UTS UNIVERSITY OF TECHNOLOGY SYDNEY

COMmunication with Families regarding ORgan and Tissue Donation after Death in Intensive Care.

by Julie Elizabeth Potter

Thesis submitted in fulfilment of the requirements for the degree of

Doctor of Philosophy

under the supervision of Prof Lin Perry, Dr Rosalind Elliott and Assoc Prof Michelle Kelly

University of Technology Sydney
Faculty of Health

January 2021

Certificate of Original Authorship

I, Julie Potter declare that this thesis, is submitted in fulfilment of the requirements for the award of Doctor of Philosophy, in the School of Nursing and Midwifery/Faculty of Health at the University of Technology Sydney.

This thesis is wholly my own work unless otherwise reference or acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

This document has not been submitted for qualifications at any other academic institution.

This research is supported by the Australian Government Research Training Program.

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Statement Indicating the Format of the Thesis

This thesis is formatted by compilation. It is formatted as a single manuscript that is compiled from published and publishable papers distributed through the thesis and presented in chapters.

Structure of the Thesis

This thesis is presented in eight chapters. Six chapters are a compilation of unpublished and published material. Of those, chapters 2 and 3 are presented in the form of peer reviewed journal articles (submitted and published, respectively). To meet journal requirements for manuscript submission, spelling includes British English (Chapter 2). References are included at the end of the thesis.

Chapter 1 presents contextual background information underpinning the research questions for this thesis and explains the significance of the work. This chapter contains material from the background section of the study protocol published in the journal *BMC Health Services Research* in 2017 (see Appendix 1).

Chapter 2 presents a systematically conducted integrative literature review of specialised communication skills training for critical care HCPs who deliver news of death or discuss withdrawal of life-sustaining treatments, and/or offer organ donation. Outcomes examined include changes to HCPs' communication skills and the effect on family consent rates for deceased organ donation. The search strategy and a typology of communication behaviours are provided in Appendix 2. This paper was submitted to the journal *Patient Education and Counseling* in July 2020 and accepted for publication on 16 March 2021.

Chapter 3 of this thesis is the accepted manuscript published in the journal *Progress in Transplantation* in 2017 (see Appendix 3). It described an innovative program using high-fidelity simulation for selected critical care healthcare professional (HCP) "designated requesters" to rehearse the family donation conversation. Published material contains the development and preliminary evaluation of the study intervention from the experiences and perspectives of HCP participants.

Chapter 4 sets out the study research methods with content expanded on the much briefer version published in the study protocol in the journal *BMC Health Services Research* in 2017 (see Appendix 1). Details have been supplemented by material published in the methods section of the paper reporting results of the primary cohort, published in the journal *Critical Care and Resuscitation* in 2018 (see Appendix

4). In this thesis, the term ‘primary cohort’ used in this paper will be referred to as the ‘unregistered subsample’: donor-eligible patients who had not previously registered their donation preferences on their NSW driver licence and/or the Australian Organ Donor Register, or who were aged 16 years or less.

Chapter 5 presents results for research questions one to three. It begins by describing the clinical settings, including staffing levels in the study ICUs and daily routines. For research questions one and three, reporting of the primary end point of the study is based on content of the publication in which these findings were reported. This paper was published in the journal *Critical Care and Resuscitation* in 2018 (see Appendix 4). For research question two, the care process secondary end points of the study, unpublished findings are presented.

Chapter 6 presents results for research questions four and five. It begins with the findings for research question four, describing the next of kin decision-makers’ reasons for their final organ donation decision at the hospital. Research question five describes abbreviated findings in relation to eligible next of kin follow up interviews at around 90 days after enrolment. It reports whether they regretted their final donation decision, either to consent or to decline donation.

Chapter 7 sets out the discussion of the main findings of the study according to the research questions. This chapter includes published material from the discussion section of the study protocol published in the journal *BMC Health Services Research* in 2017 (see Appendix 1). Regarding research question 1, this chapter contains material from the discussion section of the paper reporting results of the primary cohort, published in the journal *Critical Care and Resuscitation* in 2018 (see Appendix 4). The overall implications of the findings are situated within the Australian and international literature. This chapter concludes by describing the strengths and limitations of the project.

