relational rather than procedural. Across both qualitative accounts and survey data, legislation was rarely made central to the conversation; instead, it was introduced selectively, often when families were already receptive or when clarification was needed. This practice reflects an understanding that legal frameworks alone are insufficient to guide decision-making, with trust and relational connection taking precedence in emotionally sensitive situations. Learning transfer was strengthened through continued exposure, feedback, and reflective practice. Small, psychologically safe debriefs were particularly important in enabling Specialist Nurses to process both the technical and emotional aspects of cases. Simulation also remained valuable in building confidence and communication fluency, although there was a recognised need for greater complexity to better reflect real-world uncertainty. Alongside this, concerns about uneven exposure highlighted the risk of skill erosion, particularly where opportunities for direct practice were limited. Planned opportunities for participation, observation, and supported practice were therefore seen as essential for sustaining development.

Cultural understanding and the ability to address misconceptions formed another important dimension of learning transfer, particularly given limited public awareness of deemed consent. This increased the explanatory role of Specialist Nurses and required careful, culturally sensitive communication. More broadly, effective practice depended on interprofessional alignment. Where clinical teams coordinated their messaging, conversations with families flowed more coherently; where this was absent, Specialist Nurses were often required to reframe or repair earlier discussions. Overall, these findings show that deemed consent supports the *moveable middle* conversation but does not replace the need for skilled communication. Learning transfers best when knowledge, practice, and experience are integrated and reinforced through reflection, enabling Specialist Nurses to develop the practical judgement needed to manage the legal, emotional, cultural, and clinical complexities of donation discussions.

5.4.2. Bridging the Gap Between Training and Clinical Reality

Across observations and interviews, a persistent gap between training and clinical reality was evident, particularly during the early implementation of deemed consent. Training was typically delivered in structured and controlled environments in which scenarios followed largely predictable trajectories, emotional intensity could be moderated, and facilitators were able to pause or recalibrate the interaction as required. In contrast, practice in intensive care settings unfolded within emotionally charged and often crowded relatives' rooms, marked by acute grief, complex family relationships, cultural tensions and variable interprofessional input. At times, language used by clinicians, such as characterising ongoing treatment in overly negative terms or presenting withdrawal of treatment as the only compassionate option, implicitly shaped the context in which subsequent donation discussions occurred, complicating Specialist Nurses' later efforts to introduce donation in a gentle and supportive way.

These contextual differences meant that even well-prepared clinicians and Specialist Nurses could feel unsettled when conversations moved rapidly or deviated from anticipated pathways. This was evident in accounts such as SN3 (Chapter 4.5.9, p.127), where entry into a family discussion occurred mid-conversation, requiring immediate engagement at a point where sense-making and decision-making were already underway. Such examples illustrate how rapidly conversations can progress in practice, often without the structure or psychological safety afforded by simulation. Within these conditions, Specialist Nurses described applying the legislation in a measured and ethical way, prioritising emotional readiness, avoiding pressure, and allowing space for families to articulate their understanding of the patient's likely wishes. It was essential that families had clearly understood the breaking bad news conversation and recognised that death was imminent or had already occurred, enabling them to move forward in their understanding rather than holding on to hope that conflicted with the clinical reality. Learning transfer was therefore less about increasing the use of legal explanation and more about developing sensitivity to timing. Participants described introducing the legal context earlier, but not at the outset, to avoid it appearing abrupt or as a late addition that could be perceived as coercive. Introducing legislation too late was seen to risk reinforcing refusal, which, once expressed, was rarely revisited (Chapter 4.7.2, p. 141).

In response, Specialist Nurses consistently used language that reduced perceived threat and maintained a sense of family agency, while workforce survey findings reflected a similar approach, with legislation typically introduced later in the conversation or reserved for situations where families were uncertain (Chapter 4.8.1, p. 148). This reinforces the importance of relational trust over formal legal framing in initial interactions. Learning transfer was further supported through experience, feedback, and reflection. Smaller, trusted debriefs were particularly valued for enabling exploration of the emotional and contextual dimensions of practice without the limitations of larger forums. Simulation remained important, though participants emphasised the need for increased complexity to better reflect clinical realities, including variability in family dynamics, cultural considerations, and clinical uncertainty. Alongside this, concerns about reduced opportunities for direct practice highlighted the risk of deskilling, reinforcing the need for planned exposure and supported participation to sustain development beyond simulation (Chapter 4.8.3, p. 151). Cultural understanding and the ability to address misconceptions were also central to effective learning transfer. Misunderstandings about deemed consent required careful explanation and culturally sensitive communication, particularly given limited public awareness following its introduction during the COVID-19 pandemic (Chapter 4.7.7, pp.145-146). Importantly, learning transfer was closely linked to emotional labour and team coordination. The most effective practice occurred where Specialist Nurses, consultants or CLODs, and bedside staff aligned their approach across the care pathway. Where this alignment was absent, Specialist Nurses were often required to reframe earlier discussions to restore clarity and trust.

5.4.3. Practical Wisdom (*Phronesis*) in Everyday Decision-Making

Throughout Across the observations, *phronesis* emerged as the central mechanism through which Specialist Nurses translate training, policy, and legislation into relational practice. Donation conversations unfolded within emotionally complex environments shaped by grief, shock, cultural meaning, religious beliefs, and concerns about bodily integrity. As outlined in Chapter 2, these influences often carry greater weight than legal frameworks, and this was consistently evident at the bedside. In this context, practical wisdom was visible in how Specialist Nurses interpreted emotional cues, adjusted pacing, and made in-the-moment decisions about whether and how to introduce the law.

This judgement was particularly apparent in situations of heightened emotion. In SN7's case (4.5.8, pp.122-125), rising distress led to a decision not to introduce the legislative framework, recognising that this would likely escalate rather than support understanding. Similarly, in SR4s case (4.5.7, p.120), the family's concerns about bodily integrity signalled a deeply held belief that required a sensitive shift in approach. In both situations, restraint functioned as skilled practice, prioritising trust and emotional realism over procedural application. *Phronesis* was also seen in how uncertainty and hesitation were handled. In line with Neades (2009), Specialist Nurses and Requesters relied on their intuition when applying the legislation, particularly in choosing when to introduce or hold back from it to protect rapport and psychological safety. Observations showed that conversations worked best when they moved from clinical clarity to clear benefits, to a gently introduced legal context, and only then to discussing any known decision, helping to maintain a sense of control and reduce defensiveness. This sequencing aligns with Chapter 2, where emotional safety and clarity are identified as prerequisites for engaging with legal concepts. In more uncertain contexts, such as DCD pathways, this practical judgement became even more critical. In SR8 (Chapter 4.5.5, p.117), where uncertainty shaped the family's understanding, the Specialist Requester adapted by slowing the conversation, rebuilding rapport, and supporting an outcome that aligned with the family's values, demonstrating the integration of clinical, emotional, and cultural considerations.

Experience and reflection played an important role in strengthening this form of judgement. More experienced Specialist Nurses/Requesters demonstrated greater adaptability, while those earlier in their development relied more on structured approaches from training. Across cases, those demonstrating more developed judgement showed a consistent ability to anticipate refusal, regulate the pace of conversations, maintain emotional space, use culturally sensitive language, and align donation discussions with end-of-life care. They also recognised when introducing the law would be counterproductive and maintained trust regardless of the outcome. These patterns demonstrate that *phronesis* is not abstract but a practical and observable capability, grounded in experience and reflection.

It enables Specialist Nurses to navigate the legal, emotional, and cultural complexity of donation conversations in a way that supports informed and meaningful decision-making within the soft opt-out system. Importantly, *phronesis* was strengthened through experience and reflective practice. Specialist Requesters with greater exposure to real cases demonstrated higher order behaviours, analysing, evaluating and adapting practice, while less experienced staff relied more heavily on procedural knowledge from training. Small, trusted debriefs played a vital role in converting tacit bedside experience into explicit judgement, allowing clinicians to examine communication skills, sequencing, decision points and emotional labour without fear of scrutiny. *Phronesis* was also visible in the ability to repair conversations following poorly timed or unhelpfully framed input from others, such as when consultants' language inadvertently complicated the donation message. In these moments, Specialist Nurses drew on relational expertise that cannot be fully scripted or standardised.

5.5. A *Phronesis*-Based Evaluation Framework Grounded in Bloom's Taxonomy – Why This Framework

The analysis in Chapter 4 shows that high quality donation conversations under soft opt out rely not simply on knowledge of the law, but on the *phronetic* ability to apply that knowledge sensitively, relationally, and at the right moment. Because practice unfolds in emotionally volatile, culturally diverse, and clinically complex circumstances, a framework was required that could make practical wisdom visible, describable, and improvable. The framework is grounded in Bloom's Taxonomy, which maps how Specialist Nurses move from foundational understanding to higher order judgement enabling them to analyse context, evaluate timing and create adaptive, family centred communication strategies. Chapter 4 data demonstrate that Specialist Requesters, who have greater real-world exposure, tend to operate at higher levels of Bloom's hierarchy, analysing, evaluating, and creating adaptive communication strategies, while less experienced staff often remain at recall based or procedural levels during early practice.

These distinctions were visible across observed conversations. In cases involving high cultural sensitivity, strong religious commitments, or concern about bodily integrity (e.g., SR4, SN7), Specialist Nurses needed to interpret emotional cues, adjust sequencing, and decide whether referencing the legislation would support or harm the family, all capacities aligned with Bloom's upper tiers. This behavioural pattern reflects the Chapter 2.2.6 (p.20) literature, which highlights that decisions are strongly shaped by cultural and religious beliefs, fears of bodily harm, and trust or mistrust in clinicians. Because these influences often outweigh legal default, training programmes and assessment tools must develop judgement, not only procedural compliance.

The framework therefore emphasises sequencing skills (clinical clarity, benefits, a soft legal context, and expressed decision), alongside cultural and faith alignment, the use of threat-reducing language (e.g., 'no objection', 'consider willing'), careful attention to timing, and effective multidisciplinary planning and communication. All of these skills were repeatedly shown in Chapter 4 to determine whether families felt supported, informed, and emotionally safe. The framework also functions as an evaluation tool. Chapter 4 demonstrates that bedside *phronesis* can be seen, described, and fed back to Specialist Nurses when debriefs are structured, psychologically safe, and focused on sequencing, tone, cultural fit, and emotional load. This aligns with Chapter 2's emphasis on the need for trustworthy, culturally sensitive communication under soft opt out, particularly where bodily integrity concerns or mistrust may otherwise lead to refusal (chapter 2.2.6, p. 20). Finally, the framework supports continuous professional development by enabling teams to map their current practice (e.g., predominantly 'understand/apply') and identify targeted next steps toward higher order *phronetic* practice.

The framework offers a shared language and structure that supports reflective practice, enables alignment between Specialist Nurses and Specialist Requesters, and promotes consistency across multidisciplinary teams. This coordinated approach helps ensure that family conversations about organ donation are consistently planned, paced and timed, which is particularly important when operating within a newly introduced legislative framework. As demonstrated across Chapters 4.5–4.7, such collaborative communication strategies are central to successful, trust preserving approaches with families during end-of-life decisions. This framework (Figure 41) was developed to capture how soft opt out succeeds in practice, through Specialist Nurses and Specialist Requesters ability to combine legal knowledge with ethical sensitivity, compassion, cultural understanding, emotional awareness and timing. Using Bloom's Taxonomy, it offers a developmental pathway for building practical wisdom as lived, real time clinical expertise.

Phronesis-Based Assessment Framework Grounded in Bloom's Taxonomy

This framework is designed to support educators, mentors, and Specialist Nurses in Organ Donation by enabling both self-directed and externally guided assessment. Positioned as a developmental continuum, it offers a structured approach to recognising, cultivating, and aspiring toward expert practice. Reflective engagement is central to its use, inviting users to deepen their reflective insight through established models such as Gibbs' Reflective Cycle (1988) and Rolfe et al.'s 'What? So What? Now What?' reflective model (2001).
To enhance the refinement of advanced communication skills, it also encourages deliberate practice opportunities, fostering experiential learning, critical reflection, and the internalisation of expert behaviours.

Reference:

Gibbs, G. (1988) *Learning by Doing: A guide to teaching and learning methods*. Further Education Unit, Oxford Brookes University: Oxford.
Rolfe, G., Freshwater, D., Jasper, M. (2001). *Critical reflection in nursing and the helping professions: a user's guide*. Basingstoke: Palgrave Macmillan.

Bloom's taxonomy - six cognitive levels

The individual focuses on recalling facts and basic concepts, relying on rules and notes. Inexperienced, unable to troubleshoot, not adaptable, and has a narrow focus.	Individual can explain ideas and concepts and has some experience and understanding. They recognise complexity and are rule-focused but need assistance with prioritising tasks	This individual effectively uses information in new situations, demonstrating the ability to interpret, solve problems, and explain concepts. They are experienced and capable of prioritising tasks. With some adaptability and skills in managing complex situations, they plan well and possess strong analytical abilities.	This individual excels at drawing connections, comparing and contrasting, distinguishing details, examining, and experimenting. They understand what is important and recognise relevant priorities, leading to good decision-making. With a holistic view, they are adaptable and deliberate in their actions.	This individual is intuitive and confident, capable of justifying and standing by decisions. They excel at appraising, arguing, critiquing, and juggling tasks. With a clear vision of the big picture, they effectively act on priorities and manage complexities with ease.	This individual excels at producing new and original work. They design, develop, and construct innovative solutions, formulating ideas and investigating thoroughly.

Approach skills to be observed, reflected, and fed back upon:

Planning Conversation ☐ **Building Rapport Trust are and End of Life Care Faith** ☐ **Culture & traditions** ☐ **Communication Skills** ☐
Information about donation benefits ☐ **Legislation ODR/Deemed/HQR** ☐ **Responsiveness to Family Concerns** ☐ **Decision Making Skills** ☐
Research ☐ **Consent/Authorisation Form Completion** ☐ **Management Plan** ☐

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Skill observed: **Planning Conversation**	No structured planning conversation took place between the clinical team and key staff members.	A planning conversation was observed; however, the individual took a passive role, with limited contribution to the discussion or decision making process.	Engaged in planning conversation with consultant and bedside nurse, demonstrating an active and contributory role.	Demonstrated active engagement in the planning conversation, contributing to the discussion and shaping the family communication approach.	Conducted a planned discussion with the consultant and bedside nurse to clarify the clinical situation, confirm prior consent (e.g., ODR), identify key family members, and assess emotional readiness for donation discussions, involving others such as faith representatives where appropriate.	Facilitated a structured planning conversation with the consultant and bedside nurse, clearly outlining the intended flow of discussion. Key checkpoints were incorporated to help the family gradually come to terms with the inevitability of their loss and become emotionally prepared for the next steps, including meaningful engagement in conversations about organ donation.
Building Rapport, Trust are and End of Life Care Faith, Culture & traditions	Lacked confidence at introduction, struggled to build rapport or acknowledge basic needs, and began the conversation directly with donation.	Some effort to introduce oneself and build rapport. Family needs were assessed with closed questions. Minimal hospitality offered e.g. a drink of water. Minimal reference to End-of-Life Care (EoLC) was lacking.	Made a reasonable effort to build rapport by addressing basic needs and family support requirements. Also inquired about general EoLC requests, including faith and cultural preferences.	Built good rapport, addressed specific needs and distractions, offered support, and discussed EoLC, including faith, culture and traditions.	Built strong rapport, explored family priorities with curiosity, offered supportive strategies, and personalised meaningful EoLC tailored to faith, culture and traditions.	Intuitively connected with the family, respecting their values and end-of-life priorities, and provided space to consider the benefits of donation. EoLC was meaningfully tailored to their faith, culture and traditions.
Communication Skills	Basic communication skills were noted, but verbal and/ or nonverbal cues were missed. Conversation flow was difficult to follow, resembling a checklist approach reliant on prompts.	Some communication techniques used, but, unable to recognise skill deficits or areas for improvement. Noticed cues from family, although, responded ineffectively, making assumptions. Needed prompts to aid communication.	Some communication techniques were used, identified omissions. Acknowledged and responded to both verbal and non-verbal cues without making assumptions. Some negative/apologetic language noticed.	Demonstrated many communication techniques, identified areas for self-development and responded to verbal and non-verbal cues with open questions.	Very good communication skills and eye contact. The conversation was well-paced, with appropriate tone of language and relatable donation evidence, such as statistics. Verbal and non-verbal cues were acknowledged and responded to with curiosity and meaningful engagement, mirroring the family. Use of informational Digital Link (IDL).	Excellent communication skills. Avoiding jargon. Use of positive language tailored and responsive to the family's needs. Confidently and empathetically handled objections, using advanced communication techniques and active listening to address concerns and building trust and enabling informed, lasting decisions. Use of informational Digital Link (IDL) and other information resources (leaflets etc) to support the family where appropriate.

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Information about donation benefits	No benefits of donation were shared.	Rarity or helping others was mentioned but lacked further detail.	Discussed at least one positive benefit of donation meaningfully, such as rarity, recipient benefit, family comfort or legacy.	Provided clear examples of donation benefits with understandable detailed explanations.	Benefit information was tailored, with relatable, and tangible, information, with agility in offering alternative information demonstrated, when the initial approach was ineffective.	Ability to read the family's emotions (verbal/non-verbal), advocated for both donor families and recipients, and tailored information to the specific region or hospital, allowing families to envisage the benefits and comfort of the legacy of donation.
Legislation ODR/Deemed/ HQR	Memorised the inclusion and exclusion criteria for deemed consent/ authorisation.	Demonstrates understanding of the safeguards of inclusion and exclusion criteria.	Demonstrate explanation of deemed legislation to enable understanding by ICU colleagues and family during planning and approach conversations.	Facilitate the donation conversation by smoothly transitioning from breaking bad news, while adeptly addressing concerns and managing objections.	Evaluated an ethical dilemma, interpreting the significance of the deemed consent law where applicable, and demonstrated how this legislation can alleviate the burden of decision-making. Positive and presumptive approach demonstrated.	Creatively engaged the family in organ donation discussions, addressing concerns with innovative solutions. Know when legislation is/or is not meaningful and demonstrates the ability to flex to the individual's values and beliefs. Positive and presumptive approach demonstrated.
Responsive to family concerns	Provided some troubleshooting though the concerns were not fully resolved. The conversation lacked breadth and remained narrowly focused.	Response is limited to sympathy or normalisation overlooking concerns raised.	Responded with closed questions, attempting to problem-solve without understanding the real concern.	Explored responses with open ended questions and addressed concerns using clean language techniques to understand perspectives. p106	Sought to understand the family's beliefs, values, experiences, and perspectives, exploring concerns sensitively and supporting their priorities.	Demonstrates advanced listening, agility in handling and exploring objections. Addressing unspoken concerns and questions effectively. Patient centred focus.
Decision making skills	Seeks to understand patient's donation preferences upfront, creating decision-making pressure resulting in a potential knee-jerk reactive grief response.	Inquired about the donor's decision and/or the family's preferences regards donation.	Considered donor's values and beliefs for decision-making and family's future comfort. Addressed initial reactions appropriately.	Advocated for informed or enduring decision making, based on values and beliefs of the donor, inclusive of the family unit. Explored early reactions appropriately.	Enabled family to make value-based, proactive, lasting, and informed decision for the donor, while sensitively exploring initial responses and addressing cognitive and emotional needs.	Used positive language to help the family honour their loved one's decision. Demonstrating agility and responsiveness, during the family interaction.

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Consent /authorisation form completion and the supportive conversation	With support, the consent form was completed; further confidence could be developed in explaining all elements clearly to the family.	The consent form was completed with support, with growing confidence in explaining information clearly to the family as understanding develops.	Completed the consent form in line with legal and regulatory requirements, using it to support and structure the conversation while addressing family questions. Demonstrated an ability to introduce research opportunities, with scope to expand on detail and further explore family understanding and concerns.	Demonstrated confident and structured completion of the consent process, using experience and clinical insight to guide a clear, responsive, and individualised conversation.	Demonstrates completion of the consent form meeting legal and regulatory requirements. Is able to construct a bespoke consent conversation and form completion based on intuition and previous experience. Has a big picture vision and can manage complexities of the form completion in a one donor ethos with some ease.	Demonstrate an ability to read the family in an intuitive manner, personalising the conversation and form meeting the legal and regulatory requirements. There is a deep grasp of the situation and demonstrates a creative and curious response to concerns and family needs.
Research	Confidence in discussing research could be further developed, particularly in responding to questions and addressing concerns.	Initial responses to research-related questions were offered, with opportunities to further develop understanding and confidence in addressing family concerns.	Demonstrated an ability to introduce research opportunities, with scope to expand on detail and further explore family understanding and concerns.	Effectively integrates research into consent/authorisation discussions, aligning with donor ethos. Uses open-ended questions and strong communication to explore concerns, securing tailored consent even in the face of initial hesitancy.	Integrated discussion of research into the consent conversation, using effective communication strategies to explore concerns and support consideration of available options, supported by the considered use of family information leaflets to aid understanding.	Skilfully reads families' emotional cues, using positive, tailored language to engage them in research. Demonstrates agility in conversation and provides relatable evidence of research impact on donation and transplantation. Communicates study knowledge with clarity and relevance to the family.
Management plan	Early development of a structured management plan was evident, with opportunities to further strengthen forward planning and broader consideration of the situation.	Recognises the complexity of the donation pathway, with opportunity to further develop a broader perspective and integrate multiple priorities into planning.	Demonstrated the ability to develop clear clinical and operational plans, showing growing confidence in prioritisation, adaptability, and managing the complexities of the donation pathway.	Developed a clear and confident management plan, demonstrating the ability to prioritise effectively and consider the broader clinical, operational, and family context.	Demonstrates intuition and confidence in constructing a management plan. Ability to justify and stand by their decisions made. With a clear vision of the big picture, they effectively act on priorities and manage complexities with ease.	Developed a comprehensive and responsive management plan, demonstrating innovation and adaptability in addressing the complex clinical, operational, and family needs, with clear awareness of the wider context and long-term impact.

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Figure 41 - A Phronesis Based Evaluation Framework Grounded in Bloom's Taxonomy - for the Donation Approach

How to use the framework: The phronesis-based framework is as a ladder or continuum of practice, where knowledge and wisdom develop over time. At the early stage, as a new Specialist Nurse, practice starts with remembering facts and understanding. As confidence grows, you begin to apply this knowledge in real situations. With more experience, you move to analysing situations, reading families, recognising cues, and understanding complex dynamics. This develops into evaluating, where you weigh up options, make ethical judgements, and decide the best course of action. At the highest level, you reach creating, where your practice becomes fluid and intuitive. Here, phronesis is fully developed combining clinical expertise with emotional intelligence and the ability to read each unique situation, guiding compassionate, skilled decision-making.