Chapter 8 discusses the implications of the project for practice, policy and future research, and concludes the thesis.

The appendices to this thesis include copies of lead Human Research Ethics Committee approvals, with ratification by the UTS Human Research Ethics Committee, participant information sheet and consent forms, case report forms (CRF), copies of publications, and copyright permissions.

Publications Included in the Thesis

Paper #1	
Title:	COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT): protocol for an intervention study.
Authors:	**Potter J,** Herkes R, Perry L, Elliott R, Aneman A, Brieva J, Cavazzoni E, Cheng A, O'Leary M, Seppelt I, and the COMFORT study investigators.
Journal:	*BMC Health Services Research* 2017;(1):42. doi: 10.1186/s12913-016-1964-7
Status of publication:	Published 17 Jan 2017.
Unique contribution to knowledge	This article describes the study protocol for the implementation and evaluation of a best practice family approach intervention for "designated requesters" leading the family donation conversation in the clinical setting of an intensive care unit. Material from this article appears in the thesis introduction Chapter 1, and in the methods Chapter 4.
Paper # 2	
Title:	Simulation-based communication skills training for experienced clinicians to improve family conversations about organ and tissue donation.
Authors:	**Potter JE**, Gatward JJ, Kelly MA, McKay L, McCann E, Elliott RM, Perry L.
Journal:	*Progress in Transplantation* 2017;27(4):339-345. doi: 10.1177/1526924817731881
Status of publication:	Published online 9 Nov 2017.
Unique contribution to knowledge	This article describes an innovative program using high-fidelity simulation for selected critical care healthcare professional 'designated requesters' to rehearse the family donation conversation. Material includes evaluation of the study intervention from the experiences and perspectives of participants. This article appears in the thesis development and evaluation of the intervention Chapter 3.
Paper # 3	
Title:	COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT) intervention: a multicentre pre-post study.
Authors:	**Potter J**, Perry L, Elliott R, O'Leary M, Aneman A, Brieva J, Cavazzoni, E, Cheng A, Seppelt I, Herkes R and the COMFORT investigators.

Journal:	*Critical Care and Resuscitation* 2018;20(4):268-276
Status of publication:	Published 3 Dec 2018.
Unique contribution to knowledge	This article describes the effect of the study intervention on family consent rates for deceased organ donation in cases where the donor-eligible patient had not recorded their donation preference on a donation register or their driver licence. Material from this article appears in the thesis methods Chapter 4, primary end point results in Chapter 5, and the discussion Chapter 7.
Paper # 4	
Title:	Education and training methods for healthcare professionals to lead conversations concerning deceased organ donation: an integrative review.
Authors:	Potter JE, Elliott RM, Kelly MA, Perry L.
Journal:	*Patient Education and Counseling*
Status of publication:	Submitted 23 July 2020. Accepted for publication on 16 March 2021.
Unique contribution to knowledge	Systemically conducted integrative review on specialised communication skills training for critical care healthcare professionals who deliver news of death or discuss withdrawal of life-sustaining treatments, and/or offer organ donation in critical care settings. This article appears in the thesis literature review Chapter 2.

Journal permissions to reproduce the articles in the thesis are located in Appendix 14.

Statement of Contribution of Authors

Paper 1 COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT): protocol for an intervention study. *BMC Health Services Research* 2017;(1):42. doi: 10.1186/s12913-016-1964-7.

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Paper 2 Simulation-based communication skills training for experienced clinicians to improve family conversations about organ and tissue donation. *Progress in Transplantation* 2017;27(4):339-345. doi: 10.1177/1526924817731881.

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Conference Presentations Related to This Thesis

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Potter J, O'Leary M, Elliott R, Perry L, Aneman A, Brieva J, Cheng A, Seppelt I, Herkes R and the COMFORT investigators. COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT) intervention: a multicentre pre-post study. The Australian and New Zealand Intensive Care Society (ANZICS)/Australian Confederation of Critical Care Nurses (ACCCN) 42nd Annual Scientific Meeting on Intensive Care, Gold Coast, October 2017.