When a Specialist Nurse picks up the framework, the first step is simply to look at how it is structured. It sets out six rungs of development, Remember, Understand, Apply, Analyse, Evaluate, Create, and ties those levels to recognisable parts of the donation conversation such as planning with the team, building rapport and end of life care (including faith, culture and traditions), communication, explaining benefits, using legislation well, responding to concerns, decision making, research, completing the consent/authorisation form, and shaping a clear management plan. Seeing these elements laid out together matters because the framework is deliberately designed for both self-directed and peer guided assessment, positioned as a developmental continuum: it gives you a ladder to climb and a shared language to judge where you are today and *what one notch up* looks like next time. It also prompts reflective engagement through Rolfe et al's (2001) reflective cycle and the 'What? So what? Now what?' model and encourages deliberate practice, small, repeated trials in real situations where expert behaviours take root. Before meeting the family, and ahead of planning the breaking bad news and donation approach with the Consultant and bedside nurse, the Specialist Nurse uses the framework for a brief mental run through, either independently or alongside an observing colleague.

A review of the medical records provides essential context: the current clinical picture, which family members are expected, any previously explored end of life, faith or cultural needs, whether donation has already been mentioned, and how prepared the family appears to be in accepting the prognosis. That small act of preparation, shaped by Chapter 4's observation that real conversations sometimes happen in crowded, emotionally charged rooms with unpredictable dynamics and inconsistent cues from the wider clinical team, sets the order of talk the Specialist Nurse will aim for: rapport first, acceptance of what's happening second, followed by tangible and relatable benefits of donation and finally softly framed legislation (if appropriate). This humane sequence avoids what families experience as a *legal bolt on* at the end and replaces it with law introduced earlier but softly, as appropriate and as a support rather than a lever.

These moves reflect what Specialist Nurses in the findings said actually works at the bedside: law framed earlier but gently, not at the last minute where it risks feeling coercive, and an awareness of the 'first no' cliff where recovery is much harder once a blunt refusal has been voiced. Documentation and consent are handled with the same steadying influence. Because the framework names the competencies around consent form completion and the wider management plan, the Specialist Nurse checks that explanations are clear, proportionate and lawful; that deemed consent is described in everyday language that matches the family's values and understanding; and that the plan anticipates what the family will need next as well as what the unit and pathway require. In other words, the framework helps the Specialist Nurse hold the clinical, legal and relational pieces together, as Chapter 4 describes is needed in practice. Immediately after the conversation, the same tool turns the experience into progress. With the Specialist Nurse, the observer as a trusted colleague, conducts a debrief using 'What? So what? Now what?': first a factual replay of what happened and which framework skills were actually used; then the 'so what', why the timing and communication mattered here, including whether an early but soft legal frame prevented a bolt on feel or whether a late mention risked coercion; finally a 'now what', one small, concrete goal for next time, such as moving from a passive planning presence to facilitating a structured planning conversation with clear checkpoints, or shifting from a checklist manner to advanced listening with clean language and appropriate use of the IDL.

The Specialist Nurse also notes any 'gold dust' phrases, actions or sequencing to keep and one development area to practise. Because Specialist Nurses in the findings preferred small, trusted debriefs, to long or performative ones, this swift loop keeps learning psychologically safe and sustainable on a busy shift. Used in this way, good practice looks and feels different. There is a short planning huddle up front so roles, emotional readiness and faith or cultural needs are clear; the conversation itself unfolds in a humane order so families are not surprised by law at the end; the wording lowers threat and preserves agency, with law offered as reassurance, not pressure; the Specialist Nurse is visibly reading and responding to cues rather than reciting a script; the consent explanation is sensitive, lawful and kind; and there is always one small improvement goal captured before moving on. Over time, these small steps move the Specialist Nurse up the framework, from understanding the rules to applying them in practice, and eventually to using judgement and creativity in decision-making. So, expertise is grown in the real conditions where it is needed most. This is precisely the gap the framework was built to close: to make every day work observable, coachable and cumulative, and to translate the best of training into reliable, donor centred conversations in the clinical setting.

Chapter 6. Conclusion and Recommendations

6.1. Introduction

This thesis evaluated the Organ Donation Opt-Out Education Programme (OOEP) introduced alongside England's Organ Donation (Deemed Consent) Act 2019. Using a mixed-methods, complex systems evaluation, combining training evaluations, participant observations, semi-structured interviews, debriefs, and a workforce survey. The programme was found to be carefully designed, effectively implemented, and positively received, despite the disruption caused by COVID-19. Observations in practice showed a variation in how the legislation was referenced or applied, as well as lack of in-depth exploration of cases categorised as 'unsupported deemed consent'. The overall picture confirms that successful implementation rests on human judgement in context as much as on policy design and programme delivery.

6.2. Summary of Findings

Across settings, Specialist Nurses demonstrated a solid grasp of inclusion and exclusion criteria and the safeguards of soft opt-out. Outcomes, however, depended heavily on the Specialist Nurse's emotional and relational approach, communicating with warmth, sensitivity, and respect, supported by thoughtful timing, clear language, and the steady building of rapport and trust. The first 'no' frequently acted as a pivot that was difficult to recover from when legal framing arrived late or felt abrupt. Softer, reassuring phrasing, such as 'no objection' or 'we can consider they would be willing', together with a gentle early explanation of the default, helped ease any sense of pressure, reduce defensiveness, and support families to feel in control of their decision and maintain their sense of autonomy.

Donation after Brain Death (DBD) discussions generally benefited from the certainty provided by an established diagnosis of death, which offered families a clearer clinical context in which to consider donation. This clarity often helped Specialist Nurses guide conversations more confidently and allowed families to process the situation with fewer unknowns. Donation after Circulatory Death (DCD) conversations, by contrast, frequently involved greater uncertainty, including unpredictability around the timing of death, concerns about whether circulation would cease within the required timeframe, and the emotional weight of discussing donation before death had formally occurred. Families in DCD settings conveyed a sense of uncertainty about the process, with one family describing it as having 'too many ifs and buts,' capturing how the unpredictability inherent in DCD can heighten emotional complexity and influence readiness to consider donation. This meant that the transition from breaking bad news into donation discussions required particularly careful handling, with Specialist Nurses sensitively managing expectations, pacing the conversation in line with families' emotional readiness, and offering clear, steady reassurance amid the inherent uncertainty.

Across both DBD and DCD contexts, Specialist Nurses' visibility and presence on the unit, combined with early contact with families and collaborative planning with Consultants, Clinical Leads for Organ Donation, and bedside nurses, consistently supported higher-quality, more trusting discussions. Being physically present, building rapport early, and working as part of a coordinated 'triumvirate' approach helped families feel supported and informed, and created a more seamless transition into conversations about organ donation. Compounding these challenges was the public awareness gap created by the COVID-19 pandemic, which muted understanding of the legislation across both families and healthcare professionals. Many families had little or no knowledge of the law change, and some colleagues were uncertain about how or when it should be referenced. As a result, Specialist Nurses often found themselves needing to explain the legislation from first principles and address misconceptions at the bedside. This additional educational burden sometimes reduced confidence in raising the law and made myth-busting a more frequent part of early conversations with families.

6.3. Contribution to Knowledge

First, the thesis offers a *phronesis*-based assessment framework (Fig 37) that makes expert communication behaviours observable, coachable, and assessable. Grounded in Bloom's Taxonomy, the framework describes progression from remembering and understanding through applying, analysing, evaluating, and creating, and provides explicit criteria to guide debriefs and reflective practice. This addresses the recognised problem of subjective peer review by introducing a shared, aspirational continuum of best practice.

Second, the study explains how the SEDA model, Situation, Evaluation, Decision, Action, can be used to structure simulation scenarios in a way that allows the level of complexity to be adjusted up or down to test judgement under uncertainty. This approach develops realistic decision-making skills rather than encouraging script-following and supports stronger transfer from training into real-world practice. Third, the thesis introduces and develops the concept of the *moveable middle* within soft opt-out organ donation systems. While the notion of an ambivalent middle group appears in other behavioural contexts, this thesis establishes its relevance, scale, and practical implications for family decision-making under deemed consent. While some families held strongly polarised views, either clearly in favour or clearly against donation, such as the partner who objected due to deep concerns about bodily integrity (not wanting his partner cut up like a jigsaw) many families occupied an uncertain space where outcomes were not fixed. Positioned within the *moveable middle* were 3 expressed known decisions not to donate. Such expressed known decisions warrant sensitive, curious exploration rather than immediate closure. Because the law is permissive rather than mandatory, the shift to soft opt-out legislation has brought limited change in practice. Verbal expressions of a patient's wishes continue to act as a decisive loophole. Despite only 3.9% of individuals formally opting out via the Organ Donor Register, 20.3% of refusals are attributed to patients' prior verbal objection.

Also, allowing the *last known decision* to unfold within an information-rich, supportive conversation gives families the time and clarity needed to reach a considered, enduring decision, protecting autonomy and reducing the risk of later regret. By describing how language, sequencing, and timing help families feel safe, this thesis shows that legislation works best as conversational support rather than a coercive tool (lever). This is particularly important in Donation after Circulatory Death, where uncertainty is highest. In these situations, carefully linking the delivery of bad news to conversations about donation, using warmth, clarity, reassurance, and relational presence, helps families understand what is happening and engage meaningfully in decision-making.

Because soft opt-out legislation is permissive rather than mandatory, it has resulted in limited practical change for policy and practice. At the bedside, the aim is not to establish a refusal but to support families in reaching an informed and enduring decision that a reasonable person would consider consistent with the individual's wishes. Discussions about any last known decision should therefore feel collaborative rather than investigative, grounded in a dual-advocacy approach that holds equal regard for the potential donor, their family, and those who may benefit from transplantation. Being explicit about this can help, as questions are asked not to dispute the family's account, but to ensure decisions are accurate, fully informed, and unlikely to lead to later regret. This is especially important because verbal expressions of not wishing to donate may occur early during periods of shock or emotional overload and may not represent a settled or considered decision. This finding is consistent with Rodrigue's et al (2008), who reported that approximately one third of families later regretted decisions not to donate, suggesting that initial refusals may reflect acute emotional states rather than enduring preferences. Yet such verbal statements carry significant weight in practice; although only 3.9% of the population has formally opted out, 20.3% of refusals are attributed to prior verbal objections from the patient. Reference to the legislation should be used judiciously and only where it genuinely adds value. A more supportive approach is to build rapport and connection first, acknowledge the family's emotional state, outline the potential benefits of donation, and then offer a simple, clear explanation how *the principle of not opting out is understood as an indication that someone was willing to help save the lives of others*. This may reduce perceived burden and help the family consider what the person was likely to have supported. The gentler sequencing helps families express what they know without pressure and supports a more reflective decision. Using soft, reassuring language and avoiding sudden, late references to the law can further protect families' sense of autonomy and trust. This approach is underpinned by a professional expectation that families are given the information they need, that conversations are carried out with sensitivity to their circumstances, and that the dignity of the person who has died is upheld throughout. In practical terms, that means pacing the discussion in line with the family's emotional readiness, using warm, respectful language, and inviting narrative rather than eliciting a quick or knee-jerk yes-or-no.

When uncertainty remains, offering clear, bite-sized information, allows time to reflect, and check understanding so that any decision, support or decline, is based on what is known, not on absence of information

6.4. Recommendations

It is recommended that peer review processes be formally instituted and expanded at a national level. This will be achieved by adopting a standardised *phronesis*-based assessment framework (Fig.41), underpinned by *phronesis* and Bloom's taxonomy. The framework embeds structured guided debriefs and supports the use of an approach-skills logs to make developmental progression visible, consistent, and measurable across teams and regions. Learning should be further strengthened through the implementation of structured shared-practice sessions, supported by a national library of SEDA-aligned scenarios with adjustable levels of complexity. This would enable teams to refine adaptive decision-making and develop sophisticated, flexible communication strategies under varying degrees of emotional and operational pressure. Specialist input from linguistic and communication experts should be incorporated to enhance Specialist Nurses proficiency in active listening, interpretation of verbal and non-verbal cues, and the calibrated use of timing, building rapport and trust through patient and family centred compassionate communication, This expert guidance would support Specialist Nurses in effectively bridging from breaking bad news to discussing organ donation, employing purposeful pauses, and using clear, plain-language and soft legal framing.

The approach should avoid overly formal or legalistic terminology and instead position the law as a source of support and reassurance rather than pressure, particularly during Donation after Circulatory Death (DCD) transitions, where clarity and sensitivity are essential. Within these conversations, it remains essential to allow the last known decision to unfold gradually at the family's pace. Teaching the *moveable middle* explicitly encourages teams to approach expressed known decisions with curiosity instead of defaulting to premature closure, helping to prevent knee-jerk refusals made in emotional overwhelm, reduce later regret, and support decisions that genuinely reflect the individual's wishes. Psychologically safe debriefs should continue as a core component of practice, while training should be co-created and facilitated with experienced Professional Development Specialists and Specialist Requesters acting as coaches to reduce exposure gaps and strengthen approach skills. Finally, enhance Potential Donor Audit data to differentiate firm, well-narrated refusals from surface, reactive refusals, and to record when awareness, or misunderstanding, of the law has shaped the outcome. Particular care is needed in cases labelled 'unsupported deemed consent,' ensuring the record clearly reflects whether and how the law was referenced during the approach so that cases are not inaccurately coded simply because the law was never mentioned. This level of precision will generate higher-quality feedback and drive sustained, data-informed improvements in practice.

6.5. Study Limitations

Although based on ten observations, the study generated detailed insights that were strengthened through triangulation across multiple data sources, including evaluation scores, semi-structured interviews, debriefs, and a whole workforce survey. These complementary methods enhanced the credibility of the findings by capturing both observed practice and participant reflection. Nevertheless, the findings should be interpreted within the specific organisational and legislative context, alongside the potential influence of being observed in sensitive clinical situations. As an embedded practitioner researcher, reflexive steps were taken to reduce bias, though this remains an inherent consideration. Practical constraints also shaped data capture; notes could not be taken in real time during family conversations, meaning some finer aspects of interaction may not have been fully documented, and retrospective debriefs may have been affected by recall. While these limitations are typical of real-world clinical research, they also highlight opportunities for further work, including larger and more diverse samples, extended observation periods, enhanced data capture, and the inclusion of additional observers to further strengthen rigour and transferability.

6.6. Future Research

Further work is in progress, to pilot and refine the assessment framework as it is used in practice. A multi-region pilot aims to assess changes in competence, the narrative quality of declines, and how well learning is sustained over time, alongside improving data capture within the Potential Donor Audit, including whether legislation was referenced and how decisions are expressed. In parallel, the phronesis-based assessment framework should be explored within recruitment to test whether simulation can help identify strong candidates by revealing practical judgement and relational skill in action. This work will also focus on strengthening approaches to the *moveable middle*, those who are hesitant about donation. Using this evidence base within training could support Specialist Nurses to provide the right information, at the right time, in a way that builds understanding and confidence, helping families move towards donation where this aligns with their values.

Building on this, further research could include a linguistics-led analysis of the transition from breaking bad news into donation, with attention to DCD and DBD, to identify effective sequencing, pauses, and language choices. Comparative studies, such as testing SEDA-based scenarios against standard role-play, could examine impact on decision-making and transfer to practice. Finally, prospective classification of undecided and expressed-decision cases would allow exploration of whether early, softly framed legal context and targeted information influence outcomes without increasing perceptions of pressure.

6.7. Dissemination

I am fortunate to have had the opportunity to actively disseminate my research through multiple peer-reviewed and professional platforms. Findings have been shared in an accepted British Journal of Nursing paper, *From Legislation to Action: Measuring Success in Specialist Nurse Education and Training*, alongside additional modular evaluation publications. My work has also been recognised through a global Learning and Performance Institute Gold Award for Learning Leader of the Year, acknowledging leadership during the opt-out transition through COVID.

Further dissemination has included UK conference presentations, an online presentation delivered to audiences in Switzerland, and, most recently, an invited international presentation in Japan showcasing the research and the assessment framework. These activities, detailed in Section V at the beginning of the thesis, continue to extend the impact of the work and build communities of learning across diverse practice settings.

6.8. Conclusion

There is no single lever, neither law nor training alone, that can deliver the full potential of soft opt-out. Success depends on skilled Specialist Nurses and Requesters practicing compassionately, within supportive healthcare systems. The law is most effective as a subtle conversational support; timing, tone, and language determine whether families feel safe enough to engage. The moveable middle is often larger than it first appears, as some early refusals reflect immediate emotional reactions rather than considered decisions. The assessment framework grounded in *phronesis*, Bloom's Taxonomy and the SEDA-based approach to scenario design offer practical means to teach, coach, and measure the expert judgements that matter. Approaches to policy and practice should allow space for decisions to unfold, rather than forcing immediate binary choices. Documentation should also distinguish between firm refusals and initial or tentative responses that may benefit from sensitive, non-pressured, curiosity and exploration. Information is not coercion; it is the ethical basis for informed, enduring decisions that honour the person, protect families from later regret, and enable more lives to be saved and improved through transplantation.

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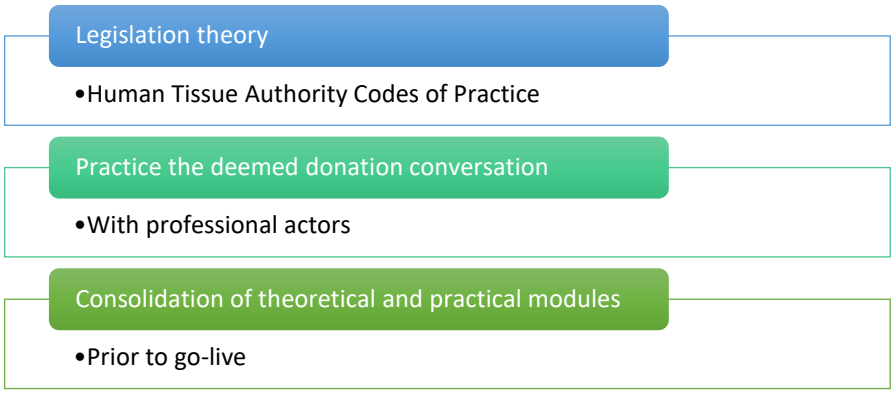
Appendices

Appendix 1 - Population, Intervention, Comparator and Outcome (PICO) framework

P	**Patient Population or problem**	Worldwide shortage for donor organs for transplantation. To help overcome this shortage several countries have introduced a deemed consent/opt-out system for organ donation. The new consent arrangements enacted on May 20th, 2020, mean that all adults over 18 will be considered potential organ and tissue donors after death, unless they decide that they do not want to be a donor, they have nominated a representative to make a decision on their behalf after death, or are in a safeguarded group. Although the law has changed and consent can be deemed, it is a 'soft' opt-out system and families will continue to be involved in discussions before organ and tissue donation can proceed. It is the role of NHS Blood and Transplants (NHSBT) Specialist Nurses in Organ Donation (Specialist Nurses) to speak with families about organ donation and seek support for organ donation. Whilst there are around 500,000 deaths per year in UK, only a very small (1%) of the population ever die in circumstances on critical care, where donation is possible. Organ donation is therefore a rare and precious gift. The potential donors themselves will either be declared dead using neurological criteria or their death will be imminent on futility grounds. These patients are nursed in hospital on a critical care unit. The problem is that the introduction of deemed consent legislation changes the way that **Specialist Nurses** broach organ and tissue donation with the potential donor families.
I	**Intervention Prognostic Factor or Exposure**	To prepare Specialist Nurses for the implementation of the opt-out law change, a specifically designed tri-modular education programme was designed, tested, delivered, and evaluated by NHSBT under the direction of the Department of Health and Social Care (DHSC). The **tri-modular education and training intervention** consisted of:

<table>
<tr><td></td><td></td><td> 
</td></tr>
<tr><td>C</td><td>Comparison or Intervention (if appropriate)</td><td>Comparison of other countries educational approach or model for implementing an opt-out legislation change</td></tr>
<tr><td>O</td><td>Outcome you would like to measure or achieve</td><td>Process evaluation:
To show how well (or not) the deemed consent education and training programme designed for the complex law change, translated in clinical practice.
To what extent it was implemented as designed, within an already complex healthcare system</td></tr>
<tr><td></td><td>What type of question are you asking?</td><td>Was the deemed consent education and training programme for the legislation change in England implemented effectively?</td></tr>
<tr><td></td><td>Type of study you want to find?</td><td>What would be the best study design/methodology?<table><tr><th>Inclusion</th><th>Exclusion</th></tr><tr><td>Empirical research only</td><td>Anything other than empirical research</td></tr><tr><td>Studies since 2015 – introduction of deemed legislation in Wales</td><td>Studies pre 2015</td></tr><tr><td>Ethical aspects</td><td>Editorials/Commentary</td></tr><tr><td>Factors influencing consent</td><td></td></tr><tr><td>Mandated choice as opposed to opt out</td><td></td></tr><tr><td>Other Countries experiences</td><td></td></tr></table></td></tr>
</table>

		Presumed consent policy versus opt in	
		Comparison studies – opt in versus opt out	
		Education – Health care professionals	
		Public awareness	
	Primary question types?	Did the education strategy designed for the Specialist Nurses Organ and Tissue Donation covering the introduction of the new deemed consent legislation in England work?	

Appendix 2 - Search strategy focussed on the reason for the organ shortage and how opt-out aims to address the shortage

# CINAHL	Query	Limiters/Expanders	Last Run Via	Results
S6	S4 AND S5	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	275
S5	‘organ donor’ OR ‘organ Donation’	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S4	‘deemed consent’ OR ‘presumed consent’ OR ‘opt out’	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S3	S1 AND S2	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	275
S2	‘organ donor’ OR ‘organ Donation’	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	9,265
S1	‘deemed consent’ OR ‘presumed consent’ OR ‘opt out’	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	1,418

Ovid Emcare <1995 to 2023 Week 07>

1 organ donor/ 5080

2 'deemed consent'.mp. 29

3 'opt out'.mp. 1179

4 'presumed consent'.mp. 195

5 2 or 3 or 4 1340

6 1 and 5 162

Embase <1974 to 2023 February 24>

1 organ donor/ 29775

2 presumed consent.mp. 492

3 deemed consent.mp. 42

4 'opt out'.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word] 3137

5 2 or 3 or 4 3563

6 1 and 5 368

7 6 368

8 limit 7 to english language 341

9 organ donor/ 29775

10 deemed consent.mp. 42

11 presumed consent.mp. 492

Ovid Emcare <1995 to 2023 Week 07>

1 organ donor/ 5080

2 'deemed consent'.mp. 29

3 'opt out'.mp. 1179

4 'presumed consent'.mp. 195

5 2 or 3 or 4 1340

6 1 and 5 162

Embase <1974 to 2023 February 24>

1 organ donor/ 29775

2 presumed consent.mp. 492

3 deemed consent.mp. 42

4 'opt out'.mp. [mp=title, abstract, heading word, drug trade name, original title, device manufacturer, drug manufacturer, device trade name, keyword heading word, floating subheading word, candidate term word] 3137

5 2 or 3 or 4 3563

6 1 and 5 368

7 6 368

8 limit 7 to english language 341

9 organ donor/ 29775

10 deemed consent.mp. 42

11 presumed consent.mp. 492

12 'opt out'.mp. 3137
13 10 or 11 or 12 3563
14 9 and 13 368
15 14 368
16 limit 15 to english language 341
Ovid MEDLINE(R) ALL <1946 to February 24, 2023>
1 organ donor/ 43586
2 presumed consent.mp. 775
3 deemed consent.mp. 31
4 'opt out'.mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word] 2004
5 2 or 3 or 4 2696
6 1 and 5 404
7 6 404
8 limit 7 to english language 378
9 organ donor/ 43586
10 deemed consent.mp. 31
11 presumed consent.mp. 775
12 'opt out'.mp. 2004
13 10 or 11 or 12 2696
14 9 and 13 404
15 14 404
16 limit 15 to english language 341
Ovid MEDLINE(R) ALL <1946 to February 24, 2023>
1 organ donor/ 43586
2 presumed consent.mp. 775
3 deemed consent.mp. 31
4 'opt out'.mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating sub-heading word, keyword heading word, organism supplementary concept word, protocol supplementary concept word, rare disease supplementary concept word, unique identifier, synonyms, population supplementary concept word, anatomy supplementary concept word] 2004
5 2 or 3 or 4 2696
6 1 and 5 404
7 limit 15 to english language 378
8 organ donor/ 43586
9 presumed consent.mp. 775
10 deemed consent.mp. 31
11 'opt out'.mp. [mp=title, book title, abstract, original title, name of substance word, subject heading word, floating

Search strategy for APA PsychINfo 3

(MAINSUBJECT.EXACT('Tissue Donation') OR organ donor OR organ donation) AND mainsubject(Education OR Training) AND (presumed consent OR deemed consent OR opt out OR opt in)

Search strategy for BNI

Set#: S2

Searched for: MAINSUBJECT.EXACT('Blood & organ donations') AND (deemed consent OR presumed consent OR opt-out OR opt in) AND (Education or training or medical education or Nurs* Education or healthcare professional education)

Databases: British Nursing Index

Results: 102

Search strategy for CINAHL 262

Search strategy for APA PsychINfo 3

(MAINSUBJECT.EXACT('Tissue Donation') OR organ donor OR organ donation) AND mainsubject(Education OR Training) AND (presumed consent OR deemed consent OR opt out OR opt in)

Search strategy for BNI

Set#: S2

Searched for: MAINSUBJECT.EXACT('Blood & organ donations') AND (deemed consent OR presumed consent OR opt-out OR opt in) AND (Education or training or medical education or Nurs* Education or healthcare professional education)

Databases: British Nursing Index

Results: 102

Search strategy for CINAHL 262

EBSCOhost

Wednesday, October 11, 2023 10:24:37 AM

#	Query	Limiters/Expanders	Last Run Via	Results
S10	S6 AND S9	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S9	S7 OR S8	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S8	(MH "Communication Skills Training") OR "Training"	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S7	(MH "Education+") OR (MH "Education, Nursing+") OR (MH "Education, Medical+") OR (MH "Education, Clinical+")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S6	S1 AND S5	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S5	S2 OR S4	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S4	(MH "Organ Donation")	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S3	S1 AND S2	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S2	"organ donor" OR "organ Donation"	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display
S1	"deemed consent" OR "presumed consent" OR "opt out"	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - CINAHL	Display

Search Strategy - Ovid MEDLINE(R) ALL <1946 to September 28, 2023>

1 'Tissue and Organ Procurement'/ 20863

2 Presumed Consent/ 575

3 Deemed consent.mp. 36

4 'opt-out'.mp. 2092

5 2 or 3 or 4 2618

6 1 and 5 534

7 Education, Nursing/ or Education, Medical/ or Education/ 116171

8 Training.mp. 597222

9 7 or 8 692646

10 6 and 9 20

Search Strategy Ovid Emcare <1995 to 2023 Week 38>

1 organ donor/ 5118

2 'deemed consent'.mp. 34

3 'opt out'.mp. 1247

4 'presumed consent'.mp. 202

5 2 or 3 or 4 1418

6 1 and 5 166

7 clinical education/ or 'outcome of education'/ or nursing education/ or medical education/ or education/ 261865

8 nurse training/ or training/ 33775

9 7 or 8 290061

10 6 and 9 14

Search Strategy Embase <1974 to 2023 September 28>

1 'Tissue and Organ Procurement'/ 120666

2 Presumed Consent/ 133947

3 Deemed consent.mp. 46

4 'opt-out'.mp. 3240

5 2 or 3 or 4 136764

6 1 and 5 2182

7 Education, Nursing/ or Education, Medical/ or Education/ 723212

8 Training.mp. 846956

9 7 or 8 1423017

10 6 and 9 126

7 or 8 692646

10 6 and 9 20

Search Strategy Ovid Emcare <1995 to 2023 Week 38>

1 organ donor/ 5118

2 'deemed consent'.mp. 34

3 'opt out'.mp. 1247

4 'presumed consent'.mp. 202

5 2 or 3 or 4 1418

6 1 and 5 166

7 clinical education/ or 'outcome of education'/ or nursing education/ or medical education/ or education/ 261865

8 nurse training/ or training/ 33775

9 7 or 8 290061

10 6 and 9 14

Appendix 4 - Applying concepts from systems thinking and complexity science in a process evaluation

.	Concept	Definition	Process evaluation from a complex systems perspective	Methods
Phase 1: A static system description (informed by systems thinking)	Elements	Entities within a system, include for example: people (agents) organisations, resources etc.	Identify components of the system begin a master list of system elements. **Specialist Nurses-Organ and Tissue Donation** **Legislation Change Team** **Public** **Department of Health** **Human Tissue Authority** **Opt-out Project team** **NHS Blood & Transplant Project Board** **Clinical Leads in Organ Donation** **Faith Leaders** **NHS App**	Concepts from systems thinking can be used to develop a **static system description** a range of qualitative data generation methods are helpful to understand and produce a description of the system structure, including interviews, focus groups, workshops, (participant) observation and documentary analysis. For example an evaluator could interview agents within the system to understand their views on
	Boundaries	Decisions about what is included and excluded in the system under observation first order judgements are boundary judgments made by actors within the system	Assess first-order boundary judgments; combined primary data and evaluation considerations (e.g., scope of the evaluation, intended audience, pragmatic issues) to create second order boundary judgement create and revise system map as a tool to guide boundary discussions judgments and depiction.	

		second order judgements are made by the evaluator	**First order:** **Train all Specialist Nurses-Organ (on the on-call rota) to the deemed consent legislation** **Second order:** **Design and Build of Training based on evolving draft Human Authority Codes of Practice (HTA CoP)**	the boundaries of the system, their role within the system and how their activities are influenced by other system elements , historical and contextual factors observe a range of system activities to identify local rules and to assess coherence within the system; and conduct a documentary review (of intervention documents, relevant policies, reports etc.) to understand the history of the system and to situate the system within its broader context.
	Levels	A description of the structure of the system- may or may not be hierarchical	Describe the structure of a system. This can include identifying system levels (considering both vertical and horizontal from dimensions) and exploring the ways in which system elements within and between levels relate and interact with one another. System structures and connections may be depicted in a (bounded) diagram. **Specialist Nurses-Organ and Tissue Donation** **Legislation Change Team** **Regional Team Managers** **Stakeholders e.g., Hub operations, Governance etc** **Public** **Faith Leaders** **Department of Health** **Human Tissue Authority**	
	Relationships	Connexions or interactions between system elements		
	Interactions	How system elements relate to each other and interact across system levels or the broader context		

			NHS Blood and Transplant Project Board	• **Good, Bad & Ugly Workshop** • **Training Needs Analysis** • **Literature Review** • **Documentary Analysis of Evaluations from Continuing Professional Practice Course** • **Organ Donor Register Overrides** • **Consent Rates** • **Reasons for Refusal**
	Perspectives	Different viewpoints of stakeholders within the system	Sample from a range of system elements; identify, assess, and report on a range of viewpoints. **Good, Bad & Ugly Workshop** **Training Needs Analysis** **Operational Temperature Checks-help inform operational readiness**	
	History	The context before initial conditions	Cast evaluative perspective beyond immediate system of inquiry and identify the broader context in which the system is located, as well as the context prior to intervention implementation. • **Literature Review** • **Documentary Analysis of Evaluations from Continuing Professional Practice Course** • **Organ Donor Register Overrides** • **Consent Rates- Reasons for Refusal**	
	Initial Conditions	how the system operates at 'baseline': these initial conditions set as system on a particular trajectory	Output of the initial stage of data collection and analysis; a relatively descriptive account that incorporates above concepts to depict the system of inquiry at a static point in time (often when an intervention is first implemented).	

			A positive/presumptive approach to organ donation is adopted where the patient has opted-in in the Organ Donor Register- the family are supported to honour X's decision to be a donor	• **Public awareness of organ donation**
	Local Rules	The principles that guide interactions and behaviour of system elements	identify 'if' – 'then' statements or rules governing patterns of behaviour in the system and of the system as a whole; used to understand and explain the ways in which interactions between system elements give rise to actions and behaviour in the system. **Best practice Guide for approaching families for organ donation** **Annual Continuing Professional Practice Course** **Regional/Cluster Shared Practice Sessions**	
Phase 2: Analysis of a system undergoing change (informed by	Nonlinearity	Inputs into the system do not necessarily result in correspondingly size effects in the system; nonlinear relationships do not follow simple input-output line	Analyse interactions between systems elements to understand chains of cause and effect; define, draw, and refine a theory of change which describe and depict the processes through which actions results in impacts, incorporating instances of	Concepts from complexity science can be used to **analyse a system undergoing change.** Data collection will have a perspective

complexity science)	Feedback	positive or negative response that may alter the intervention and its impacts. Positive feedback loops: change amplifies further change; negative feedback loops change dampens down further change	feedback; evaluator may wish to draw causal-loop diagrams to visualise feedback loops. **1.4. Analysis of tri- modular evaluation questionnaires** **2.1 Analysis of on-line digital training footage**	element, with data generated longitudinally or at more than one time point in order to assess the ways in which the intervention of the system adapt and co-evolve with each other and that broader context. Qualitative data generation methods may include interview, focus groups, workshops, (participant) observation documentary analysis. These methods can be used to track changes overtime and to understand the process by which change occurs. The data generated can be
	Adaption	Adjustments in system behaviour in response to internal and external change	Over a time, both home in on system elements and widen out evaluative gaze to system as a whole; ask 'how do elements change their interactions with other system elements overtime in response to the intervention?'; 'how does the system change in response to the intervention?'; 'to what extent does the system absorb intervention?'. **Embedding the legislation- deemed consent debriefs** **Monitoring of deemed consent rates**	
	Dynamism	Change in the state of the system that happens over time; time and evolution	Spend sufficient time in the field generating data to analyse system change over time; conceptualise both the system and evaluation as dynamic. **COM-B Behavioural Change Theory**	

			2.2 Participant observation (shadowing) a convenience sample of a potential pool of 28 SNOD's **2.3 Semi-structured interview and debrief following shadowing period** **2.4 Semi-structured interviews offered to all SNOD's**	used to produce the narrative of the system undergoing change that underscores the factors that either amplify or dampen change, how the system and intervention adapt and evolve over time, any unintended consequences and how system elements' interactions generate emergent properties over time. Quantitative methods to measure impact could include interrupted time series analysis system dynamics modelling, agent-based modelling network analysis.
	Emergent Properties	Properties of a complex system that cannot be directly predicted from elements within it and more than just the sum of its parts; collective behaviours	More evaluated focus from system elements to system as a whole and ask: 'what types of system-level properties have emerged overtime following the introduction of the intervention?'; explore system-level properties that cannot be attributed to individual elements.	
	Co-evolution	System changes in response to its environment or another system; both systems change and evolve as a result	Look both vertically and horizontally; look at system elements in the system as a whole and ask: 'in what ways does the system-and the environment it is in-change in response to the intervention?'. **COVID-19 shift from classroom to virtual training delivery**	
	Unintended Consequence's	As a result of nonlinearity and feedback loops complex systems; are characterised	Maintain an open stance and be open to unexpected impacts; follow-up on possible	

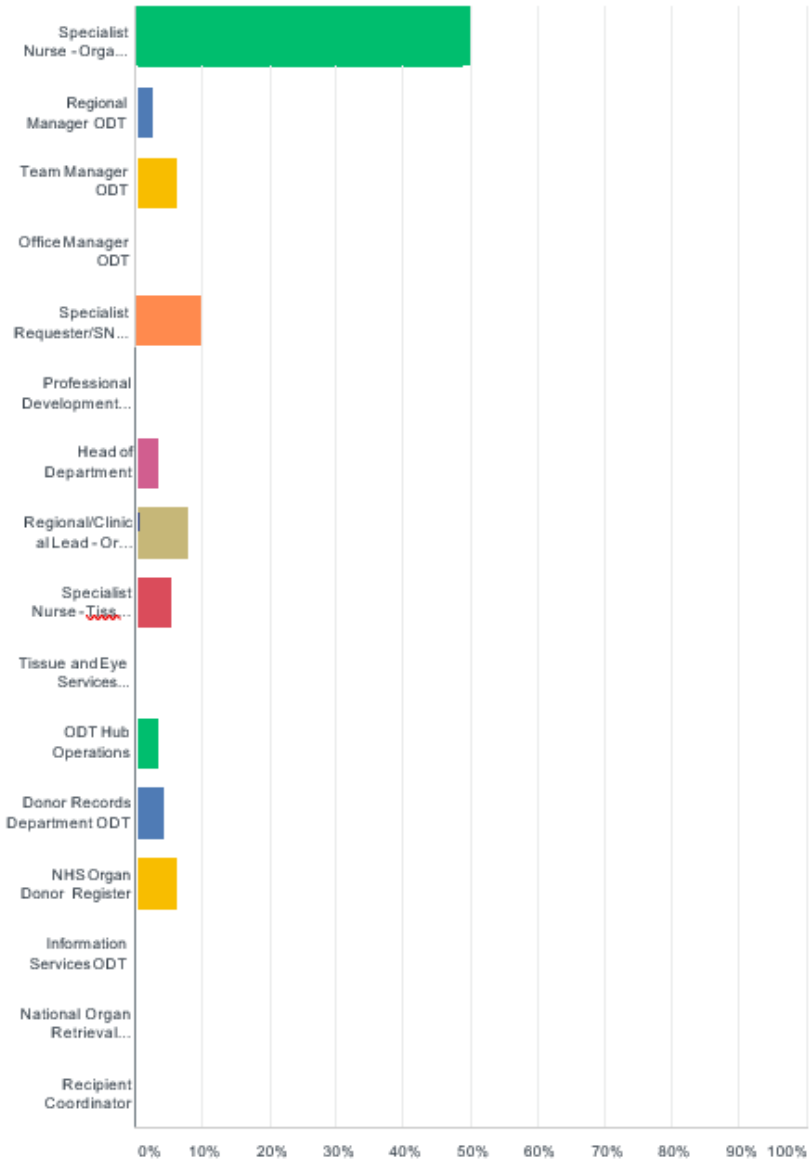
		by unanticipated processes and outcomes	impacts that may not feature in the original theory of change. **Changed the way education and training delivery happens since- heavier focus on on-line delivery**	**2.2 Participant observation (shadowing) a convenience sample of a potential pool of 28 SNOD's** **2.3 Semi-structured interview and debrief following shadowing period** **2.4 Semi-structured interviews offered to all SNOD's**
	System Trajectories	Includes path dependency, attractor state, phase space, phase transition and bifurcation/tipping points. Qualitatively, the path a system follows through time, moving through different states, including periods of stability and instability.	Narrative of a system undergoing change; output of date analysis is a 'system story' that incorporates concepts from systems thinking and complexity science. • **Consult with Donor Family Advisory Group** • **Deemed Approach Framework** • **Review deemed consent rates- note any themes/trends** • **Further embed education and training-Cycle of Continuous improvement**	

Appendix 5 - Training Needs Analysis Survey

Deemed Consent Legislation training needs survey

Q1 Please select the job title that best fits your role in organ donation and transplantation

Answered: 117 Skipped: 0



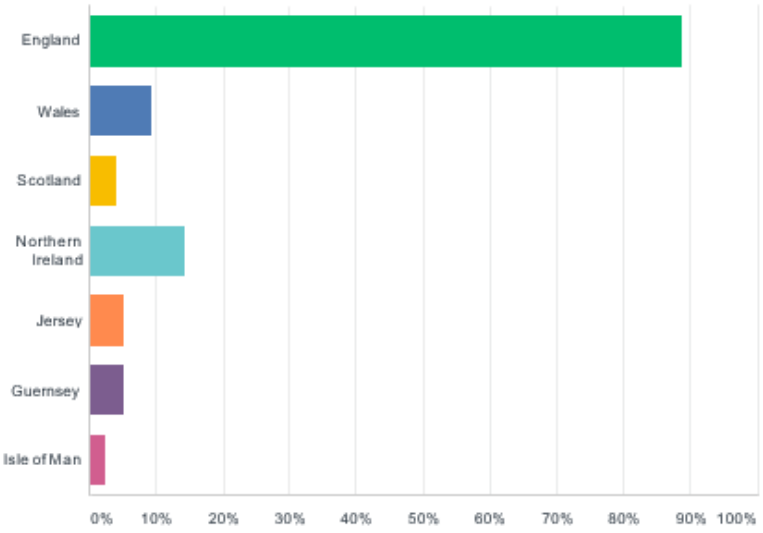
ANSWER CHOICES	RESPONSES

1 / 13

Specialist Nurse - Organ Donation	48.72%	57
Regional Manager ODT	2.56%	3
Team Manager ODT	5.98%	7
Office Manager ODT	0.00%	0
Specialist Requester/SNOD Family Care	9.40%	11
Professional Development Specialist	1.71%	2
Head of Department	3.42%	4
Regional/Clinical Lead - Organ Donation	7.69%	9
Specialist Nurse - Tissue Donation	5.13%	6
Tissue and Eye Services Manager	1.71%	2
ODT Hub Operations	3.42%	4
Donor Records Department ODT	4.27%	5
NHS Organ Donor Register	5.98%	7
Information Services ODT	0.00%	0
National Organ Retrieval Service	0.00%	0
Recipient Coordinator	0.00%	0
TOTAL		117

Q2 In which UK region do you workPlease tick all that apply

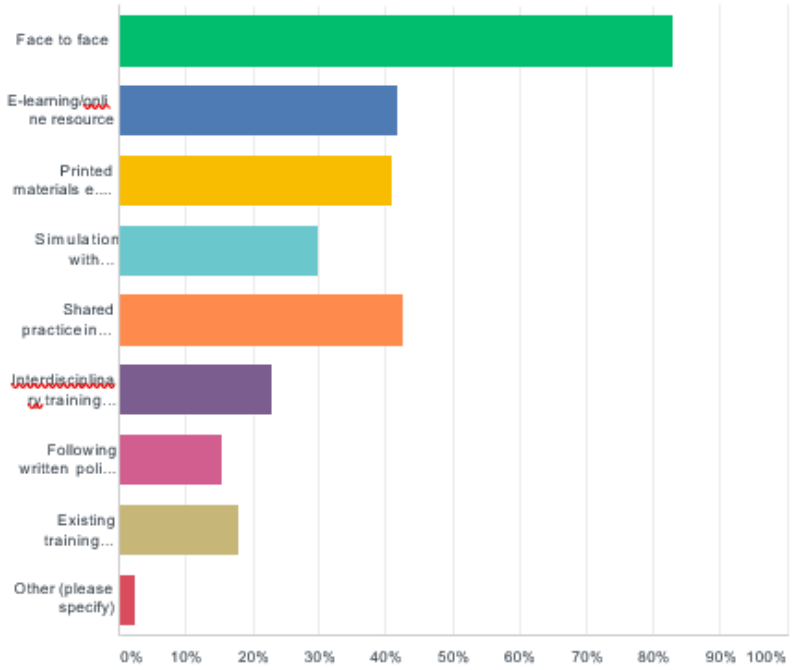
Answered: 117 Skipped: 0



ANSWER CHOICES	RESPONSES	
England	88.89%	104
Wales	9.40%	11
Scotland	4.27%	5
Northern Ireland	14.53%	17
Jersey	5.13%	6
Guernsey	5.13%	6
Isle of Man	2.56%	3
Total Respondents: 117		

Q3 Training Please select your preferred choice(s) for legislation training

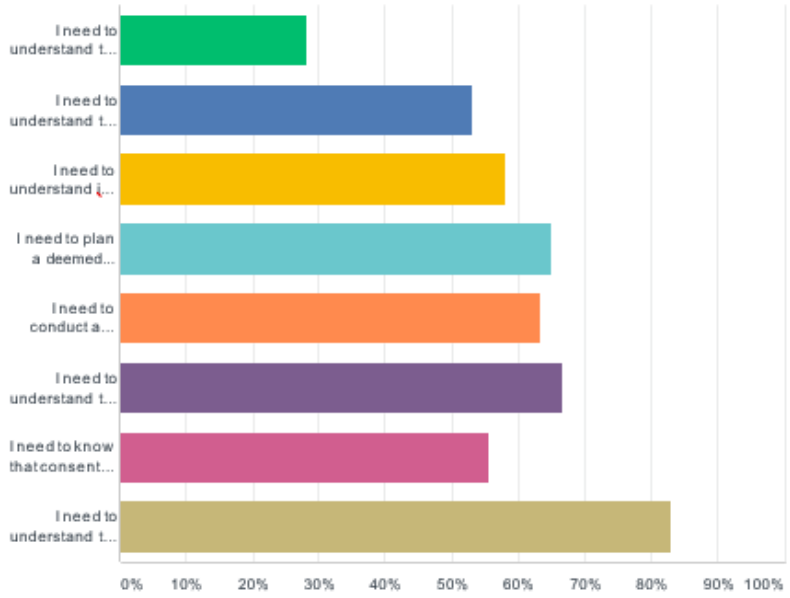
Answered: 117 Skipped: 0



ANSWER CHOICES	RESPONSES	
Face to face	82.91%	97
E-learning/online resource	41.88%	49
Printed materials e.g booklet/flow chart	41.03%	48
Simulation with professional actors/role play	29.91%	35
Shared practice in teams	42.74%	50
Interdisciplinary training e.g. SNODs/CLODs/Tissue Services	23.08%	27
Following written policy and procedures	15.38%	18
Existing training platform e.g. EASY/Shine Academy	17.95%	21
Other (please specify)	2.56%	3
Total Respondents: 117		

Q4 Please outline your involvement regards the deemed consent legislationPlease select all that apply

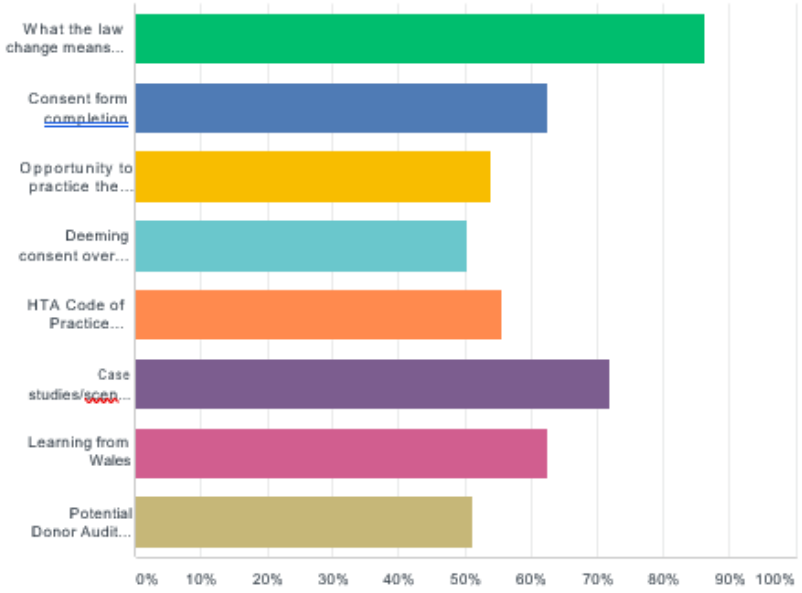
Answered: 117 Skipped: 0



ANSWER CHOICES	RESPONSES	
I need to understand the law, so I can refer potential donors	28.21%	33
I need to understand the law in order to check the Organ Donor Register	52.99%	62
I need to understand if a registered/expressed decision has been made	58.12%	68
I need to plan a deemed consent conversation	64.96%	76
I need to conduct a deemed consent conversation	63.25%	74
I need to understand the legislation to apply it to the decisions I make	66.67%	78
I need to know that consent has been legally secured before retrieval can proceed	55.56%	65
I need to understand the law, in case I am asked about it	82.91%	97
Total Respondents: 117		

Q5 What would you like to see in the legislative changes training package?Please choose whichever apply i.e. some, all or none?