Potter J, Perry L, Elliott R, Kelly M, McKay, L. Evaluation of an innovative simulation workshop in communication skills to lead the family donation conversation. The 12th Congress of the World Federation of Critical Care Nurses, Brisbane, April 2016. Connect The World of Critical Care Nursing 2016;10(2):54.

Potter J, Perry L, Elliott R, Kelly M, O'Leary M. Training methods for health professionals to lead conversations concerning deceased organ donation: literature review. The ANZICS/ACCCN 39th Annual Scientific Meeting on Intensive Care, Melbourne, October 2014.

Potter J, Perry L, Elliott R, O'Leary M. Training methods for health professionals to lead conversations concerning deceased organ donation: literature review. NSW Organ and Tissue Donation Service Forum, Sydney, September 2014.

Potter J, Perry L, Reed C, Herkes R, COMFORT study management committee. COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT) study. The Prince of Wales Hospital Nursing Symposium, Sydney, May 2014.

Potter J, COMFORT study management committee. COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT) study. Transplant Nurses Association National Conference, Sydney, October 2013.

Potter J, COMFORT study management committee. COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT) study.

The ANZICS CTG 15th Annual Meeting on Clinical Trials in Intensive Care, Noosa, March 2013.

Potter J, COMFORT study management committee. COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT) study. NSW Organ and Tissue Donation Service Forum, Sydney, November 2012.

Other Published Works Related to This Thesis

Potter J, O'Leary MJ. Obtaining consent for cadaveric organ donation in Australia. *Internal Medicine Journal* 2013;43(7):737-39. doi: 10.1111/imj.12191.

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Abbreviations

AODR, Australian Organ Donor Register;

A-V, Audio visual;

CPD, continuing professional development;

CRF, case report form;

CST, communication skills training;

DCD, donation (or donor) after circulatory death;

DBD, donation after brain death;

DR, Designated requester;

ED, emergency department;

EOL, end of life;

FDC, Family Donation Conversation;

HCP, healthcare professional;

ICU, Intensive care unit;

MERSQI, Medical Education Research Study Quality Instrument;

NDD, neurological determination of death;

NR, not reported or unclear;

NS, non-significant;

NSW, New South Wales;

NURSE, Name Understand Respect Support Explore;

OD, organ donation;

OPO, Organ Procurement Organisation;

OSCE, Observed Structured Clinical Examination;

PEP, Professional Education Package;

PICU, Paediatric Intensive Care Unit;

RMS, Roads and Maritime Services registry;

RN, registered nurse;

SANOK, Senior available next of kin;

SFM, standardised family member;

SPIKES, Setting Perception Invitation Knowledge Emotions Summary and Strategy;

SP, standardised participant;

UK, United Kingdom;

US, United States

Glossary of Terms

This section provides definition for terms and phrases used in this project.

Term	*Definition*
Brain death	An historical expression for death determined by neurologic criteria where permanent absence of whole brain function has been shown on bedside clinical testing of brainstem reflexes and apnoea, or additional radiological imaging of brain perfusion if unable to perform clinical tests (ANZICS Death and Organ Donation Committee 2019; Kotloff et al. 2015). In this thesis the term 'brain death' will be used interchangeably with the more correct term of neurologic determination of death.
Donation after circulatory death	Donation or Donor after Circulatory Death (DCD) refers to Modified Maastricht Category III controlled DCD (cDCD) cases within the hospital, when withdrawal of life-sustaining therapy is planned and followed by expected circulatory arrest (Thuong et al. 2016). In Australia, circulatory determination of death requires 3 to 5 min absence of circulation (ANZICS Death and Organ Donation Committee 2019).
Designated requester	A healthcare professional such as an intensive care specialist doctor "intensivist", experienced critical care nurse or social worker selected by their department, and who had completed or was completing mandatory national training (Professional Education Package, core and practical modules) and the New South Wales Simulation Training Workshop.
Donor-eligible patient	A patient considered to be a potential organ donor because of a devastating brain injury or lesion or a patient with circulatory failure, and apparently medically suitable for organ donation. Also, their clinical condition was suspected to fulfil neurologic criteria for death, or the cessation of circulatory and respiratory functions was anticipated to occur within a timeframe that would have enabled organ recovery. Termed a *donor-eligible patient* in this thesis.
Healthcare professional	A term including specialist intensive care doctors such as intensivists; trainee doctors such as registrars or residents; registered nurses, specialist critical care nurses, donation specialist nurses; and social workers.
Managing intensivist	Senior intensive care doctor/staff specialist or an advanced trainee (fellow) / senior registrar who had passed the Fellowship exam, responsible for the clinical management of the donor-eligible patient.