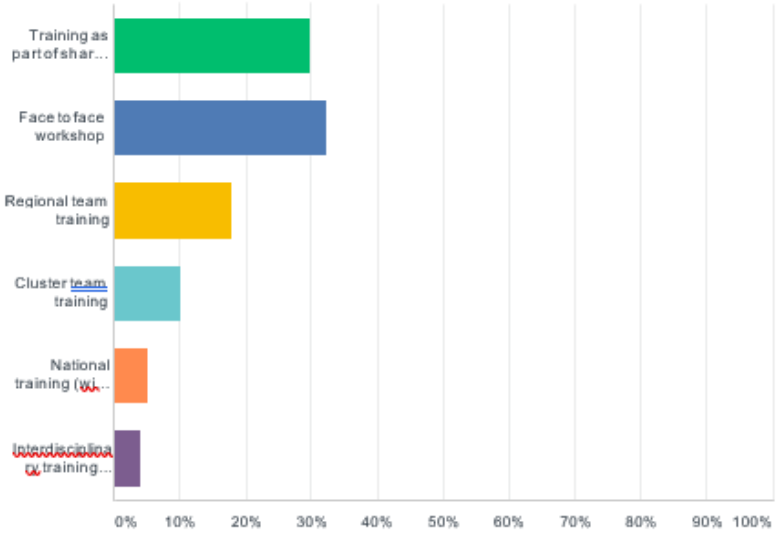
Answered: 117 Skipped: 0



ANSWER CHOICES	RESPONSES	
What the law change means in clinical practice?	86.32%	101
Consent form completion	62.39%	73
Opportunity to practice the deemed consent conversation in a safe environment	53.85%	63
Deeming consent over the telephone	50.43%	59
HTA Code of Practice /Procedural document training	55.56%	65
Case studies/scenarios	71.79%	84
Learning from Wales	62.39%	73
Potential Donor Audit completion (for deemed consent)	51.28%	60
Total Respondents: 117		

Q6 Format of trainingWhat suits you/your team best?

Answered: 117 Skipped: 0



ANSWER CHOICES	RESPONSES	
Training as part of shared practice	29.91%	35
Face to face workshop	32.48%	38
Regional team training	17.95%	21
Cluster team training	10.26%	12
National training (with your colleagues across the UK)	5.13%	6
Interdisciplinary training e.g. SNODs/CLODs/Tissue Services	4.27%	5
TOTAL		117

Q7 Thinking about your specific role in the organisationWhat training/resources will help you understand your role in thelegislation change?

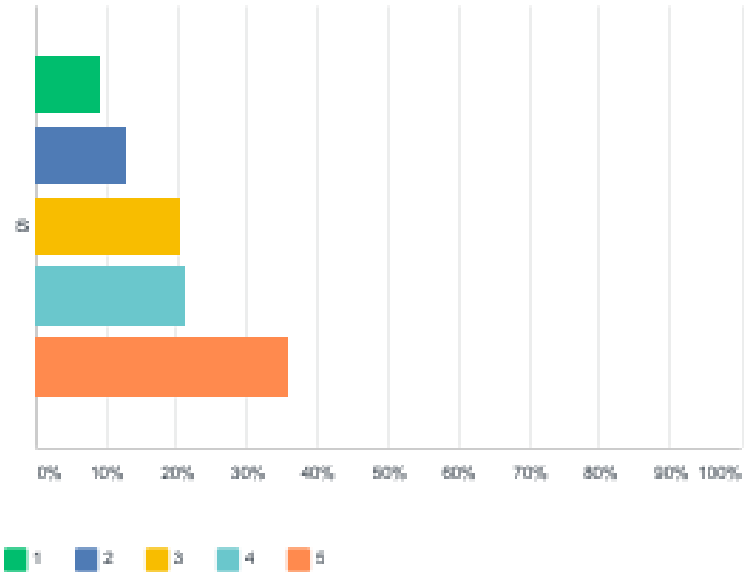
Answered: 117 Skipped: 0

Q8 What region specific training needs do you have?Cross-cover different regions/territories, diverse population etc.

Answered: 117 Skipped: 0

Q9 Please rank your view on face to face training with the opportunity to practice the 'deemed' donation conversation with professional actors1 star being poor and 5 stars being excellent

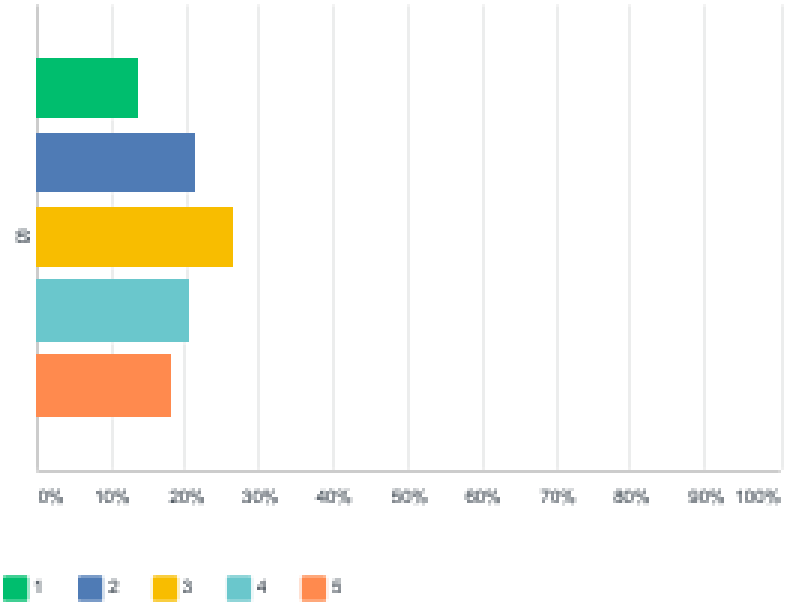
Answered: 117 Skipped: 0



	1	2	3	4	5	TOTAL	WEIGHTED AVERAGE
All	9.40% 11	12.82% 15	20.51% 24	21.37% 25	35.90% 42	117	3.62

Q10 Please rank your view on face to face training with the opportunity to practice the 'deemed' donation conversation without professional actors1 star being poor and 5 stars being excellent

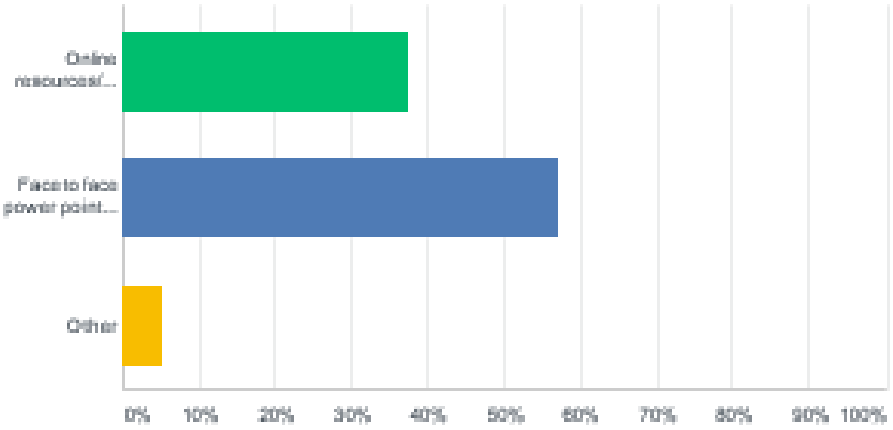
Answered: 117 Skipped: 0



	1	2	3	4	5	TOTAL	WEIGHTED AVERAGE
Q5	13.68% 16	21.37% 25	26.50% 31	20.51% 24	17.95% 21	117	3.08

Q11 Acute Hospital ColleaguesWhat training materials/resources will help in educating our NHS/Health Board Doctors and Nurses?

Answered: 112 Skipped: 5



ANSWER CHOICES	RESPONSES	
Online resources/ e-learning package	37.50%	42
Face to face power point presentation (that can be tweaked/personalised)	57.14%	64
Other	5.36%	6
TOTAL		112

Appendix 6 - Email for Participant Recruitment

UNIVERSITY OF BIRMINGHAM

Email for Participant Recruitment -
Shadowing Specialist Nurse on-call, Debrief and Semi-Structured Interview OR
Semi-Structured interview (if not shadowed on-call)

Study No:

Study title: Evaluation of the Education Intervention for the Deemed Consent Law Change

Dear Specialist Nurse-Organ Donation,

Many thanks for your interest in my research study, to evaluate the education and training delivered to support the implementation of the deemed consent legislation. I hope the presentation I delivered at the team meeting on xxxx provided you with the background information about the study.

In brief, the focus of the research is on the donation conversation, since the deemed consent legislation changed, to understand how the education and training in the classroom transfers into clinical practice. You may re-call my intention is to shadow Specialist Nurses whilst on-call over a period of 3 months. For those Specialist Nurses I do not get the opportunity to shadow on-call, an opportunity of an interview will still be offered. So that all Specialist Nurses will get an opportunity to be involved in the study, should they wish to participate.

I have attached copies of the participant information sheet and consent form, which I'd appreciate you reading, digesting and asking any questions you may have. Once you're comfortable that you want to participate, please email both forms to the researcher [redacted] with your electronic signature added.

There will be an opportunity to go through this information once again and for you to ask any questions when I meet with you on-call or for an interview.

Following the donation conversation observation, there will be an opportunity to debrief and to participate in a semi-structured interview to further assist in understanding about the education and training provided in relation to the law change. The debrief and semi-structured interview should take no longer than 30-40 minutes.

For those Specialist Nurses that the researcher doesn't get opportunity to shadow; they will still be offered the opportunity of an interview which will take approximately 30 minutes.

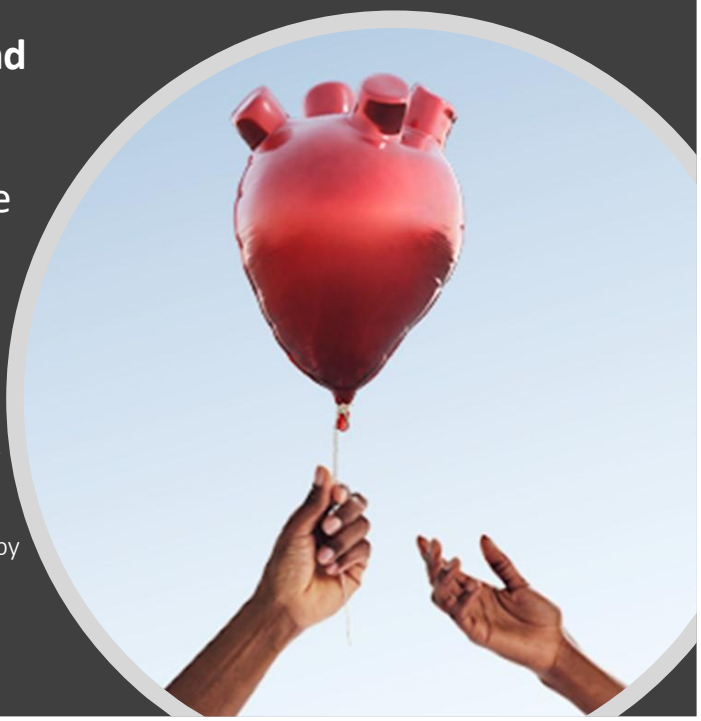
Many thanks for considering,

Cathy Miller.

Appendix 7 - Poster to Recruit Research Participants

The Organ Donation Law in England Has Changed.

Please Share Your Perception of the Education and Training Received



Further Information and an Opportunity to Participate in this Research Study will be provided at the Organ Donation Team Meeting on Tuesday 13 th October 2020.

In the meantime any questions or queries can be raised by contacting the Researcher [redacted]

Appendix 8 - Optional Debrief for Potential Donor Family

UNIVERSITY OF BIRMINGHAM

Optional Debrief for Potential Donor Family

Study title: Evaluation of the Education Intervention for the Deemed Consent Law Change

The purpose of this document is to provide you with further information about the researcher's study (Cathy Miller, an employee of NHS Blood and Transplant), that you met today and kindly allowed to observe the Specialist Nurse having a sensitive conversation with you, following the loss of your loved one. Firstly, please may I offer my sincere condolences, prior to explaining any further details about the research.

The focus of the research is on the Specialist Nurse holding a sensitive end of life donation conversation with potential donor families. The aim of the research is to understand how the education and training in the classroom transfers into clinical practice. We are particularly interested in this after the deemed consent legislation change for organ donation. Observing the Specialist Nurses interaction with you as family member(s) will be valuable in assessing the impact of the education and training that was provided for the Specialist Nurse with regards to the law change.

What is the purpose of the research?

The research is conducted as part of a Doctoral study, sponsored by the University of Birmingham. The purpose of the research is to evaluate the education and training the Specialist Nurses have received for the law change around organ donation. The researcher would like to understand if the education programme worked and how the training helps to enable the Specialist Nurses in supporting potential donor families in the critical care unit at the hospital.

The research will focus on what elements of the training are useful and how could the training be better. The study will explore learning in the classroom being transferred into the hospital setting. The information gained will help to inform and replicate and/or further develop education and training to meet the needs of Specialist Nurses and donor families who are meeting for the first time, in what is often, traumatic, and sudden circumstances. Findings from the research could enhance the current implementation of the law in the UK and support other countries wishing to introduce a new law around organ donation and could help inform other education and training programmes.

Will information used in the study be kept confidential?

Any information observed will be anonymised e.g. approximate age, sex, cause of death, number of people present in the end of life conversation and their relationship with the deceased. So that you are not identifiable. We will keep all information about the research safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that nothing will be attributed to the Specialist Nurse or you as a family member or your loved one by name. The results of the research study will be included within the researcher's doctoral thesis. It is hoped the findings of this research study will be published, so that the information will be made available for other professionals and services to view.

All data will be managed in accordance with the General Data Protection Regulation (GDPR), Data Protection Act (DPA) (2018) and University of Birmingham Research Data Management Policy (2018). After the interview the observation notes will be analysed. Data will be anonymised by using codes on observation transcripts. Data will be protected on the researcher's password protected laptop. The data from the study will be stored in accordance with GDPR guidance and then destroyed confidentially (ten years following study completion).

Appendix 9 - Participant Observation Proforma

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STRUCTURAL PART OF THE DONATION CONVERSATION

Were the following behaviours and language used, ratings are based on the provided Blooms Taxonomy scale (page 8). In the comments space provided for each item, give examples of the behaviour and/or language observed.

1. Was the planning conversation effective i.e., was the deemed consent legislation discussed and reference made to inclusion/exclusion criteria?

Not observed	Yes	No	Comments

2. Were appropriate health care professionals involved in the planning conversation i.e., Specialist Nurse/Consultant/Bedside Nurse?

Not observed	Yes	No	Comments

3. Was the Specialist Nurses role in the planning conversation active or passive, demonstrating negotiation and influencing skills in providing clarity and answer any questions about the deemed legislation?

Not observed	Active	Passive	Comments

4. How many family members were involved in the end-of-life care and donation conversation (document in comments box) and was this appropriate?

Not observed	Yes	No	Comments

5. Breaking bad news - confirming understanding and acceptance of loss. Did the family understand that death was imminent or had been declared?

Not observed	Yes	No	Comments

6. Did the Specialist Nurse check in to see if family have anyone else to support them or come in to say last goodbyes?

Not observed	Yes	No	Comments

7. Did the Specialist Nurse discuss religious/faith/traditions/beliefs/cultural support?

Not observed	Yes	No	Comments

RAPPORT BUILDING

8. When building rapport with the family, did the Specialist Nurse introduce themselves to the family, offering condolences, taking time to ask about the patient as a person - before discussing donation?

Not observed	Yes	No	Comments

9. Did COVID-19 have an impact on communication? i.e. wearing personal protective equipment, consent by telephone/digital means?

Not observed	Yes	No	Comments

10. Did the Specialist Nurse display non-verbal communication skills e.g. reading body language, active listening, conversation encouragers, effective use of pauses, eye contact and appropriate use of touch?

Not observed	Yes	No	Comments

USE OF LEGISLATION IN THE DONATION CONVERSATION

11. Did the Specialist Nurse seamlessly transition into the donation conversation, leading with the benefits of donation versus leading with the law?

Not observed	Yes	No	Comments

12. Did the Specialist Nurse use language around deemed consent such as 'considered' 'willing' to be in 'support' of or 'not opting out' so 'lacking objection' to organ donation etc?

Not observed	Yes	No	Comments

13. Was the Specialist Nurse able to clearly communicate the legislation to the family, clarifying any queries about whose decision it is?

Not observed	Yes	No	Comments

14. Was the Specialist Nurse confident and clear in their communication regards the legislation to the family?

Not observed	Yes	No	Comments

15. Did the family express any thoughts about the legislation (or anything else related to donation) and if so, were they addressed appropriately?

Not observed	Yes	No	Comments

16. Was the Specialist Nurse able to navigate the conversation with the family, showing adaptability in their approach, such as parking the conversation, exploration of misconceptions, clarifying what donation entailed?

Not observed	Yes	No	Comments

17. Was the Specialist Nurse's language around the legislation positive?

Not observed	Yes	No	Comments

18. Was the Specialist Nurse able to deal with challenges and bring the donation decision back to the potential donor?

Not observed	Yes	No	Comments

19.If donation proceeded under deemed consent, where was the consent form signed?

Not observed	Yes	No	Comments

20. When summarising - did the Specialist Nurse mention the legislation as part of consent form completion, whilst offering contact details, keepsakes, family information leaflets, information regarding recipient outcomes?

Not observed	Yes	No	Comments

21.Did the Specialist Nurse complete the consent form before or after the Medical and Social History Questionnaire?

Not observed	Before	After	Comments

Participant observation summary

22. What went particularly well?

23. What would be better if?

Outcome:

Supported Deemed Consent	Unsupported Deemed Consent	Expressed Known Decision	Excluded	Other/Comments

Blooms Taxonomy Level:

Structural Part of the Donation Conversation	Rapport Building	Use of legislation in the donation conversation	Overall Level Rating
1 2 3 4 5 6	1 2 3 4 5 6	1 2 3 4 5 6	1 2 3 4 5 6

Specialist Nurse/Requester being observed:

Print

Sign
Date: **Time:**

Researcher/Observer:

Print
Sign
Date: **Time:**

Appendix 10 - Assessment Guide for Participant Observation

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Were the following behaviours and language used, ratings are based on the provided Blooms Taxonomy scale. In the comments space provided for each item, give examples of the behaviour and/or language observed.

STRUCTURAL PART OF THE CONVERSATION	
Question	**Examples of the behaviour and/or language expected**
1. How effective was the planning conversation; were appropriate health care professional's involved?	• Did the Specialist Nurse consider the following as part of the planning conversation? • Organ Donor Register checked • Establish the team: Consultant, Specialist Nurse, and Bedside Nurse • Coroner involvement • Consultant plan (Neurological Death Tests/Withdrawal of Life Sustaining Treatment) • Conversations to date and family perception of the situation • Meet in private, allow time • Clarify clinical situation • Key family members by name • Family dynamics, spokesperson, Next of Kin • Who will be in the room? • Faith, belief and cultural considerations • Barriers to communication i.e. interpreter required • Agree timing of conversation (Specialist Nurse time to build a relationship / assess the family's readiness to discuss donation) • Agree a process of approach and who will be involved • How will team members be introduced? • Who will lead the initial discussion (breaking bad news)? • How will the transition to donation be made / by whom? • Discuss decoupling with the consultant in the planning conversation, in case the conversation is moving too fast- the Consultant can break bad news and you can come out of the room and talk about how the family's readiness to discuss End of Life care. • Explain the use of pauses and silences-to help ensure they are not filled by a well-meaning colleague

2. Was the Specialist Nurses role in the planning conversation active or passive?	Did the Specialist Nurse actively influence the planning conversation, negotiating clear and identified roles? Or Did the Specialist Nurse adopt a more passive role, led by the Consultant?
3. How many family members were involved in the end of life care and donation conversation and was this appropriate?	Family members involved in the donation conversation, due to the sensitive nature, should be limited to key family members only. Please note how many family members were involved?
4. Breaking bad news - confirming understanding and acceptance of loss?	Was the Specialist Nurse involved in the end of life conversation- breaking bad news and checking acceptance of loss? Who led the end of life conversation- breaking bad news and checking acceptance of loss? Was this approach what was agreed at the initial planning stage?
5. Check in to see if family have anyone else to suport them or come in to say last goodbyes?	Did the Specialist Nurse check in to see if the family needed anyone else to come in and say their last goodbyes and support them or take care of things at home i.e. children/pets?
6. Offer of religious/faith/beliefs/cultural support?	Did the Specialist Nurse consider faith/beliefs/cultural support for the family? Were any resources accessed i.e. Faith and beliefs DAT/Jewish Hotline.
7. Were any concerns raised and addressed appropriately?	Did the Specialist Nurse explore any concerns, addressing myths/misconceptions?
8. Was there a seamless transition into end of life care/donation conversation- leading with the benefits of donation (no Organ Donor Registration)?	Did the Specialist Nurse seamlessly transition from end of life/breaking bad news conversation in donation conversation? Did the Specialist Nurse lead with the benefits of organ donation? Did the specialist Nurse discuss the legislation? If the legislation was discussed, was this at an appropriate time point? If the legislation was not discussed and deemed consent applied, why was this?

9. Summarising- contact details-keepsakes-recipient outcomes	Did the Specialist Nurse summarise the conversation, provide contact details and discuss next steps, including recipient outcomes?
RAPPORT	
Question	**Examples of the behaviour and/or language expected**
10. Rapport with family, introduction to family - offering condolences-time taken to ask about the patient as a person- before discussing donation.	Did the Specialist Nurse build rapport with family by? • Introducing themselves professionally • Shaking the family members hand, bearing in mind any cultural sensitivities? • Ask about the patient as a person-before discussing donation?
11. Did COVID 19 have an impact on communication? i.e. wearing personal protective equipment, consent by digital means.	Was the specialist Nurses donation conversation impacted by COVID-19 i.e. wearing a face mask, digital/ telephone consent as opposed to face to face? How well did the Specialist Nurse respond to any impact of COVID-19? Did the Specialist Nurse provide the family access to the? • Information Digital Link-bearing in mind, audio and visual senses-provides shared understanding of the donation process • Leaflets/website
12. Use of non-verbal communication: active listening, eye contact and appropriate use of touch.	Did the Specialist Nurse pay attention to/pick up on non-verbal cues from the family? Did the Specialist Nurse pay attention to the family's perception of their own non-verbal cues? Was touch used to display empathy? If so, was touch used appropriately i.e. touch on the forearm or shoulder-paying attention to cultural sensitivities. Did the Specialist Nurse demonstrate? • Listening to understand • Asking deeper questions • Conversational encouragers • Avoid interruptions • Avoid distractions • Withhold judgement

Appendix 11 - Participant Information Sheet for Semi-Structured Interview

UNIVERSITY OF BIRMINGHAM

Participant Information Sheet for Semi-Structured Interview

Study No:

Study title: Evaluation of the Education Intervention for the Deemed Consent Law Change

This informed consent form is to ask for your permission to participate in a semi-structured interview, following the education and training you received as part of the recent deemed consent law change. The focus of the research is to understand how the education and training in the classroom transfers into clinical practice.

The semi-structured interview should take no longer than 30-40 minutes.

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

The Specialist Nurse is the focus of the research, navigating the end of life and donation conversation now the legislation has changed around consent for organ donation. The Specialist Nurses interaction with the family will be valuable in assessing the impact of the education and training with regards to the law change. Due to the sensitive nature of the observation, any information recorded, will be pseudo-anonymised, so that any information pertaining to you or that of the family are not identifiable as part of the study. Any details recorded to add context to the study will be pseudo-anonymised to prevent any trace back to the patient or patient's family. An example might be SNOD 1, SNOD 2 and age, sex, diagnosis of the deceased, how many family members in the room etc.

Before you decide whether you want to participate, it is important for you to understand why the research is being done and what it will involve.

What is the purpose of the research?

My name is Cathy Miller and I work for NHS Blood and Transplant. As part of my Doctoral studies I am undertaking research, sponsored by the University of Birmingham. The purpose of the research is to evaluate the education and training the Specialist Nurses have received for the law change around organ donation. The research wants to understand if the education programme worked and how the training helps to support Specialist Nurses in supporting donor family's in the critical care unit at the hospital.

I am interested to know; what elements of the training are useful and how could the training be better. The study will explore learning in the classroom being transferred into the hospital setting. The information gained will help to inform and replicate and/or further develop education and training to meet the needs of Specialist Nurses and donor families who are meeting for the first time, in what is often, traumatic, and sudden circumstances.

I am going to give you information and invite you to be part of this research. You do not have to decide today whether you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

The purpose of the research is to evaluate the implementation of the education and training programme for the law change around organ donation.

Why have I been chosen?

You have been invited to participate in this current study as you are a Specialist Nurse having end of life conversations with potential donor families, since the introduction of a new law around organ donation. By discussing the education and training you received, I will endeavour to understand how the training supports your end of life and donation conversations with potential donor families and where there may be gaps between theory and practice.

Do I have to take part?

It is up to you to decide whether to take part. Any participation in this research study is entirely on a voluntary basis. You have the right to withdraw from the study at any time. If you change your mind during the data collection just let the researcher know. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have unless you withdraw within 6 weeks, where your data will be deleted.
It important for you to know that if you choose not to take part or withdraw from the study this will not affect the training and education that you receive.

What will happen if I decide to take part?

If you choose to take part in the study, I will ask you some questions as part of a face to face or on-line interview, regards the legislation and the education and training programme and make some notes. With your permission I will record our conversation with an encrypted audio recorder, so that I can refer to it for accuracy when analysing the themes for writing up the research.

I have a duty of care to protect you and those not involved in the study, for example, family, friends, and work colleagues. So, for confidentiality reasons, I will avoid recording anyone's name or personally identifiable information. Administrative support (within NHS Blood and Transplant) will be sought for transcribing the interview and a confidentiality agreement will be in place. The interview will be de-identified to prevent any personal identifiable information being disclosed. The recording will be deleted after it has been transcribed.

What are the potential benefits and risks of taking part?

Findings could support other countries wishing to introduce a new law around organ donation and could help support other education and training programmes. Although no risks are anticipated, if in the unlikely event the researchers observation causes any distress, then with your permission, either the researcher will support you, or I will request that your Team Manager supports you and/or signposts you to any additional support you may need. However, the researcher is a qualified Specialist Nurse and Executive Coach and therefore trained to recognise and respond to distress. This study cannot guarantee any benefits to you and you will not be reimbursed for your participation. However, the observation is not considered to be onerous and may offer you support and assurance at a difficult time.

What if there is a problem?

Taking part in this research is not intended to cause you any problems. However, if you have any concerns regarding the conduct of the research, please do not hesitate to contact the researcher in the first instance, who will signpost you to the most appropriate person/service.

Formal complaints about any aspect of this research should be emailed to:
researchgovernance@contacts.bham.ac.uk

Appendix 12 - Consent Form for Semi-Structured Interviews

UNIVERSITY OF BIRMINGHAM

Consent Form for Semi-Structured Interview

Study No: 287067

Study title: Evaluation of the Education Intervention for the Deemed Consent Law Change in England

Consent to take part in Research

1. I..... voluntarily agree to participate in this research study. ☐
2. I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind. ☐
3. I understand that I can withdraw permission to use data from my interview within six weeks after the interview, in which case the material will be deleted. ☐
4. I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study. ☐
5. I understand that participation involves being interviewed for 30-40 minutes to help the researcher understand how I perceived the deemed consent legislation training and how I apply that learning in clinical practice. My experiences could help identify the successful elements of the deemed consent education programme and highlight any gaps. ☐
6. I understand that I will not benefit directly from participating in this research. ☐
7. I agree to my interview being audio-recorded. ☐
8. I understand that all information I provide for this study will be treated confidentially. ☐
9. I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about. ☐
10. I understand that disguised extracts from my interview may be quoted in the researchers' thesis, conference presentations and published papers. ☐
11. I understand that if I inform the researcher that myself or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission. ☐
12. I understand the original audio recordings will be retained securely on the researchers' password protected work laptop until the exam board confirms the results of the researchers' thesis. ☐
13. I understand the data from the study will be stored in accordance with GDPR guidance and then destroyed confidentially (10 years following study completion). ☐
14. I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above. ☐

When completed: 1 for participant; 1 for researcher file. 1

15. I understand that I am free to contact any of the people involved in the research to seek further clarification and information. Names, degrees, affiliations and contact details of researchers (and academic supervisors when relevant) ☐

16. I understand the sponsor, its representatives or regulatory authorities may request to access the research data for auditing/monitoring purposes ☐

17. I agree to take part in the above study ☐

Name of Research Participant ----------

Signature of Research Participant ----------

Date: ----------

I believe the participant is giving informed consent to participate in this study

Name of Researcher----------

Signature of Researcher ----------

Date: ----------

Appendix 13 - Semi-Structured Interview Questions and Debrief Topic Guide

UNIVERSITY OF BIRMINGHAM

Evaluation of the Education Intervention for the Deemed Consent Law Change

Research Project: Semi-Structured Interview and Debrief Guide for Specialist Nurse in Organ Donation

*Response to questions will guide the subsequent semi-structured interviews as part of Stage 2.3.

SEMI-STRUCTURED INTERVIEW QUESTIONS AND DEBRIEF- TOPIC GUIDE

Introduction, overview of study, consenting:

Thank you for seeing me today and offering to take part in this study. I would like first to outline the study so that you are able to decide whether you wish to proceed further (re-cap Participant Information Sheet). Sign consent form × 2 (one for participant and information sheet, one for interviewer).

The interview part of the study, is an opportunity to discuss your understanding of the deemed consent legislation, and your experience of the education and training provided and how that relates to the context of the recent on-call I shadowed with you.

So, the topics I wish to address are:

- Your understanding of the deemed consent legislation in England
- Your experience of the education and training programme for deemed consent
- Following our discussion, there will be an opportunity to debrief-following the shadow on-call

Please feel free to ask questions at any stage during the interview and/or debrief. I might make a few notes in case I want to come back to something later. I want to assure you that your personal information will be kept confidential, only viewed by myself and my academic supervisor Dr Kotzee. The data collected will de-identified to a geographical region in England and your NHS role.

Interview Discussion/Debrief: Topics/questions:

Topic	Possible Questions	Possible Follow Up Questions	Probes
Background information on the interviewee	What is your current role?	How long have you been in post? Do you have any lead role (s)? What is your background?	Legislation change/Quality/Research/Health Informatics Critical Care/Emergency Department
Views on understanding and awareness of the new deemed consent system	What's is your understanding of the new deemed consent legislation? What do you think of the new system?	What do you understand the inclusions/exclusions to be? Something positive or maybe not so?	Go on Can you tell me more?

	Does the legislation influence the donor family conversation?		
Re-cap on modular training	Can you re-call the education and training you received for deemed consent? What (if anything) was memorable for you?	Videos Quiz Shared Practice Actors Resources-captured phrases Facilitation	Can you tell me more?
Views on and attitudes toward Education and Training in supporting you in the clinical context to having a deemed PLANNING conversation	What aspects of the education and training support (facilitate) you in planning a deemed consent conversation? What aspects of the education and training hinder (barrier) you when planning a deemed consent conversation?	Videos On-line resources on SHINE academy Scenarios with Actors Resources Facilitation Group discussion	And...anything else?
Views on and attitudes toward Education and Training in supporting you in the clinical context, when conducting a deemed consent conversation	What aspects of the education and training support (facilitate) you in having a deemed consent conversation? What aspects of the education and training hinder (barrier) you when conducting a deemed consent conversation?	Videos On-line resources on SHINE academy Scenarios with Actors Resources Facilitation Group discussion Captured phrases	
Overall views on and attitudes toward Education and Training received for the	What (if anything) worked well? What (if anything) could be better if?	Videos On-line resources on SHINE academy Scenarios with Actors Resources Facilitation	And...anything else?

deemed consent legislation:	What (if anything) particularly helps in the context of clinical practice? What gaps or further training needs do you have?	Group discussion Captured phrases	
Impact of COVID-19 impacting the implementation of the deemed consent legislation.	Do you think COVID-19 impacted the implementation of the legislation?	Impact on your role/workload? Education and training received/missed? In what way?	Go on.
Preferred mode of training	What was your overall preferred method of training? Was there a variety of teaching methods used to meet your individual learning needs?	Face to Face Zoom On-line resources Shared practice with Professional actors PowerPoint Presentation Webinar Recorded video Captured phrases What methods were useful? What could have been more useful?	
Connecting the theory of the training to clinical practice	How did the training help you or not, when deeming consent in practice?	Can you think of any cases?	
Consent form completion and documentation	Which section do you complete for deemed consent? How do you capture deemed consent in the medical records?	What wording, if any, do you use with the family, when completing this section? Do you drawn on any resources to help you?	
Have you taken part in a deemed debrief?	If so, what was your experience of the debrief? If not, would you find a debrief valuable?		

Closing remarks and thank you	Finally, is the anything else you would like to add, about anything else, before we close? Thank you very much for your time today.		

DEBRIEF:

What? So What? Now What?

What?

In the 'what' phase the participant will answer questions like:

- What was your experience of the deemed consent legislation in the clinical context?
- Who did you interact with?
- What emotions came up?
- When did you feel in control/frustrated/confused?

*This phase affirms that the participants experience as legitimate knowledge

So What?

Ask participants to interpret the meaning of their experience. They should move towards identifying what they are learning and how their perspective is changing.

The facilitator can ask questions like:

- Have you seen ever seen something similar?
- How does this relate to the larger world or bigger picture?
- What difference does this make for you?
- What ways did you see the mission of NHS Blood and Transplant being served an not being served?

*Eventually, the participant should be able to articulate what they now understand differently.

Now What?

Looks to the future. Armed with their new knowledge and perspective, participants consider the implications of the legislation and decide how it impacts their practice. It is valuable for the participant to outline concrete steps to take to implement their new understanding.

Sometimes it is helpful to ask:

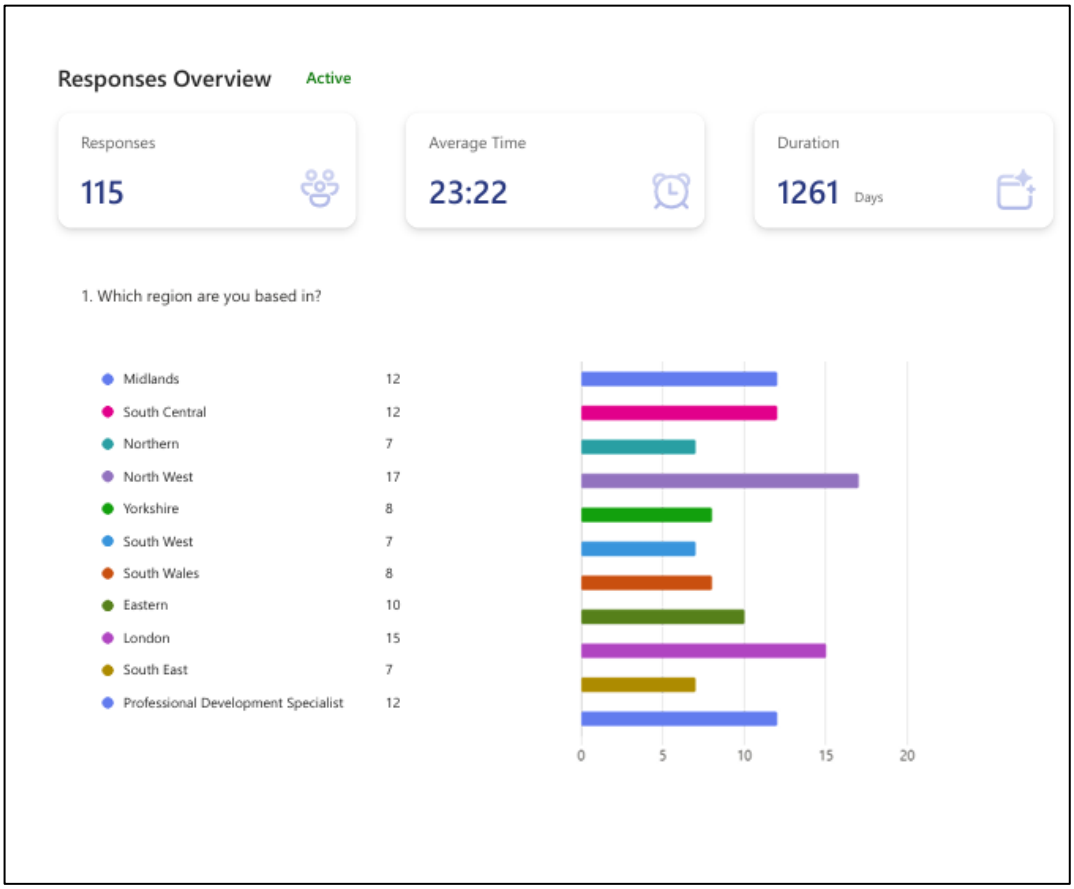
- "What do we need to learn about, if we're to understand this issue better?

Or

- Simply , "Now what...?."

*The participant might feel inspired to make changes or be overwhelmed by the work to be done. In either case, realistic and meaningful steps can be considered.

Appendix 14 - Whole Workforce Potential Deemed Approach Survey



4. Where do you *usually* introduce deemed legislation into the approach conversation?

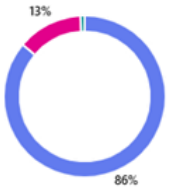
Beginning- Leading with the legislation	10
After discussing the benefits of organ donation	102
Not at all	3

5. How confident are you in raising the Deemed Consent Legislation?

Extremely confident	46
Somewhat confident	64
Somewhat unconfident	5
Extremely unconfident	0

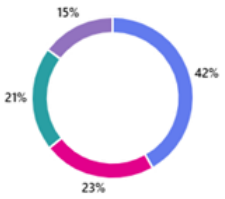
6. Where do you ascertain understanding of the patient's last know decision in the conversation?

At the beginning of the approach conversation- before mentioning the legislation	99
Later on- after mentioning the legislation	15
Not at all	1



7. How do you describe the Deemed legislation to a potential donor family?

Legislation	48
Law	26
System for donation	24
Other	17



8. If other applies to the question above, please detail below:

114
Responses

Latest Responses
"n/A"
"NA"
"The way organ donation works in England"
...

13 respondents (11%) answered donation works for this question. Update

9. Could you describe how you usually structure your deemed approach in a paragraph/few bullet points below?

115
Responses

Latest Responses
"After establishing that potential donor is not on the ODR and the family hav..."
"In Wales, more often than not families bring up deemed in some capacity. If ..."
"X is in a position where they can help others through the gift of organ donat..."
...

52 respondents (45%) answered family for this question.

10. Are there any other comments you would li... ...sent approach features in your work?

114
Responses

Latest Responses
"n/a"
"Difficult with consultants sometimes when they want to lead the conversatio..."
"My deemed conversation changes depending on the conversation/response..."
...

47 respondents (41%) answered families for this question. Update

11. Where do you turn for advice/guidance regards the deemed consent approach?

115
Responses

Latest Responses
"Rest of team/TM."
"My peers who approach day in and day out."
"Deemed consent section on SharePoint Colleagues"
...

33 respondents (29%) answered colleagues for this question.

Appendix 15 - Participant Information Sheet for Retrospective Observation of Specialist Nurses- Organ Donation Participating in the on-line digital Continuous Professional Practice Course

UNIVERSITY OF BIRMINGHAM

Participant Information Sheet

Retrospective observation of Specialist Nurses in Organ Donation participating in the on-line/digital Continuous Professional Practice Course.

***Focus on deemed consent scenario and to test observation tool.**

Study No:

Study title: Evaluation of the Education Intervention for the Deemed Consent Law Change

This sheet is to provide information about the research study evaluating the education and training, delivered to support the implementation of the deemed consent legislation in England. The focus of the research is two-fold; firstly, to focus on the on-line/digital education and training for deemed consent (as opposed to an assessment of the Specialist Nurses practice) and secondly, to test an observation tool. The observation tool will be used in the next stage of the researcher's study, when shadowing Specialist Nurses on-call in the clinical environment having conversations around organ donation.

The researcher seeks to understand how the modular education and training, delivered as part of the legislation change, transfers into ongoing education and practical training sessions. This will be undertaken by observing the Specialist Nurse conducting an end of life donation conversation in the on-line/digital training environment following the deemed consent legislation implementation. Therefore, the focus of the research is on the deemed consent scenario to test the observation tool, whilst observing the donation conversation between the Specialist Nurse and a potential donor family, simulated by professional actors.

Please read and digest this information and let the researcher know if you have any objections to participating in the research. Prior to starting the Continuous Professional Practice Course (CPPC) the facilitator will confirm with the participants, that they have no objection to the course being recorded, for retrospective analysis by the researcher.

The video footage will not be shared wider than the research team, who will review the footage in confidence, focusing on the deemed consent scenario and testing/finessing the researchers observation tool. It is an important opportunity to test the observation tool, prior to the researcher using the observation tool in the live environment, when shadowing the Specialist Nurse discussion donation with potential donor families, in the next stage of her research study.

Due to the nature of sharing practice in CPPC, it is recognised information may be discussed about real cases. Therefore, information will be pseudo-anonymised, such as SNOD 1, SNOD 2, so that any information pertaining to you or that of the family are not identifiable as part of the study. This is to prevent any trace back to the Specialist Nurse, patient or patient's family. An example might be SNOD 1, SNOD 2 and age, sex, diagnosis of the deceased etc.

If you decided to participate in the research study, it is important for you to understand why the research is being done and what it will involve and your right to withdraw.

What is the purpose of the research?

My name is Cathy Miller and I work for NHS Blood and Transplant. As part of my Doctoral studies I am undertaking research, sponsored by the University of Birmingham. The purpose of the research is to evaluate the education and training the Specialist Nurses have received for the law change around organ donation. The research wants to understand if the education programme worked and how the training helps to support Specialist Nurses in supporting donor family's in the critical care unit at the hospital.