Term	*Definition*
Medically suitable	A potential organ donor was deemed medically suitable to donate one or more organs for transplantation if they did not meet medical exclusion criteria. These criteria included transmissible diseases such as HIV, recent or metastatic cancer other than primary cerebral cancer, and untreated systemic infection (donor/organ reasons). (Definitions from the national DonateLife Audit, the tool used in classifying hospital deaths retrospectively for reporting). Medical suitability exclusions were divided into "donor/organ" and "system" categories. Examples of system reasons include potential organ donors who were not anticipated to become brain dead and were not eligible for the circulatory death pathway either due to age or were anticipated to die outside a timeframe that would enable organ recovery; or lack of recovery teams; or of a suitable recipient(s) (Dominguez-Gil et al. 2011).
Unregistered subsample	The subsample including cases where the registers (NSW Roads and Maritime Services registry (driver licence) and the Australian Organ Donor Register) had been checked and no details had been found of an individual's registered donation preferences, or when the registers were not accessed because individuals were aged 16 years or less.

Abstract

Introduction: Demand for organs for transplantation exceeds supply; family consent rates for deceased organ donation could increase with improving communication skills of the healthcare professionals responsible for the family donation conversation.

Aim: To implement and trial a 'best practice' approach for offering deceased organ donation, to test whether the intervention increases the proportion of families providing consent; to examine families' decision-making experiences and rates of decisional regret three months later.

Methods: A multicentre mixed methods study with a pre-post intervention component was performed in nine NSW intensive care units. Compared with pre-intervention controls, a prospective cohort of families of potential deceased organ donors were assigned to the "COMFORT" intervention. Families were offered bereavement aftercare and an interview 90 days later to provide their experiences.

The primary end point was the proportion of families consenting to organ donation in patients without registered donation preferences. Secondary end points were healthcare professionals' adherence rates to the intervention, identification of predictors of the donation decision, and the proportion of families regretting their donation decision at 90 days. Descriptive statistics and logistic regression modelling were used to examine outcome data, with content analysis for free text responses.

Results: In total 417 patients were enrolled in the study. For patients without registered donation preferences consent was obtained in 87 of 164 (53%) cases during the intervention period compared to 14 of 25 (56%) cases pre-intervention ($p = .83$). The odds of obtaining consent during the intervention period relative to the pre-intervention period were 1.13, (95% CI, 0.48-2.63); $p = .78$.

Characteristics independently associated with family consent were identified: when families first mentioned organ donation (OR 4.34; 95% CI, 1.79-10.52; $p = .001$), presence of an independent designated requester (OR 3.84; 95% CI, 1.35-10.98; $p = .012$), the number of donation conversations per case (OR 3.35; 95% CI, 1.93-5.81; $p < .001$), and patients of non-Christian religion (OR 0.18; 95% CI, 0.04-0.91; $p = .038$). Interviewees overwhelmingly ($n = 127$, 97%) agreed their decision had endured at three months after enrolment.

Conclusion(s): Uptake of some components of the COMFORT intervention was incomplete, and while the intervention as a whole did not significantly increase the organ donation consent rate, some elements exerted significant effect. Further work is required to identify those best practice elements that are most important and supportive for families making donation decisions; to determine strategies that might improve uptake and adherence by managing teams.

Chapter 1: Introduction

This chapter sets out the background to the thesis, using some material from the study protocol paper published in the journal *BMC Health Services Research* in 2017 (see Appendix 1).