I am interested to know, what elements of the training are useful and how could the training be better. The study will explore learning in the classroom being transferred into the hospital setting. The information gained will help to inform and replicate and/or further develop education and training to meet the needs of Specialist Nurses and donor families who are meeting for the first time, in what is often, traumatic and sudden circumstances.

The purpose of the research is to evaluate the implementation of the education and training programme for the law change around organ donation.

Why have I been chosen?

You have been invited to participate in this current study as you are a Specialist Nurse having end of life conversations with potential donor families, since the introduction of a new law around organ donation. By observing on-line/digital training showing Specialist Nurses conducting end of life and donation conversations with the potential donor families (played by professional actors) will help the researcher identify, whether the education and training was helpful in supporting you conduct end of life and donation conversations with potential donor families and where there may be gaps between theory and practice. It is also an opportunity to test the observation tool.

What happens next?

A team of reviewers from NHS Blood and Transplant will support the researcher in reviewing the training footage, namely the National Clinical Lead for Organ Donation, Chief Nurse/Head of Education and Professional Development/ Continuing Professional Practice Course (CPCC) trainer/Operations and Nursing Workstream Lead for Operations & Nursing. The review process will enable the observation proforma to be tested as a tool to measure training in the classroom translating into the clinical environment. It is not an assessment tool to assess individual practice. It is also an opportunity to test the observation tool and allow for the proforma to be tweaked, prior to use in the real/live environment whilst observing the Specialist Nurse having a donation conversation with potential donor families.

Do I have to take part?

It is up to you to decide whether to take part. Any participation in this research study is entirely on a voluntary basis. You have the right to withdraw from the study at any time. If you change your mind during the data collection just let the researcher know. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have unless you withdraw within 6 weeks, where your data will be deleted. It important for you to know that if you choose not to take part or withdraw from the study this will not affect the training and education that you receive.

What are the potential benefits and risks of taking part?

The observation of Specialist Nurse participating in on-line/digital training offers an opportunity to see how the theoretical training in the classroom supports Specialist Nurses conducting end of life and donation conversations in the simulated training environment with professional actors. The simulated training observations will be compared with Specialist Nurses conducting end of life and donation conversations in the live environment and clinical context. All this information will help understand where the education and training work well and identify any gaps and recommendations for practice.

Findings could also support other countries wishing to introduce a new law around organ donation and could help inform other education and training programmes.

What if there is a problem?

Taking part in this research is not intended to cause you any problems. However, if you have any concerns regarding the conduct of the research, please do not hesitate to contact the researcher in the first instance, who will signpost you to the most appropriate person/service.

Formal complaints about any aspect of this research should be emailed to: researchgovernance@contacts.bham.ac.uk

How will we use information about you?

We will need to use information provided by you during the observation of the on-line/digital training footage.

This information will be pseudo-anonymised, such as SNOD 1, SNOD 2, so that you are not identifiable. People will use this information to do the research or to check the researchers records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

More about how your information is used.

You can find out more about how we use your information

- at www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team

by sending an email to researchgovernance@contacts.bham.ac.uk

Will my taking part in the study be kept confidential?

Observations made on the video footage, will be summarised in the researchers report and will not be shared with anybody outside the research team, and nothing will be attributed to you by name. The video recording will be retained and deleted following the researcher's successful examination. The knowledge that we get from this research will be shared with you, before it is made widely available to the public. Each participant will receive a summary of the results.

All data will be managed in accordance with the General Data Protection Regulation (GDPR), Data Protection Act (DPA) (2018) and University of Birmingham Research Data Management Policy (2018). After the interview the observation notes will be analysed. Data will be anonymised by using codes on observation transcripts. Data will be protected on the researcher's password protected

laptop. The data from the study will be stored in accordance with GDPR guidance and then destroyed confidentially (ten years following study completion).

If you wish to make a complaint relating to breaches of data protection legislation or you have concerns about the processing of personal identifiable information you may do so in writing and contact details are as follows:

Data Protection Officer
The University of Birmingham
Edgbaston
Birmingham, B15 2TT
Tel: 0121 414 3916
Email: dataprotection@contacts.bham.ac.uk

What will happen to the results of the research study?

The researcher will be happy to provide you with a summary of the research at the completion of the study. The results of the research study will be included within the researcher's doctoral thesis. It is hoped the findings of this research study will be published, so that the information will be made available for other professionals and services to view.

Who has reviewed the study?

This research has been reviewed and received ethical approval from the Nottingham 1 Research Ethics Committee and University of Birmingham to ensure participants' interests are protected. This study has also been reviewed and approved by NHS Blood and Transplant Research Innovation and Novel Technologies Advisory Group (RINTAG).

If you would like to discuss anything or have further questions at any time, please contact Cathy Miller, Researcher.

Cathy Miller
Education and Governance Workstream Lead-Legislation Implementation
NHS Blood and Transplant
University of Birmingham

Thank you for taking the time to read this information. This information is for you to keep.

Enc. Participant Information for observing training on a digital platform-deemed consent scenario.

Appendix 16 - Consent Form for Retrospective Observation of Specialist Nurses- Organ Donation Participating in the on-line digital Continuous Professional Practice Course

UNIVERSITY OF BIRMINGHAM

Consent Form:
For retrospective observation of Specialist Nurses in Organ Donation participating in the on-line/digital Continuous Professional Practice Course.

Study No:

Study title: Evaluation of the Education Intervention for the Deemed Consent Law Change
Consent to take part in Research

Please initial box

1. I..... voluntarily agree to participate in this research study. ☐
2. I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind. ☐
3. I understand that I can withdraw permission to use data from my interview within six weeks after the interview, in which case the material will be deleted. ☐
4. I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study. ☐
5. I understand the focus of the research is two-fold; firstly, to focus on the on-line/digital education and training for deemed consent (as opposed to an assessment of me as an individual) and secondly, to test an observation tool. ☐
6. I agree to being observed whilst participating on the Continuing Professional Practice Course. ☐
7. I understand that I will not benefit directly from participating in this research. However, my shared experiences could help identify the successful elements of the deemed consent education programme, highlight any gaps and test the researcher's observation tool, in readiness for the next stage of the research. ☐
8. I agree to the training being video recorded and analysed by the research team. ☐
9. I understand that all information I provide for this study will be treated confidentially. ☐
10. I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details shared during CPPC, which may reveal my identity or the identity of people I speak about. ☐
11. I understand that disguised extracts from the training footage may be quoted in the researchers' thesis, conference presentations and published papers. ☐

When completed: 1 for participant; 1 for researcher file

Version 2 06.02.2021 IRAS 287067

13. I understand the data from the study will be stored in accordance with GDPR guidance and then destroyed confidentially (10 years following study completion).

14. I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above. ☐

15. I understand that I am free to contact any of the people involved in the research to seek further clarification and information. Names, degrees, affiliations and contact details of researchers (and academic supervisors when relevant) ☐

16. I understand the sponsor, its representatives or regulatory authorities may request to access the research data for auditing/monitoring purposes ☐

17. I agree to take part in the above study ☐

Name of Research Participant ----------

Signature of Research Participant ----------

Date: ----------

I believe the participant is giving informed consent to participate in this study

Name of Researcher----------

Signature of Researcher ----------

Date: ----------

Appendix 17 - Participant Information Sheet Shadowing Specialist Nurse on-call, Debrief and Semi-Structured Interview

UNIVERSITY OF BIRMINGHAM

Participant Information Sheet for
Shadowing Specialist Nurse on-call, Debrief and Semi-Structured Interview

Study No:

Study title: Evaluation of the Education Intervention for the Deemed Consent Law Change

This informed consent form is to ask for your permission to observe the donation conversation between you and a potential donor family, following the recent deemed consent law change. The focus of the research is on the donation conversation, since the deemed consent legislation change, to understand how the education and training in the classroom transfers into clinical practice.

Following the donation conversation observation, there will be an opportunity to debrief and to participate in a semi-structured interview to further assist in understanding about the education and training provided in relation to the law change. The debrief and semi-structured interview should take no longer than 30-40 minutes.

This Informed Consent Form has two parts:

- **Information Sheet (to share information about the study with you)**
- **Certificate of Consent (for signatures if you choose to participate)**

You will be given a copy of the full Informed Consent Form

The Specialist Nurse is the focus of the research, navigating the end of life and donation conversation now the legislation has changed around consent for organ donation. The Specialist Nurses interaction with the family will be valuable in assessing the impact of the education and training with regards to the law change. Due to the sensitive nature of the observation, any information recorded, will be pseudo-anonymised, so that any information pertaining to you or that of the family are not identifiable as part of the study.

Any details recorded to add context to the study will be pseudo-anonymised to prevent any trace back to the patient or patient's family. An example might be SNOD 1, SNOD 2 and age, sex, diagnosis of the deceased, how many family members in the room etc.

Before you decide whether or not you want to participate, it is important for you to understand why the research is being done and what it will involve.

What is the purpose of the research?

My name is Cathy Miller and I work for NHS Blood and Transplant. As part of my Doctoral studies I am undertaking research, sponsored by the University of Birmingham. The purpose of the research is to evaluate the education and training the Specialist Nurses have received for the law change around organ donation. The research wants to understand if the education programme worked and how the training helps to support Specialist Nurses in supporting donor family's in the critical care unit at the hospital.

I am interested to know; what elements of the training are useful and how could the training be better. The study will explore learning in the classroom being transferred into the hospital setting. The information gained will help to inform and replicate and/or further develop education and training to meet the needs of Specialist Nurses and donor families who are meeting for the first time, in what is often, traumatic, and sudden circumstances.

I am going to give information and invite you to be part of this research. You do not have to decide today whether you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

The purpose of the research is to evaluate the implementation of the education and training programme for the law change around organ donation.

Why have I been chosen?

You have been invited to participate in this current study as you are a Specialist Nurse having end of life conversations with a potential donor family, since the introduction of a new law around organ donation. By observing your end of life and donation conversation with the potential donor family and through subsequent debrief and semi-structured interview, you will help me identify, whether the education and training was helpful in supporting you conduct end of life and donation conversations with potential donor families and where there may be gaps between theory and practice.

Do I have to take part?

It is up to you to decide whether to take part. Any participation in this research study is entirely on a voluntary basis. You have the right to withdraw from the study at any time. If you change your mind during the data collection just let the researcher know. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have unless you withdraw within 6 weeks, where your data will be deleted. It important for you to know that if you choose not to take part or withdraw from the study this will not affect the training and education that you receive.

What will happen if I decide to take part?

If you choose to take part in the study, I will ask for your support, in asking permission from the potential donor family (without me being there), to check that they are comfortable for me, as your Specialist Nurse colleague to sit in on the conversation. It is important that the family's consent is sought for the researcher to observe the Specialist Nurse as the focus of the research and their verbal agreement (or otherwise) should be recorded on NHS Blood and Transplant's Donor Path and in the patients' medical records entry . I will make notes whilst I observe you and the potential donor family having a discussion. The conversation between you and the donor family will not be audio-recorded. With your permission, I will audio-record the follow up debrief and interview between you and I with an encrypted audio recorder. So, that I can refer to it for accuracy when analysing the themes for writing up the research.

I have a duty of care to protect you and those not involved in the study, for example, family, friends, and work colleagues. So, for confidentiality reasons, I will avoid recording anyone's name or personally identifiable information. Administrative support (within NHS Blood and Transplant) will be sought for transcribing the debrief and interview and a confidentiality agreement will be in place. The debrief and interviews will be de-identified to prevent any personal identifiable information being disclosed. The recording will be deleted after it has been transcribed.

What are the potential benefits and risks of taking part?

The shadowing on-call and subsequent debrief and interview offers an opportunity to support and peer review the Specialist Nurse applying deemed consent in the clinical context, based on what's taught in practice. The real-time feedback could count as part of your Nursing and Midwifery Council revalidation.

Findings could also support other countries wishing to a new law around organ donation and could help inform other education and training programmes. Although no risks are anticipated, if in the unlikely event the researchers observation causes any distress, then with your permission, either the researcher will support you, or I will request that your Team Manager supports you and/or signposts you to any additional support you may need. However, the researcher is a qualified Specialist Nurse and Executive Coach and therefore trained to recognise and respond to distress. This study cannot guarantee any benefits to you and you will not be reimbursed for your participation. However, the observation is not considered to be onerous and may offer you support and assurance at a difficult time.

What if there is a problem?

Taking part in this research is not intended to cause you any problems. However, if you have any concerns regarding the conduct of the research, please do not hesitate to contact the researcher in the first instance, who will signpost you to the most appropriate person/service.

Formal complaints about any aspect of this research should be emailed to:
researchgovernance@contacts.bham.ac.uk

How will we use information about you?

We will need to use information provided by you (during the observation period, debrief and semi-structured interview) for this research project. This information will include your name, contact details and any information you wish to share when answering the research questions, pertaining to the legislation change and/or training provided.

This information will be pseudo-anonymised, such as SNOD 1, SNOD 2, so that you are not identifiable. People will use this information to do the research or to check the researchers records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

More about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/patientdataandresearch
- www.hra.nhs.uk/information-about-patients/
- by asking one of the research team

by sending an email to researchgovernance@contacts.bham.ac.uk

Will my taking part in the study be kept confidential?

Information that you choose to discuss with the researcher, will not be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you before it is made widely available to the public. Each participant will receive a summary of the results.

As this research is being completed as part of an academic course, the other people that will see the anonymised transcript, will be the university research supervisors, Dr Ben Kotzee and Dr Sarah Aiston.

All data will be managed in accordance with the General Data Protection Regulation (GDPR), Data Protection Act (DPA) (2018) and University of Birmingham Research Data Management Policy (2018). After the interview the observation notes will be analysed. Data will be anonymised by using codes on observation transcripts. Data will be protected on the researcher's password protected laptop. The data from the study will be stored in accordance with GDPR guidance and then destroyed confidentially (ten years following study completion).

If you wish to make a complaint relating to breaches of data protection legislation or you have concerns about the processing of personal identifiable information you may do so in writing and contact details are as follows:

Data Protection Officer
The University of Birmingham
Edgbaston
Birmingham, B15 2TT
Tel: 0121 414 3916
Email: dataprotection@contacts.bham.ac.uk

What will happen to the results of the research study?

The researcher will be happy to provide you with a summary of the research at the completion of the study. The results of the research study will be included within the researcher's doctoral thesis. It is hoped the findings of this research study will be published, so that the information will be made available for other professionals and services to view.

Who has reviewed the study?

This research has been reviewed and received ethical approval from the Nottingham 1 Research Ethics Committee and the University of Birmingham to ensure participants' interests are protected. This study has also been reviewed and approved by NHS Blood and Transplant Research Innovation and Novel Technologies Advisory Group (RINTAG).

If I decide to take part what do I have to do?

If you decide you would like to participate in this research study, the researcher will go through the information sheet again to allow you to give informed consent to take part. If you consent to taking part in the research you will be asked to sign a form to confirm that you have given your informed consent and fully understand why the research is being completed, and what is expected of you.

If you would like to discuss anything or have further questions at any time, please contact Cathy Miller, Researcher.

Cathy Miller
Education and Governance Workstream Lead-Legislation Implementation
NHS Blood and Transplant
University of Birmingham

Cathy Miller:
Participant information for
shadowing Specialist Nurse on-call, debrief and semi-structured
interview Stages 2.2. & 2.3

Thank you for taking the time to read this information. This information is for you to keep.

Enc. Participant Information for End of Life and Donation Conversation, Debrief and Semi-Structured Interview

Appendix 18 - Consent Form for Shadow on-call (participant observation), Semi-Structured Interview and Debrief

UNIVERSITY OF BIRMINGHAM

Consent Form for Shadow on-call (participant observation), Semi-Structured Interview and Debrief

Study No: 287067

Study title: Evaluation of the Education Intervention for the Deemed Consent Law Change
Consent to take part in Research

Please initial box

1. I..... voluntarily agree to participate in this research study. ☐
2. I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind. ☐
3. I understand that I can withdraw permission to use data from my interview within six weeks after the interview, in which case the material will be deleted. ☐
4. I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study. ☐
5. I understand that participation involves being shadowed on-call in clinical practice and subsequently followed up with a short interview (30-40 minutes) and an opportunity for a debrief. The researcher hopes to understand how I perceived the deemed consent legislation training and how I apply that learning in clinical practice. My experiences could help identify the successful elements of the deemed consent education programme and highlight any gaps. ☐
6. I understand that I will not benefit directly from participating in this research, other than using the debrief as part of my NMC revalidation. ☐
7. I agree to my interview being audio-recorded. ☐
8. I understand that all information I provide for this study will be treated confidentially. ☐
9. I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about. ☐
10. I understand that disguised extracts from my interview may be quoted in the researchers' thesis, conference presentations and published papers. ☐
11. I understand that if I inform the researcher that myself or someone else is at risk of harm they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission. ☐
12. I understand the original audio recordings will be retained securely on the researchers' password protected work laptop until the exam board confirms the results of the researchers' thesis. ☐

13. I understand the data from the study will be stored in accordance with GDPR guidance and then destroyed confidentially (10 years following study completion).

14. I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above. ☐

15. I understand that I am free to contact any of the people involved in the research to seek further clarification and information. Names, degrees, affiliations and contact details of researchers (and academic supervisors when relevant) ☐

16. I understand the sponsor, its representatives or regulatory authorities may request to access the research data for auditing/monitoring purposes ☐

17. I agree to take part in the above study ☐

Name of Research Participant ----------

Signature of Research Participant ----------

Date: ----------

I believe the participant is giving informed consent to participate in this study

Name of Researcher----------

Signature of Researcher ----------

Date: ----------

Why have I been chosen?

You have been invited to participate in this current study as you are a Specialist Nurse having end of life conversations with potential donor families, since the introduction of a new law around organ donation. By discussing the education and training you received, I will endeavour to understand how the training supports your end of life and donation conversations with potential donor families and where there may be gaps between theory and practice.

Do I have to take part?

It is up to you to decide whether to take part. Any participation in this research study is entirely on a voluntary basis. You have the right to withdraw from the study at any time. If you change your mind during the data collection just let the researcher know. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have unless you withdraw within 6 weeks, where your data will be deleted.
It important for you to know that if you choose not to take part or withdraw from the study this will not affect the training and education that you receive.

What will happen if I decide to take part?

If you choose to take part in the study, I will ask you some questions as part of a face to face or on-line interview, regards the legislation and the education and training programme and make some notes. With your permission I will record our conversation with an encrypted audio recorder, so that I can refer to it for accuracy when analysing the themes for writing up the research.

I have a duty of care to protect you and those not involved in the study, for example, family, friends, and work colleagues. So, for confidentiality reasons, I will avoid recording anyone's name or personally identifiable information. Administrative support (within NHS Blood and Transplant) will be sought for transcribing the interview and a confidentiality agreement will be in place. The interview will be de-identified to prevent any personal identifiable information being disclosed. The recording will be deleted after it has been transcribed.

What are the potential benefits and risks of taking part?

Findings could support other countries wishing to introduce a new law around organ donation and could help support other education and training programmes. Although no risks are anticipated, if in the unlikely event the researchers observation causes any distress, then with your permission, either the researcher will support you, or I will request that your Team Manager supports you and/or signposts you to any additional support you may need. However, the researcher is a qualified Specialist Nurse and Executive Coach and therefore trained to recognise and respond to distress. This study cannot guarantee any benefits to you and you will not be reimbursed for your participation. However, the observation is not considered to be onerous and may offer you support and assurance at a difficult time.

What if there is a problem?

Taking part in this research is not intended to cause you any problems. However, if you have any concerns regarding the conduct of the research, please do not hesitate to contact the researcher in the first instance, who will signpost you to the most appropriate person/service.

Formal complaints about any aspect of this research should be emailed to:
researchgovernance@contacts.bham.ac.uk

Appendix 19 - Whole Workforce Survey - Participant Information

UNIVERSITY OF BIRMINGHAM

Participant Information Sheet

Completing Microsoft Forms Survey-Regard's potential deemed approach conversation

Study No:287067

Study title: Evaluation of the Education Intervention for the Deemed Consent Law Change

This sheet is to provide information about the research study evaluating the education and training, delivered to support the implementation of the deemed consent legislation in England. The focus of this aspect of the research is to solidify my findings, as I reach the end of the observational part of my research, shadowing the Specialist Nurses -Organ Donation out in practice, combined with data gathered during debrief and semi-structured interviews. To understand if the findings from the cohort being studied, applies across England/Wales, I invite you to participate in a short survey to solidify my understanding and make recommendations for future education and training regards the legislation.

What is the purpose of the research?

My name is Cathy Miller and I work for NHS Blood and Transplant. As part of my Doctoral studies, I am undertaking research, sponsored by the University of Birmingham. The purpose of the research is to evaluate the education and training the Specialist Nurses have received for the law change around organ donation. The research wants to understand if the education programme worked and how the training helps to support Specialist Nurses in supporting donor families in the critical care unit at the hospital.

I am interested to know; what elements of the training are useful and how could the training be better. The study will explore learning in the classroom being transferred into the hospital setting. The information gained will help to inform and replicate and/or further develop education and training to meet the needs of Specialist Nurses and donor families who are meeting for the first time, in what is often, traumatic, and sudden circumstances.

I am going to give you information and invite you to be part of this research. You do not have to decide today whether you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

The purpose of the research is to evaluate the implementation of the education and training programme for the law change around organ donation.

Why have I been chosen?

You have been invited to participate in this current study as you are a Specialist Nurse having end of life conversations with potential donor families, since the introduction of a new law around organ donation. By discussing the education and training you received, I will endeavour to understand how the training supports your end of life and donation conversations with potential donor families and where there may be gaps between theory and practice.

Do I have to take part?

It is up to you to decide whether to take part. Any participation in this research study is entirely on a voluntary basis. You have the right to withdraw from the study at any time. If you change your mind during the data collection just let the researcher know. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have unless you withdraw within 6 weeks, where your data will be deleted.
It important for you to know that if you choose not to take part or withdraw from the study this will not affect the training and education that you receive.

What will happen if I decide to take part?

If you choose to take part in the study, you will consent by voluntarily completing the Microsoft forms survey. The survey asks questions about how and when you broach the subject of deemed consent.

I have a duty of care to protect you and those not involved in the study, for example, family, friends, and work colleagues. So, for confidentiality reasons, I will not be requesting your name as part of the survey.

What are the potential benefits and risks of taking part?

Findings could support other countries wishing to introduce a new law around organ donation and could help support other education and training programmes. There are no risks anticipated in completing the survey.

What if there is a problem?

Taking part in this research is not intended to cause you any problems. However, if you have any concerns regarding the conduct of the research, please do not hesitate to contact the researcher in the first instance, who will signpost you to the most appropriate person/service.

Formal complaints about any aspect of this research should be emailed to:
researchgovernance@contacts.bham.ac.uk

How will we use information about you?

The survey is anonymous, and you will not be asked to share any identifiable information about you. We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

More about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/patientdataandresearch
- www.hra.nhs.uk/information-about-patients/
- by asking one of the research team

by sending an email to researchgovernance@contacts.bham.ac.uk

Will my taking part in the study be kept confidential?

Information that you choose to discuss with the researcher, will not be shared with anybody outside the research team, and nothing will be attributed to you by name.
The knowledge that we get from this research will be shared with you before it is made widely available to the public. Each participant will receive a summary of the results.

As this research is being completed as part of an academic course, the other people that will see the anonymised transcript, will be the university research supervisor, Dr Ben Kotzee.

All data will be managed in accordance with the General Data Protection Regulation (GDPR), Data Protection Act (DPA) (2018) and University of Birmingham Research Data Management Policy (2018). After the interview the observation notes will be analysed. Data will be anonymised by using codes on observation transcripts. Data will be protected on the researcher's password protected laptop. The data from the study will be stored in accordance with GDPR guidance and then destroyed confidentially (ten years following study completion).

If you wish to make a complaint relating to breaches of data protection legislation or you have concerns about the processing of personal identifiable information you may do so in writing and contact details are as follows:

Data Protection Officer
The University of Birmingham
Edgbaston
Birmingham, B15 2TT
Tel: 0121 414 3916
Email: dataprotection@contacts.bham.ac.uk

What will happen to the results of the research study?

The researcher will be happy to provide you with a summary of the research at the completion of the study. The results of the research study will be included within the researcher's doctoral thesis. It is hoped the findings of this research study will be published, so that the information will be made available for other professionals and services to view.

Who has reviewed the study?

This research has been reviewed and received ethical approval from the Nottingham 1 Research Ethics Committee and University of Birmingham to ensure participants' interests are protected. This study has also been reviewed and approved by NHS Blood and Transplant Research Innovation and Novel Technologies Advisory Group (RINTAG).

If I decide to take part what do I have to do?

If you decide you would like to participate in this research study, your consent will be gained by willingly completing the Microsoft Forms survey.

If you would like to discuss anything or have further questions at any time, please contact Cathy Miller, Researcher.

Cathy Miller
Education and Governance Workstream Lead-Legislation Implementation

NHS Blood and Transplant
University of Birmingham

Thank you for taking the time to read this information. This information is for you to keep.

Appendix 20 - Research Innovation and Novel Technologies Advisory Group (RINTAG) Approval

NHS
Blood and Transplant

Tooting Blood Donor Centre
75 Cranmer Terrace
London
SW17 0RB

Tel: 0203 123 8582
clare.denison@nhsbt.nhs.uk
Clare Denison
Innovation & Research – Lead Specialist ODT

Mrs Cathy Miller

Sent via e-mail to: cathy.miller@nhsbt.nhs.uk; research.office@nhsbt.nhs.uk

13 July 2020

Dear Mrs Miller,

RE: Was the deemed consent education and training programme for the legislation change in England implemented effectively? (ODT Study № 104)

I am writing to thank you for contacting the Organ Donation and Transplantation Research Team regarding the above research proposal, wherein you request to evaluate the deemed consent education and training programme.

The Research, Innovation and Novel Technologies Advisory Group (RINTAG) have thoroughly reviewed your proposal and I am pleased to confirm that your request has been approved.

Please continue to keep the Research team informed of your progress with your Health Research Authority/Confidentiality Advisory Group applications. Once these approvals have been received and confirmation forwarded to the team, your study can be marked as 'live' on the ODT Research Registry.

Please note that your study should go live within 6 months of receiving this letter, or otherwise you will be asked to re-submit your application. If you have any queries then please feel free to contact me or the ODT Research team.

Yours sincerely,

Clare Denison
Innovation & Research - Lead Specialist ODT

Copy to:
Hannah Tolley (ODT Research Project Manager)
Maggie Stevens (Specialist Nurse for Research)

Appendix 21 - University of Birmingham Ethical Approval

UNIVERSITY OF BIRMINGHAM

FINANCE OFFICE

Dr Mrs Cathy Miller
School of Education
University of Birmingham

Tuesday, 8 December 2020

Dear Mrs Cathy Miller

Project Title: **Was the deemed consent education and training programme for the legislation change in England implemented effectively?**
IRAS ID: **287067**
Sponsor Reference: **RG_20-093**
UoB Ethics Reference: **ERN_20-1076**

Under the requirements of UK Policy Framework for Health and Social Care Research, the University of Birmingham agrees to act as Sponsor for this project. Sponsorship is subject to you obtaining a favourable ethical opinion, HRA approval and NHS R&D management approval where appropriate.

As Chief Investigator, you must ensure that local study recruitment does not commence until all applicable approvals have been obtained. Where a study is or becomes multi-site you are responsible for ensuring that recruitment at external sites does not commence until local approvals have been obtained.

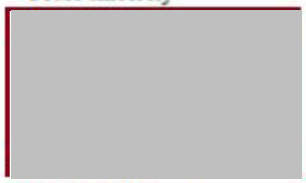
Following receipt of all relevant approvals, you should ensure that any subsequent amendments are notified to the Sponsor, REC, HRA and relevant NHS R&D Office(s), and that an annual progress report is submitted to the Sponsor, REC and NHS R&D departments where requested.

Please ensure you are familiar with the University of Birmingham Code of Practice for Research (http://www.birmingham.ac.uk/Documents/university/legal/research.pdf) and any appropriate College or School guidelines.

Finally please contact researchgovernance@contacts.bham.ac.uk should you have any queries.

You may show this letter to external organisations.

Yours sincerely



Dr Birgit Whitman
Head of Research Governance and Integrity

Appendix 22 - Research Ethics Committee

NHS
Health Research Authority

East Midlands - Nottingham 1 Research Ethics Committee

The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Tel: 02071048199

16 December 2021

Mrs Cathy Miller
NHS Blood and Transplant
Vincent Drive
Edgbaston
Birmingham
B15 2SG

Dear Mrs Miller

Study title:	**Was the deemed consent education and training programme for the legislation change in England implemented effectively?**
REC reference:	**21/EM/0009**
Protocol number:	**RG_20-093**
Amendment number:	**AM 01**
Amendment date:	**13 November 2021**
IRAS project ID:	**287067**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Completed Amendment Tool [Completed Amendment Tool]	1.5	13 November 2021
Letters of invitation to participant [Recruitment Email]	1	30 November 2021
Other [Microsoft Forms Survey]	1	30 November 2021
Participant information sheet (PIS) [Participant Information Sheet (PIS)]	1	22 November 2021

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

NHS
Health Research Authority

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: https://www.hra.nhs.uk/planning-and-improving-research/learning/

IRAS Project ID - 287067:	Please quote this number on all correspondence

Yours sincerely

PP
Chair

Mr Paul Hamilton

E-mail: Nottingham1.rec@hra.nhs.uk

Copy to:

NHS
Health Research Authority

East Midlands - Nottingham 1 Research Ethics Committee

Attendance at Sub-Committee of the REC meeting held via correspondence.

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Elerina Kellezi	Lecturer in Psychology	Yes	
Mr Oliver Matias	PHD Student	Yes	Chaired the meeting.

Also in attendance:

Name	*Position (or reason for attending)*
Ms Mia Cooper	Approvals Administrator

1.	Consenting family members for observations and data collection a) Thank you for providing a brief consent script and debrief document for use after the consultation. I would advise the debrief outlines the types of data that will have been collected (sex of the patient, cause of death, number of people present and relationships, approximate age of patient) and assurances that no identifiable data has been collected. Please confirm the document will be made available to all families after the consultation b) With regard to the data being collected, please clarify how this will be obtained given you won't have permission to access medical records for research purposes? Will you only record this data if it become apparent from the discussion? The advice you initially received from the University governance team advised there should not be a request to use any patient data you are privy to. Has this issue been resolved with the university given you now intend to collect sex, age and cause of death?	**Response from the applicant** a) I have added a sentence in to show that: ‘ I will capture some anonymised demographics about your loved one such as approximate sex, cause of death, number of people present in the end of life conversation and their relationship with the deceased’. I can confirm the debrief document will be offered to all families approached regards donation. b) Yes, I will only collate and record the data that comes to light during the observation of the breaking bad news and donation discussion, as I don’t have permission to success medical records. Yes, this issue has been resolved, as I am not requesting access to any medical records, only data recorded during the observation will be pseudo anonymised e.g. sex of the patient, cause of death, number of people present and relationships, approximate age of patient.
2.	Given your confirmation that the video recording of training has already been undertaken as part of service evaluation, is my assumption correct that the PIS you have created for this group is no longer applicable?	Correct. University Ethics Application (AER) has been updated to reflect this and re-submitted via IRAS V11.

3.	All Information Sheets Original query: Please incorporate the HRA's recommended transparency wording in the section titled 'What are your choices about how your information is used?'. In the 'More about how your information is used?' section please include the following link: www.hra.nhs.uk/patientdataandresearch (or a link to equivalent information on the University of Birmingham's website). The link above has been incorporated in place of the HRA's 'information about patients' link. Please ensure both are present (apologies if this wasn't clear in my previous wording. Follow up: The following sentences are missing and require insertion - 'We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you'. - 'This information will include [insert list of identifiers]' (after the sentence beginning 'We will need to use information from you....').	Added the HRA's recommended transparency wording in as requested to PIS for stages 2.2 & 2.3 and 2.4. Added this wording in as requested and highlighted in yellow on the PIS for stages 2.2 & 2.3 and 2.4 Added identifiers as requested- Highlighted in yellow on the PIS for stages 2.2 & 2.3 and 2.4. **'This information will include your name, contact details and any information you wish to share when answering the research questions, pertaining to the legislation change and/or training provided'.**
4.	Organisation Information Document – Both The OID for NHS BT should list 'Principal Investigator' rather than 'Local Collaborator' as taking responsibility for activities at the site, given that you are employed there and will be undertaking the activities yourself.	Amended OID for NHSBT as requested, showing Cathy Miller as the PI.

Appendix 24 - Health Research Authority Approval

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Mrs Cathy Miller
Head of Education and Professional Development
NHS Blood and Transplant
Vincent Drive
Edbgbaston
Birmingham
B15 2SGN/A

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

12 April 2021

Dear Mrs Miller

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Was the deemed consent education and training programme for the legislation change in England implemented effectively?**
IRAS project ID:	**287067**
Protocol number:	**RG_20-093**
REC reference:	**21/EM/0009**
Sponsor	**University of Birmingham**

I am pleased to confirm that HRA and Health and Care Research Wales (HCRW) Approval has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **287067**. Please quote this on all correspondence.

Yours sincerely,

Helen Poole

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Mrs Cathy Miller, NHS Blood and Transplant*

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	Version	Date
Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [CAG not required]	1	24 September 2020
Copies of materials calling attention of potential participants to the research [Poster to recruit participants]	1	29 September 2020
Evidence of Sponsor Insurance or Indemnity (non NHS Sponsors only) [287067 Insurance Letter]	1	08 December 2020
Interview schedules or topic guides for participants [Semi-structured Interview and Debrief post shadow on-call]	2	12 November 2020
Interview schedules or topic guides for participants [Semi-structured Interview Questions Stage 3]	2	12 November 2020
IRAS Application Form [IRAS_Form_09122020]		09 December 2020
Letter from sponsor [Sponsor Letter University of Birmingham]	1	08 December 2020
Letters of invitation to participant [recruitment email for stage 2.1 review of digital on-line training]	1	30 November 2020
Letters of invitation to participant [287067 Recruitmnet email for stage 2.2 2.3 2.4]	1	30 November 2020
Non-NHS/HSC Site Assessment Form [OID NHS Blood and Transplant]		
Non-validated questionnaire [Semi-structured Interview and Debrief post shadow on-call]	1	29 September 2020
Organisation Information Document [NHS Blood and Transplant RINTAG approval 287067]	1	13 July 2020
Other [Debrief Potential Donor Family]	2	17 March 2021
Other [Ethics Form University of Birmingham]	11	19 March 2021
Other [287067 Ethics Proposal University of Birmingham]	9	28 November 2020
Other [287067 Clinical Trials Coverage University of Birmingham]	1	01 August 2020
Other [287067 Employee Liability University of Birmingham]	1	01 August 2020
Other [List of Hospitals Participating]		
Other [Observation proforma Stage 2.2]	3	24 February 2021
Other [287067 Stage 2.1a Assessment Guide for Participant Observation video footage and shadow on-call]	1	16 February 2021
Other [REC Response]	1	24 February 2021
Other [Ethics Form University of Birmingham]	10	18 February 2021
Other [Individual NHS Hospitals in the Midlands]	1	06 November 2020
Other [287067 Stage 2.1. Participant Observation Form for digital training and shadow on-call]	2	01 November 2020
Other [287067 Stage 2.1a Assessment Guide for Participant Observation video footage and shadow on-call]	1	15 November 2020
Participant consent form [287067 consent form stage 2.2 2.3]	2	06 February 2021
Participant consent form [Consent Form for Semi Structured Interview Stage 2.4]	2	
Participant Information sheet (PIS) [Participant Information for shadow on call semi structured interview and debrief Stages 2 and 3]	4	17 March 2021
Participant Information sheet (PIS) [287067 stage 2.4 participant information sheet semi structured interview]	3	17 March 2021
Research protocol or project proposal [Qualitative Protocol]	0.1	10 July 2020
Response to Request for Further Information [Formal Response to		30 March 2021

HRA Assessment Queries]		
Response to Request for Further Information [Email correspondence - confirmation that NHSBT Memorandum of Understanding covers CI's role]		09 April 2021
Schedule of Events or SoECAT [Schedule of Events]	2	24 February 2021
Schedule of Events or SoECAT [SoE NHSBT]	2	24 February 2021
Summary CV for Chief Investigator (CI) [CV 287067]		
Summary CV for student [CV 287067]	1	25 September 2020
Summary CV for supervisor (student research) [287067 Academic Supervisor CV]	1	
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Thesis Presentation]		

Appendix 25 - Research Approval from NHSBT R&D

NHS Blood and Transplant

Cathy Miller
Organ Donation and Transplantation
NHS Blood and Transplant

NHS Blood & Transplant
c/o National R&D Office
500 North Bristol Park
Northway
Filton
Bristol
BS34 7QH

Email: research.office@nhsbt.nhs.uk

21st April 2021

Dear Cathy,

NHSBT ID: EdD-21-05
Title: Evaluation of the deemed consent education intervention: A Specialist Nurse in Organ Donation perspective.
Dates: June 2021 – September 2023

Following review of the above named project, I can confirm your project proposal is approved by the NHSBT R&D Office. Your project is seeking to understand whether the deemed consent education and training programme for the legislation change is implemented effectively.

Approval has been obtained from the RINTAG Strategy Group. You therefore have operational support to proceed with your project.

This approval is granted on the basis that the research has obtained HRA and REC approval and no further approvals have been identified. The project must follow the agreed protocol and be conducted in accordance with all NHSBT policies and procedures, especially those relating to research and data management.

As a condition of your approval, please ensure that the R&D Office is sent a copy of the report for this project once it is complete. If you have any questions relating to this approval please contact the NHSBT R&D Office (research.office@nhsbt.nhs.uk) quoting the Reference Number: EdD-21-05.

Yours sincerely

NHSBT R&D Office

Appendix 26 - 15 Fundamental Principles: UK Policy Framework for Health and social Care Research

Identification and Management of Ethical Risk	
Ethical Risk	**Management**
Safety	To ensure the safety and well-being of the individual participants prevails over the interests of science and society. Putting the potential donor family and Specialist Nurses first, over and above the research, making sure the correct safeguards and information were explained.
Competence	The researchers' seconded post was Education and Governance Workstream Lead for the Deemed Consent legislation change and her substantive post was Head of Education at NHS Blood and Transplant. The researchers' nursing background was in Intensive Care and as she previously worked as a Specialist Nurse. The research was conducted under the supervision of Dr Kotzee.
Scientific and Ethical Conduct	Assessing the benefits of research, proportionate to the potential for harm was an essential role for the researcher and her supervisor making sure the research was scientifically sound, before applying for ethical and governance committee scrutiny from NHSBT RINTAG, UoB, HRA, REC and NHSBT R&D.
Patient, Service User and Public Involvement	A representative from the Donor Family Network, along with a professor from palliative care and other experts observed and provided feedback on the legislation training, as part of a 'critical friends day'. The 'critical friends' provided positive and encouraging feedback on the use of simulation scenarios with professional actors.
Integrity, Quality and Transparency	The research was designed, reviewed, managed, and undertaken in a manner that ensured integrity, quality, and transparency.
Protocol	The Application for Ethical Approval at University of Birmingham (Appendix Q) was provided as the protocol. In addition, a protocol template was completed for NHSBT R&D.
Legality	The researcher and her supervisor worked closely with the sponsor Dr Birgid Whitman (Head of Research Governance and Integrity) and Harmeet from research governance, to ensure the relevant legislation and

	guidance in respect of managing and conducting the research was adhere to.
Benefits and Risks	Prior to the research project starting, anticipated benefits for the individual participants and other present and future recipients of the educational and training under research was weighed against the foreseeable risks and inconveniences once they were mitigated against. Although no risks are anticipated, if in the unlikely event the researcher's observation causes any distress, then with your permission, either the researcher will support you, or I will request that your Team Manager supports you and/or signposts you to any additional support you may need. However, the researcher is a qualified Specialist Nurse and Executive Coach and therefore trained to recognise and respond to distress. The study could not guarantee any benefits to the Specialist Nurse, and they were not reimbursed for their participation. However, findings could support other countries wishing to introduce a new law around organ donation and could help support other education and training programmes or the debrief and reflection aspects could be used as part of their Nursing and Midwifery Council (NMC) revalidation. The observation was not considered to be onerous and may offer you support and assurance at a difficult time.
Approval	The researcher received ethical approval from NHSBT RINTAG, UoB, HRA, REC and NHSBT R&D.
Information about the Research	Participant Information Sheets were given to all SNOD's participating in the observation semi-structured interview and debrief aspects of the research. An optional debrief information sheet was also offered to potential donor families to inform them about the research.
Accessible Findings	The researcher promised to share the findings of the study with participants, whether positive or negative. The findings will be published/made accessible, with adequate consent and privacy safeguards, in a timely manner after the study has finished, in compliance with any applicable regulatory standards.
Choice	Participation in the research study was on an entirely voluntary basis. Participants had the right to withdraw from the study at any time. If they

	changed your mind during the data collection, they were asked to let the researcher know. The participants were advised that they could stop being part of the study at any time, without giving a reason, but that their information that the researcher already had would be kept, unless their withdrawal was within 6 weeks, where their data would be deleted. It was important for participants to know that if they choose not to take part or withdraw from the study that the training and education they receive would not be affected.
Insurance and Indemnity	The university of Birmingham provided Clinical Research Insurance under their membership of UMAL.
Respect for Privacy	All information collected for or as part of the research project was recorded, handled, and stored appropriately and in such a way and for such time that it can be accurately reported, interpreted, and verified, while the confidentiality of individual research participants remains appropriately protected. The information was pseudo-anonymised, such as SNOD 1, SNOD 2, So that they were not identifiable.
Compliance	The researcher was aware that sanctions for non-compliance with these principles may include appropriate and proportionate administrative, contractual, or legal measures by funders, employers, relevant professional and statutory regulators, and other bodies.

Appendix 27 - Amendment Tool to Request Inclusion of Oxford university Hospital as part of the research study

Amendment Tool

v1.5 25 Mar 2021

For office use

QC: No

Section 1: Project information

Short project title*:	Evaluation of deemed consent education Programme in England
IRAS project ID* (or REC reference if no IRAS project ID is available):	287067
Sponsor amendment reference number*:	AM NS 01
Sponsor amendment date* (enter as DD/MM/YY):	13 July 2021
Briefly summarise in lay language the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study. If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained (note: this field will adapt to the amount of text entered)*:	To extend the research approval to one more Hospital- Oxford University Hospital. The reason for extending the study, is the increase the observation opportunity. The Midlands have had a run of potential donors on the Organ Donor Register, who are excluded from my study. Whereas, OUH with high donation potential, including a Neurological and Adult Intensive Care Unit, has had a run of unsupported 'deemed consents' and would benefit from the insight the research could offer. OUH is also logistically, as close, to the researcher as some of the Midlands Hospitals. The Regional, Team Manager and Consultant are all supportive of this approach and appreciate the next step is to submit the amendment for approval. Once approved, the Local Information Pack (already prepared) can be emailed to OUH's Research and Development department to assess capacity and capability. The participant information sheets, and consent forms remained unchanged. It is proposed that awareness meetings and recruitment of participants from the South-Central Organ Donation Services Team will be carried out in the same way, as the researcher raised awareness and recruited participants in the Midlands. In short, extending the study to include one further Hospital (OUH) will increase the likelihood of observing 8-10 approaches for organ donation, where deemed consent applies.

Project type (select):	● Specific study ○ Research tissue bank ○ Research database			
Has the study been reviewed by a UKECA-recognised Research Ethics Committee (REC) prior to this amendment?:	● Yes		○ No	
What type of UKECA-recognised Research Ethics Committee (REC) review is applicable? (select):	● NHS/HSC REC ○ Ministry of Defence (MoD REC)			
Is all or part of this amendment being resubmitted to the Research Ethics Committee (REC) as a modified amendment (i.e. a substantial amendment previously given an unfavourable opinion)?	○ Yes		● No	
Where is the NHS/HSC Research Ethics Committee (REC) that reviewed the study based?:	England	Wales	Scotland	Northern Ireland
	●	○	○	○
Was the study a clinical trial of an investigational medicinal product (CTIMP) OR does the amendment make it one?:	○ Yes		● No	
Was the study a clinical investigation or other study of a medical device OR does the amendment make it one?:	○ Yes		● No	
Did the study involve the administration of radioactive substances, therefore requiring ARSAC review, OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve the use of research exposures to ionising radiation (not involving the administration of radioactive substances) OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve adults lacking capacity OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve access to confidential patient information outside the direct care team without consent OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve prisoners OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve children OR does the amendment introduce this?:	○ Yes		● No	
Did the study involve NHS/HSC organisations prior to this amendment?:	● Yes		○ No	
Did the study involve non-NHS/HSC organisations OR does the amendment introduce them?:	○ Yes		● No	

	England	Wales	Scotland	Northern Ireland
Lead nation for the study:	●	○	○	○
Which nations had participating NHS/HSC organisations prior to this amendment?	■	□	□	□
Which nations will have participating NHS/HSC organisations after this amendment?	■	□	□	□

Section 2: Summary of change(s)

Please note: Each change being made as part of the amendment must be entered separately. For example, if an amendment to a clinical trial of an Investigational medicinal product (CTIMP) involves an update to the Investigator's Brochure (IB), affecting the Reference Safety Information (RSI) and so the information documents to be given to participants, these should be entered into the amendment tool as three separate changes. A list of all possible changes is available on the "Glossary of Amendment Options" tab. To add another change, tick the "Add another change" box.