Organ transplantation is an effective treatment for individuals with end-stage organ failure, often extending recipients' lives and improving their quality of life. Worldwide, the problem of how to improve access to life-saving transplantation by increasing rates of deceased organ donation is a challenge (Australian and New Zealand Organ Donation Registry (ANZOD) 2018; Council of Europe & Organización Nacional de Trasplantes (ONT) 2018). For this reason Australia's donation rates have been under intense government scrutiny for well over a decade (Bendorf et al. 2012). In Australia over the past decade, surveys of community willingness to donate have consistently shown higher rates of support (69%) than actual family organ donation consent rates of 54% to 61% (Opdam 2015), below the national target consent rate of 75% (Marck et al. 2014). Moreover, from 2000 – 2011, rates of deceased organ donors per million population were consistently lower in New South Wales (NSW) compared with other states and territories, despite having the highest number of donor registrations (NSW Ministry of Health 2012).

The possibility of realising deceased organ donation is infrequent, with less than two percent of audited deaths in Australian hospitals meeting medical suitability criteria (Organ and Tissue Authority 2014a). A potential organ donor is someone who has sustained an unsurvivable neurological injury (brain death confirmed or anticipated within 24 hours with ongoing treatment) or circulatory failure, is mechanically ventilated and appeared to meet medical suitability criteria (Dominguez-Gil et al. 2011; NSW Ministry of Health 2012). Termed a *donor-eligible patient* in this thesis, authorisation, or consent, to donate (terminology depending on local jurisdiction (MacDonald & Shemie 2017)) may be provided by the patient's registered donation decision, or (more often) by their families. For families, making donation decisions on their family member's behalf occurs at a time of intense grief and emotion. These decisions have been shown to be open to influence by the timing, approach and communication skills of the healthcare professionals (HCP)s offering organ donation (Simpkin et al. 2009); leading to calls for standardised communication training for HCP requesters (Traino, Molisani & Siminoff 2017).

Defining Death and Consent

Procurement of organs and tissues from a deceased person for transplantation can proceed only after death is legally certified and consent has been provided. In Australia there are legal definitions of death, and the *Human Tissue Act* (1983b) death is defined as: (a) irreversible cessation of all function of the person's brain (neurological or 'brain' death); or (b) irreversible cessation of circulation of blood in the person's body (circulatory death), the traditional cardiac standstill. For organ donation to proceed subsequent to circulatory death, doctors need to anticipate that death will occur in a predetermined timeframe subsequent to withdrawal of life sustaining treatments (Citerio et al. 2016).

Informed consent for donation is governed in Australia by State and Territory legislation. In NSW, the *Human Tissue Act* (1983a) authorises the senior available next of kin (SANOK) as substitute decision maker. For example, the decision-maker on behalf of an adult hierarchy is: first choice, spouse or partner, then adult children, parents, and adult siblings. A donor-eligible patient, without cognitive capacity, can provide first person consent by having 'opted-in' or 'opted-out' during their lifetime by registering on the Australian Organ Donor Register (AODR) or via their driver licence. From 2005, this registration provides valid consent when the SANOK is unable to be located in time for donation to proceed (Australian Health Ministers' Conference 2005). In NSW in accordance with the government plan (NSW Ministry of Health 2012), the *Human Tissue Act* was amended in October 2012 to permit exploration of a registered 'no'. Also, the option for individuals to register their first person consent as a donor (or a 'non-donor') on their driver licence was removed in NSW from November 2012, rationalising the process to a single national register.

Difficult Conversations

Offering organ donation is increasingly recognised as part of routine end-of-life care in an intensive care unit (ICU) (Citerio et al. 2016; Domínguez-Gil, Murphy & Procaccio 2016). Healthcare professionals have responsibilities for care of the patient in life, and for deceased donor management alongside supporting families throughout the process. Offering organ donation to families can be one of the most difficult responsibilities for HCPs, irrespective of previous experience or practitioner expertise. To facilitate families making an informed decision, critical care doctors and nurses need

to build trusting relationships with families, often within a short time. For example, trust and authentic communication may be achieved when HCPs have the confidence to use words such as “death” and “dying”, delivering straightforward, clear messages to families (Levin et al. 2010). This can be challenging when the end-of-life or donation conversation may occur at the first meeting between distressed families and an individual HCP (Oroy, Stromskag & Gjengedal 2013; Sarti, Sutherland, Healey, Dhanani, Hartwick, et al. 2018).