Change 1				
Area of change (select)*:	Participating Organisations			
Specific change (select - only available when area of change is selected first)*:	Addition of sites undertaking the same activities as existing sites			
Further information (free text - note that this field will adapt to the amount of text entered):	Addition of Oxford University Hospitals NHS Trust as a new research site.			
Applicability:	England	Wales	Scotland	Northern Ireland
Where are the participating NHS/HSC organisations located that will be affected by this change?*:	■	□	□	□
Will all participating NHS/HSC organisations be affected by this change, or only some? (please note that this answer may affect the categorisation for the change):	○ All		● Some	

Add another change: □

Section 3: Declaration(s) and lock for submission

Declaration by the Sponsor or authorised delegate

- I confirm that the Sponsor takes responsibility for the completed amendment tool
- I confirm that I have been formally authorised by the Sponsor to complete the amendment tool on their behalf

Name (first name and surname)*:	Dr Birgit Whitman
Email address*:	researchgovernance@contacts.bham.ac.uk

Lock for submission

Please note: This button will only become available when all mandatory (*) fields have been completed. When the button is available, clicking it will generate a locked PDF copy of the completed amendment tool which must be included in the amendment submission. Please ensure that the amendment tool is completed correctly before locking it for submission.

Lock for submission

After locking the tool, proceed to submit the amendment online. The "Submission Guidance" tab provides further information about the next steps for the amendment.

Section 4: Review bodies for the amendment

Please note: This section is for information only. Details in this section will complete automatically based on the options selected in Sections 1 and 2.

Review bodies																
UK wide:						England and Wales:				Scotland:				Northern Ireland:			

	RSC	Competent Auth - MHRA - Medicines	Competent Auth - MHRA - Devices	ARSAC	Radioactive Substances	UK/IG/Governance	RSC (HCA)	CAG	HNFTB	HRA and HCRW	RSC (WWA)	PBPP	SPR (RAEC)	National coordinating	HSC REC	HSC Data Guardian	Pharmacy	National coordinating	Category:
Change 1:						(Y)				(Y)									New site
Overall reviews for the amendment:																			
Full review:						N				N									
Notification only:						Y				Y									
Overall amendment type:	Non-substantial, no study-wide review required																		
Overall Category:	New site																		

Appendix 28 - Operational Temperature check Survey Questions

1. Are you clear on the rationale for legislation change? (1-10)
2. Do you feel there is clear leadership advocating the change within your team? (1-10)
3. Do you feel you understand deemed legislation & the impact it will have on you and your role? (1-10)
4. What will that change mean for you in practice? (Please tell us)
5. Do the communications and engagement provide you opportunities to get informed and provide feedback? (1-10)
6. Are you confident the training will equip you with the necessary skills to perform?
7. What other areas would you like us to focus on in the following months? (Please tell us)

Appendix 29 - Participant Observations - Approach Table

Hospital	Date	Diagnosis	Sex	Age	DBD /DCD	Formal Timing of Approach	Interprofessional Planning	Interprofessional Approach	Number of Family Present	Outcome Supported/ Unsupported Deemed	Prior Knowledge of the Legislation	Comments
Anonymised for confidentiality		ICH found at bottom of stairs	M	60's	DBD	After 1st set of BSDT's	SR, Consultant & BSN	2 part conversation over the telephone. Consultant BBD & SR approach. 2 separate calls.	1 Brother (wife in the background)	Supported Deemed Consent	YES	Family had a good grasp of the legislation, felt this is something his brother would want to do.
Anonymised for confidentiality		OOH CA found at home in bed	F	50's	DCD	Prior to WLST	SR, Consultant & BSN	SR, Consultant & BSN	Daughter & Husband: Patient's Husband and 2 teenage step-children.	Expressed Known Decision	Unknown	Not to be a donor-buried intact

Anonymised for confidentiality	Accident at work Hanging	M	40's	DCD	Prior to WLST	Yes. Consultant, & SNOD	Yes Consultant and SNOD. **Not** BSN.	7 Partner + Patients Brothers and Sisters	Expressed Known Decision	Unknown	Did not want organ donation for his father- wanting body buried whole. Family said that he wouldn't have wanted it either, when SR asked was that his wish too? Family unanimously agreed. No further exploration. Unhelpful choice of language by Consultant 'preserve his dignity',

Anonymised for confidentiality		ICH	F	40's	DCD	Prior to WLST	Yes. Consultant, BSN & SR	Yes Consultant, SR & BSN	Daughter, Partner, Mom, patients Brother & Wife	Unsupported Deemed	Awareness of the legislation- saying 'you can't do anything without our permission, can you?'	Wanted body buried whole 'whole jigsaw, not little pieces'. Definite 'no' despite exploration from SR.
		Cardiac Arrest- Hanging	M	Mid 20's	DBD	After 1st set of BSDT's	Yes Consultant, BSN & SR	YES. consultant stayed and BSN contributed- offering to support 4 & 6 year old children coming into ITU.	7	Supported Deemed Consent	No views expressed about the legislation	3 Children aged 2, 4 & 6. Mom came forward- pro-donation.
		ICH	F	60's	DBD	After 1st set of BSDT	Yes. Consultant & SNOD	Yes Consultant, SNOD & BSN	2 Patients' son & daughter	Expressed Known Decision	Unknown	Legislation not mentioned. When daughter signed up to ODR her Mom

												frowned upon it, when explored by SNOD daughter voiced it was a **spiritual belief**.
Anonymised for confidentiality		Brain Tumour- complications	F	30's	DCD	Prior to WLST	Yes. CLOD & SNOD	Yes CLOD, SNOD & BSN	10	Unsupported Deemed Consent	Not mentioned by SNOD/SR (Hybrid) Unknown	Against our religion if you take organs out of the body- they don't go whole to God. Arguably a known Decision- Sister said when discussing organ donation she said 'why would anyone

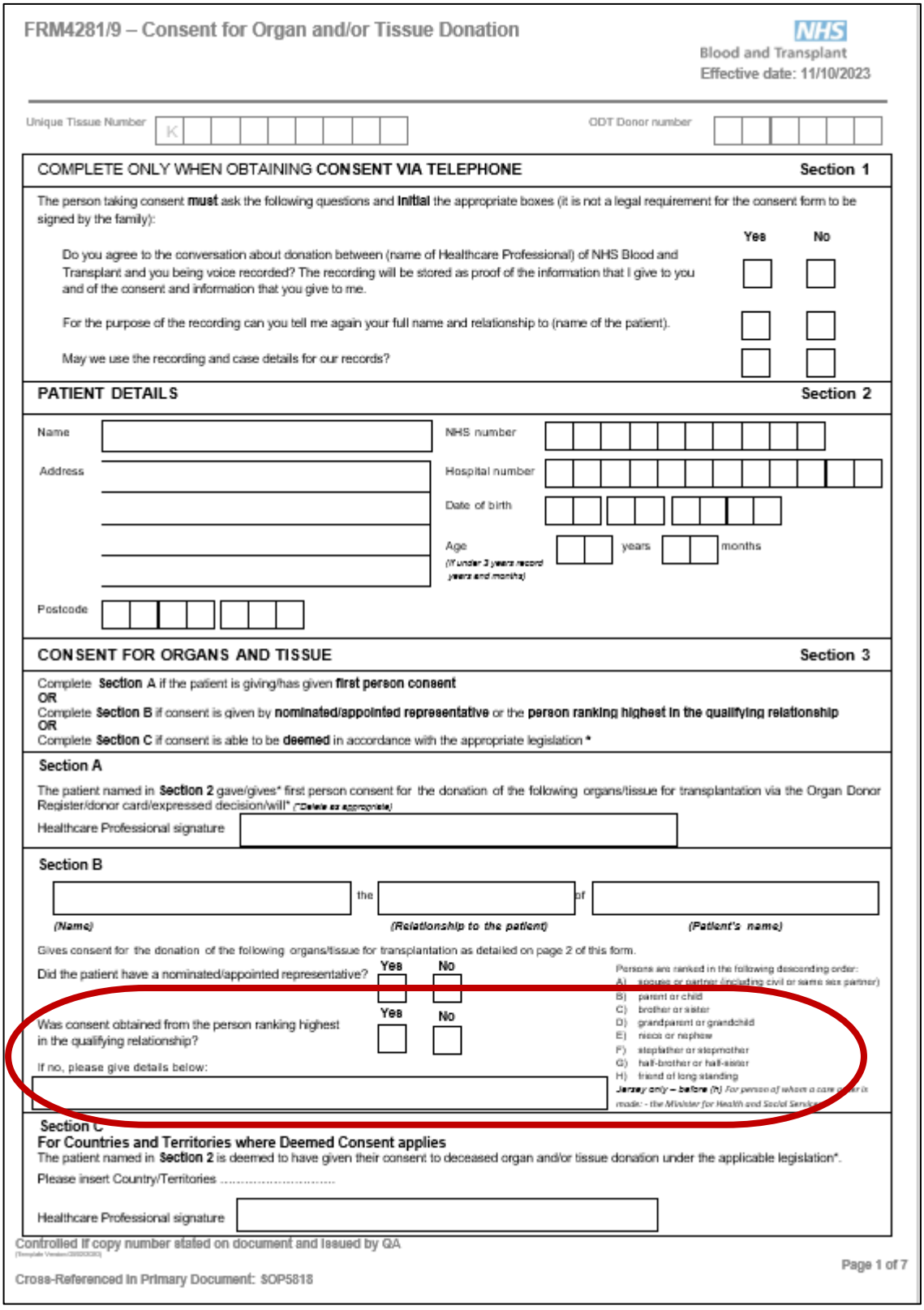
											want to do that'.
Anonymised for confidentiality	OOHCA PE	M	Late 50's	DCD	Prior to WLST	No SR & BSN (Consultant mentioned donation the night before as the daughters friend was an ICU nurse)	SR & BSN	4 Wife, Son, Daughter & Fiancée	Supported Deemed-Tissue donor	Family 'Did not think he even knew about the law change'.	Wanted to be there when his heart stopped. Tissue donation. Sound byte of heartbeat, heart tracing as keepsakes for daughters upcoming wedding.
Anonymised for confidentiality	ICH	M	50's	DBD	After 1st set of BSDT's	Consultant, BSN & SR. Consultant telephoned family	No. Telephone approach- with estranged Niece. Not visiting the unit-didn't drive.	Niece (early 30's)	Unsupported Deemed-Been through enough. Comorbiditi es-wheel	Unknown Did not respond adversely to the law being mentioned.	Nurse (<12 months in post) broke bad news -used words 'passed away' and suggested a pause, and that

						prior to testing.	SR & BSN in approach over the telephone.		chair bound-sheltered accommodation. Previous ICH/stroke.		the Specialist Nurse would call back in 15 mins. Complex situation on the unit-paed admission to adult ITU. IDL may have been useful.
Anonymised for confidentiality	ICH	F	60's	DBD	After 1st set of BSDT	Yes. Clinical Lead Organ Donation & SR	After BSDT Conversation CLOD and BSN	5 Partner and partners children x2 and patients2 sisters	Supported Deemed	Yes	Leveraged the legislation, supported family in having the conversation with the patients brothers who weren't in the room.

Anonymised for confidentiality	ICH	F	Mid 70's	DBD	Not approached-Liver accepted by Birmingham. SR consulted with TM who agreed the patient was not medically suitable-multiple comorbidities- necrotic toes-missing etc.	N/A	Non-approach-NMS	Husband	Non-approach-NMS	Unknown	Donor DW TC. Not suitable Consultant informed-then abandoned 2nd set of BSDT's. Were family asked about OD-No-reason on PDA - pressure on ITU beds.
Anonymised for confidentiality		M	40's	DBD	Not approached	Not approached	Not approached	Extended family from London	Not approached	Not approached	Awaiting Mom to arrive from Nigeria-stuck at airport with

											COVID. Family arrived from London- awaiting a miracle.
Anonymised for confidentiality		F	40's	DCD	Prior to WLST	Yes SR, Consultant & BSN	Conversation Parked	Partner & Mom (Awaiting Brother & Daughter)	Conversation Parked		Arrived on unit just Conversation was taking place. Parked until the following day.

Appendix 30 - Consent Form for Organ and/or Tissue Donation



FRM4281/9 – Consent for Organ and/or Tissue Donation

NHS Blood and Transplant
Effective date: 11/10/2023

Unique Tissue Number K

ODT Donor number

COMPLETE ONLY WHEN OBTAINING CONSENT VIA TELEPHONE — **Section 1**

The person taking consent **must** ask the following questions and **initial** the appropriate boxes (it is not a legal requirement for the consent form to be signed by the family):

	Yes	No
Do you agree to the conversation about donation between (name of Healthcare Professional) of NHS Blood and Transplant and you being voice recorded? The recording will be stored as proof of the information that I give to you and of the consent and information that you give to me.		
For the purpose of the recording can you tell me again your full name and relationship to (name of the patient).		
May we use the recording and case details for our records?		

PATIENT DETAILS — **Section 2**

Name

Address

Postcode

NHS number

Hospital number

Date of birth

Age (If under 3 years record years and months) ____ years ____ months

CONSENT FOR ORGANS AND TISSUE — **Section 3**

Complete **Section A** if the patient is giving/has given **first person consent**
OR
Complete **Section B** if consent is given by **nominated/appointed representative** or the **person ranking highest in the qualifying relationship**
OR
Complete **Section C** if consent is able to be **deemed** in accordance with the appropriate legislation *

Section A

The patient named in **Section 2** gave/gives* first person consent for the donation of the following organs/tissue for transplantation via the Organ Donor Register/donor card/expressed decision/will* *(*Delete as appropriate)*

Healthcare Professional signature

Section B

_____ (Name) the _____ (Relationship to the patient) of _____ (Patient's name)

Gives consent for the donation of the following organs/tissue for transplantation as detailed on page 2 of this form.

Did the patient have a nominated/appointed representative? Yes ☐ No ☐

Was consent obtained from the person ranking highest in the qualifying relationship? Yes ☐ No ☐

If no, please give details below:

Persons are ranked in the following descending order:
A) spouse or partner (including civil or same sex partner)
B) parent or child
C) brother or sister
D) grandparent or grandchild
E) niece or nephew
F) stepfather or stepmother
G) half-brother or half-sister
H) friend of long standing
Jersey only – before (h) For person of whom a care order is made: - the Minister for Health and Social Services

Section C
For Countries and Territories where Deemed Consent applies
The patient named in **Section 2** is deemed to have given their consent to deceased organ and/or tissue donation under the applicable legislation*.

Please insert Country/Territories .....

Healthcare Professional signature

Controlled if copy number stated on document and issued by QA

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Cross-Referenced In Primary Document: SOP5818

Unique Tissue Number K

ODT Donor number

CONSENT FOR DONATION

Section 4

Please initial appropriate box

	Yes	No	Exclusion	Coroner Restriction
Kidneys	☐	☐	☐	☐
Liver	☐	☐	☐	☐
Liver for Hepatocytes	☐	☐	☐	☐
Pancreas	☐	☐	☐	☐
Pancreas for Islet Cells	☐	☐	☐	☐
Heart	☐	☐	☐	☐
Heart for Valves	☐	☐	☐	☐
Lungs	☐	☐	☐	☐
Bowel	☐	☐	☐	☐
Multivisceral*	☐	☐	☐	☐
*If yes, please specify explicitly				
Other**	☐	☐	☐	☐
**If yes, please specify explicitly				
Eyes	☐	☐	☐	☐
Skin	☐	☐	☐	☐
Bone	☐	☐	☐	☐
Tendons (Ankle & Knee)	☐	☐	☐	☐
Femoral Artery	☐	☐	☐	☐
Meniscus	☐	☐	☐	☐
Other Tissue***	☐	☐	☐	☐
***If yes, please specify explicitly				
Blood Vessels (see core information)	☐			

ONLY USE IN CIRCUMSTANCES WHEN FAMILIES DO NOT WANT INFORMATION

All Abdominal Organs (including Liver for Hepatocytes, Pancreas for Islet cells)

Yes ☐ No ☐

Blood Vessels (see core information) ☐

All Cardiothoracic Organs

Yes ☐ No ☐

All Tissues (excluding Liver for Hepatocytes, Pancreas for Islet cells)

Yes ☐ No ☐

NATIONAL REFERRAL CENTRE USE ONLY

All Tissues

Yes ☐ No ☐

Do you consent to the patient being transferred from his/her place of death to the NHSBT Tissue services donation facility or an alternative establishment i.e. another hospital mortuary for the donation procedure to be undertaken, if applicable?

Yes ☐ No ☐ N/A ☐

Unique Tissue Number K

ODT Donor number

CONSENT FOR SCHEDULED PURPOSES Section 5

Reminder - Deemed Consent does not apply to Scheduled Purposes

Organs and/or tissue can also be used for the Scheduled Purposes* listed below:

Scheduled Purposes Include:
Research
Education or Training related to Human Health
Clinical audit
Quality Assurance
Performance Assessment

*only relevant Scheduled Purposes listed.

	Yes	No	N/A
1. There is also an opportunity to support transplantation/healthcare through the removal of samples, for example blood, urine and/or tissue samples from specific organs which can then be used in approved research projects. Do you believe the patient would agree to this **and** do you consent?	☐	☐	☐

	Yes	No
2. On occasion, organs/tissues you have agreed to donate may be found to be unsuitable when removed for transplant. However, these organs/tissues can be used in research (or other Scheduled Purposes as detailed above) to improve healthcare in the future, do you consent to this?	☐	☐

3. Organs/tissues/samples may also be donated and used to improve future healthcare.
Do you consent to the removal and storage of specific organ/tissues/samples for research or other Scheduled Purposes as detailed above?

A. In QUOD-Licensed Hospitals Only

	Yes	No	N/A
Heart	☐	☐	☐
Lungs	☐	☐	☐
Diabetic Pancreas	☐	☐	☐
B. Centre-Licensed Specific Studies	☐	☐	☐

(For questions 1 & 3B - Please detail specific organ/tissue/samples in notes on page 6).

Any research or other Scheduled Purposes restriction? Yes ☐ No ☐ N/A ☐

If yes, please provide detail

Organs and/or tissue will be used and stored for a Scheduled Purpose in accordance with The Human Tissue Act (2004)

Organs and/or tissue and/or material that are not used will be disposed of as per local establishment policy in accordance with the Human Tissue Act (2004).

Unique Tissue Number K | | | | | | | | | | ODT Donor number | | | | | | |

SHARING OF INFORMATION REQUIRED TO SUPPORT ORGAN AND TISSUE DONATION — Section 6

Core information

Blood samples will be obtained from the patient for testing, including pregnancy (for organ donors only, if applicable), tissue typing, HIV, Hepatitis, HTLV and Syphilis. These samples may be subsequently stored for future testing as necessary.

In order to ensure the safety and quality of transplantation, if an abnormality were found during the retrieval/ processing, tissue sample(s) will be taken for analysis and subsequently stored for potential further testing.

In the event of *any* screening results that may have implications for the family, relevant individuals may be contacted if their health could be affected.

For paediatric donation only:
Blood samples will be obtained from the patient and the patient's mother where the patient is under 18 months old and/or the patient has been breast fed in the last 12 months for testing, including tissue typing, HIV, Hepatitis, HTLV and Syphilis. These samples may be subsequently stored for future testing as necessary. In the event of any screening results that may have implications for the family, relevant individuals may be contacted if their health could be affected.

Organ donation:
Tissue samples for example, lymph node and spleen that have been obtained for screening will be subsequently biopsied, analysed and stored for future testing as necessary.
Blood vessels will be retrieved and stored to support organ transplant or other surgical procedures, if not used within 14 days will be disposed of in accordance with the hospital/tissue establishment policy.

Tissue donation:
The tissue donated (including hepatocytes and heart for valves) for transplantation will be stored for extended periods in tissue establishments whilst it is prepared for transplantation.

Surrounding tissue:
As part of the organ and/or tissue retrieval process surrounding tissue will be removed to support the safety and quality of transplantation. Only where necessary will this include part or whole organs.

The patient's medical records have/will be accessed by relevant healthcare professionals to obtain a past medical/behavioural history. This information may be passed on a need-to-know basis to other healthcare professionals in support of the donation and transplantation process. This information may also be retained by the Organ Donation Teams/Tissue Establishment.

The information collected from you on the consent form will be stored securely and only be used in support of the donation and transplantation process. For further information please see the privacy statement on NHSBT's website:
https://www.nhsbt.nhs.uk/privacy/

Core information has been provided ☐

Applicable legislation:
Consent is obtained in accordance with the following legislation and good practice guidance:

Human Tissue Act (2004)
Human Transplantation (Wales) Act 2013 *
Human Transplantation and Anatomy (Jersey) Law 2018 *
The Human Tissue Authority Codes of Practice
Organ Donation (Deemed Consent) Act 2019 *
The Human Tissue Authority Code of Practice for organ donation to support the Human Transplantation (Wales) Act 2013
Mental Capacity Act (2005)
Mental Capacity Act (Northern Ireland) 2016
General Data Protection Regulation 2016

Unique Tissue Number K | ODT Donor number

CONFIRMATION OF CONSENT — Section 7

I have understood the above and I have had the opportunity to ask questions which have been answered to my satisfaction.

Patient/Relationship to patient

Name (Please print) | Signed

Date 20 | Time (24hr)

Address of person giving consent | Email address

Telephone number

Mobile

Co-signatory Name (Where applicable) (Please print) | Signed

Relationship to patient | Email address

Telephone number/mobile

Healthcare Professional Details (Witness)

Designation

Name (Please print) | Signed

Date 20 | Time (24 hr)

Healthcare Professional Ascertaining Consent

Designation

Name (Please print) | Signed

Date 20 | Time (24 hr)

Information leaflets given to family? ☐ **OR** **Information leaflets to be sent to the family?** ☐

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