Organ donation conversations challenge HCPs, and intensive care clinicians and donation specialists have reported avoiding raising the topic of deceased donation for cultural reasons or not to add to the families’ distress (Oroy, Stromskag & Gjengedal 2013; Thomas, Milnes & Komesaroff 2009; Williams et al. 2003). Critical care physicians and nurses may be unprepared for such interactions; may not be suitably trained or skilled in specialised communication (Williams et al. 2003), or adequately supported by experienced mentors, or provided sufficient opportunities to maintain competency and confidence in this area of practice. These deficits may lead to feelings of anxiety, helplessness, discomfort and avoidance of timely discussions regarding end-of-life care (Ahern et al. 2012; Levin et al. 2010). Healthcare professionals need to understand and know how to manage these issues rather than allowing family members’ grief and emotional reactions to bar organ donation conversations. Families have described organ donation as bringing comfort and meaning to the death, rather than increasing their grief (Sque, Long & Payne 2005; Walker & Sque 2016). This could be the case even when family members declined organ donation (Kentish-Barnes et al. 2018).

This is a distressing and emotional time for bereaved families. Families are often emotionally overwhelmed by events leading to the patient’s hospitalisation, may have little time to understand the situation, and experience anxiety, depression, symptoms of traumatic stress, and fatigue (McAdam et al. 2010; Pochard et al. 2005). These symptoms reduce their ability to understand the complex medical information necessary to make an informed decision about ICU treatments and organ donation (Eyler & Jeste 2006; Rodriguez et al. 2008). Many do not know their family member’s wishes for deceased donation (de Groot et al. 2012; Martínez et al. 2001), and make their donation decision based on their own attitudes and beliefs. They may be more inclined to agree to donation when their experiences or understanding of donation are positive (Walker, Broderick & Sque 2013). Factors such as the patient not registering their donation

wishes, a lack of consensus within the family group, conflict and disagreement between family members, have been associated with families declining donation (de Groot et al. 2016; Martínez et al. 2001; Rodrigue, Cornell & Howard 2008). Where family decisions have not aligned with the patient's values and preferences (most commonly declining donation when their loved one had registered agreement), these decisions may be subsequently regretted (Jacoby & Jaccard 2010; Rodrigue, Cornell & Howard 2008). Both positive and negative influences on families' decisions can follow situational factors from the hospital, such as their perceptions of the patient's treatment and care, the quality of information, support and overall consideration and care for families shown by HCPs (Lopez et al. 2018; Sque et al. 2018). Families have reported greater satisfaction when physicians verbalised emotional support (Stapleton et al. 2006), responded with empathy, and made space for families to speak (October et al. 2018).

Current Donation Request Processes - Family Meetings

Interprofessional ICU team-family meetings regarding end-of-life care are fundamental in re-orienting families to the transition of care from curative, signifying hope in the patient's recovery, to palliative, with death an inevitable outcome. Procedural guidelines for the conduct of these meetings are well-established (Billings 2011; Billings & Block 2011; Levin et al. 2010). The guiding principle for end-of-life care and organ donation conversations is "patient-centeredness" through eliciting the patient's values and a sense of their identity from family members and significant others (Jakimowicz, Perry & Lewis 2017). When family members are unaware of the patient's wishes they need to use "substituted judgement", taking account of their family member's values and preferences for medical treatment and organ and tissue donation at the end of life (Levin et al. 2010).

Professional organisations in intensive care medicine and health authorities provide guidelines for high quality communication between families and HCPs regarding end-of-life care and organ donation. For example, in the United Kingdom (UK), a family approach was recommended, planning the donation conversation with the managing team and the specialist donation nurse (NHS Blood and Transplant 2017). This approach included key elements recognised as best practice in end-of-life communication such as ensuring the family understood the patient had died or death was inevitable before raising donation. Similarly, guidelines in Australia and New

Zealand (ANZ) recommended that the family meeting take place in a private room and that health professionals communicate clearly, listen to the family and demonstrate compassion by their words and actions (ANZICS Death and Organ Donation Committee 2013).

Current Donation Request Processes - Specialist Requesters

Good practice guidelines recommend that communicating the 'bad news' of death, and the offer of deceased donation be undertaken by HCPs who have been trained and have specific knowledge and skills to do so (National Transplant Organization 2011; NHS National Institute for Health and Clinical Excellence (NICE) 2011; Organ and Tissue Authority 2017). Internationally, practice varies on requester designation and processes. In Spain, critical care physicians (intensivists or anaesthesiologists) employed as "transplant coordinators" lead all aspects of donor management in the procurement hospital, including responsibility for the organ donation conversation/family interview. Some transplant coordinators meet family members while working in the role of the managing intensive care doctor, treating patients before they become eligible for deceased donation (Shemie, MacDonald & Canadian Blood Services-Canadian Critical Care Society Expert Consultation Group 2014). This model of managing intensive care doctors also working as donation physician specialists has been implemented in tertiary care hospitals, after adaptation to local requirements, in countries including Canada, Australia, parts of the United States (US), the UK and France. Role responsibilities vary between jurisdictions, but have in common responsibility for offering organ donation to bereaved families, with support of a specialist donation nurse (Kentish-Barnes et al. 2017; Shemie, MacDonald & Canadian Blood Services-Canadian Critical Care Society Expert Consultation Group 2014). However, in Australia, even in busy intensive care units (ICU), donor-eligible patients are infrequent; many (42%) intensive care doctors conduct less than four organ donation conversations every year (Mullins, Simes & Yuen 2012), limiting opportunities to practice the necessary specialised communication skills. Donation conversations can be lengthy, and this may be challenging for intensivists responsible for other critically ill patients.

In the US, from 1998, federal regulations required mandatory notification of impending deaths to an Organ Procurement Organisation (OPO) and use of "designated

requesters" when initiating the donation offer. Initiation of the request encompassed any mention of deceased donation to family members, providing information about the donation process, and the actual request for authorisation (Kotloff et al. 2015). Designated requesters were experienced HCPs who have completed specific training in offering deceased donation, attaining the requisite knowledge and skills, and who have time allocated to help families through the donation process. Most designated requesters are OPO coordinators (critical care nurses), or nurses, intensive care doctors, pastoral care workers or social workers (Kotloff et al. 2015).

Education to Prepare Requesters for Organ Donation Conversations

Effective communication for organ donation conversations requires specialised skills including recognition of grief reactions, understanding of cultural issues, sensitive exploration of any decision to decline donation, and the ability to care for families by providing information and emotional support (Matesanz et al. 2011; Simpkin et al. 2009; Vincent & Logan 2012). Donation education and training for HCPs working in critical care areas has been recommended by UK national guidelines and as part of a national reform agenda in Australia (Collins 2014; Organ and Tissue Authority 2019c). Evaluation of uptake of the UK recommendations showed over half of respondents (56.2%) received education during post-registration continuing professional development sessions (CPD), with most sessions delivered informally by specialist nurses in organ donation. Attendance at CPD sessions was directly related to HCPs' self-reported improved attitudes and greater confidence to participate in donation activities (Collins 2014).

Education and training for HCPs about deceased donation has been recognised as a priority, needing a formal structure including interprofessional, experiential learning (MacDonald & Shemie 2017; Williams et al. 2003). Development of curricula and certification for donation physician specialists has occurred in consultation and collaboration with professional colleges and societies (Shemie, MacDonald & Canadian Blood Services-Canadian Critical Care Society Expert Consultation Group 2014), including in Australia (Grallelis, Van Weerdenburg & Mehakovic 2017).

Specialised Communication Training

In Australia, a national program of specialised training in family-centred communication regarding organ donation, developed in collaboration with the Gift of Life Institute (Philadelphia, USA), was introduced in October 2011 (Mulvania et al. 2014). This program, delivered in two workshops over three days, incorporated face-to-face presentations of theory followed by practical training with role-play exercises (Grallelis, Van Weerdenburg & Mehakovic 2017). This approach, referred to as the Organ and Tissue Authority Family Donation Conversation (FDC) core and practical modules, has been adopted as 'best practice'; intensive care specialists and organ donation HCPs elect to attend. The College of Intensive Care Medicine made completion of the core workshop a mandatory training requirement for intensive care trainees from 2014 (College of Intensive Care Medicine of Australia and New Zealand 2014). However, role-play alone may not adequately replicate the emotional nature of donation conversations (Nestel, Sanko & McNaughton 2017; Schlegel et al. 2012).

In NSW, training for HCPs selected as "designated requesters" to lead donation conversations (NSW Ministry of Health 2012), was supplemented by a simulation program. Piloted in 2012, the program used real donation scenarios with simulated participants played by professional actors (Potter, Gatward, et al. 2017). Healthcare professionals were able to rehearse, review and reflect on their developing effective communication skills when offering donation in a protected learning environment, and thereby become more comfortable discussing these topics. These 'best practice' methods involving use of specialised requesters to lead deceased organ donation discussions with families were based on work from other countries adapted to but not formally tested in Australian conditions.

Significance

In NSW in the years preceding this study the rate of consent for deceased organ donation was consistently below benchmark and target. The variable communication skills of HCPs who discussed organ donation may have resulted in families making decisions they later regretted, particularly if they declined donation and later felt they should have agreed. Best practice intervention methods for requesting consent for donation of solid organs after death have been developed in other countries but have not been formally trialled in Australia. This doctoral research responded to this gap by

identifying ‘best practice’, implementing and evaluating this as an intervention. This study examined implementation of a ‘best practice’ family approach intervention and identified its effectiveness in terms of family consent rates, and of later decisional satisfaction or regret by the family decision-maker.

The pragmatic design chosen for this study was intended to identify ‘what works’ in usual clinical settings when requesting organ donation in critical care areas, in terms of the changes in practice HCPs were willing and able to adopt; the effect on desired outcomes, and family experiences. It was intended that the findings of this study would be indicative of the potential benefits of the intervention in real-world settings and be relevant and transferrable to clinical settings in other states and countries.

Research Aims, Objectives and Questions

Aims

The aim of this study was to examine the process of organ donation decision-making, and evaluate whether changes in requesting practices resulted in changed rates of family consent for organ donation. A secondary aim was to examine SANOK’s experiences of making decisions for organ donation for their family member and whether changed requesting practices resulted in families’ donation decisions that were sustained over time.

Objectives

The objectives of this project were.

To determine if an evidence-based intervention could increase the family consent rate for deceased organ donation compared to current standard practice, in the subsample of donor-eligible patients who had not registered their donation preferences.

To explore the adherence by HCPs to the six core components of the evidence-based intervention in the clinical setting.

To explore SANOKs’ experiences of making decisions for organ donation for their relative in the clinical setting

Research Questions

For donor-eligible patients who had not registered their donation preferences, comparing current standard practice to an evidence-based intervention including communication training using interaction with simulated participants for designated requesters ("the intervention"), are there differences in terms of SANOK consent rates for deceased organ donation?

How feasible and acceptable for HCPs is implementation of this intervention: do HCPs adhere to core components of the intervention?

For donor-eligible patients who had not registered their donation preferences and where the intervention was in use, what, if any, characteristics of the decision-making process occurring in hospital predicted the family donation decision?

For all donor-eligible patients where an evidence-based intervention (as above) was in use, what do SANOK report in relation to the rationale for their final decision in hospital, either to consent or decline organ donation?

What proportion of SANOK reported that they regretted their final donation decision, either to consent or to decline donation, at around 90 days after enrolment?

Hypothesis for Research Question One

There will be no difference in consent rates for deceased organ donation by SANOK of donor-eligible patients without a registered donation preference, before and after an evidence-based intervention.

Researcher's Position and Motivation

The candidate brought to this project a unique perspective from working in a variety of roles in critical care settings over many years. Extensive clinical experience in general intensive care and cardiothoracic nursing was obtained in metropolitan and regional settings, followed by over 10 years research experience implementing clinical trials in intensive care. Many investigator-initiated studies use a process of delayed consent, and the candidate had extensive experience of discussing participation with substitute decision-makers, the families of critically ill patients during the consent process, and with intensive care survivors in follow up phone calls. Involvement in these roles afforded the candidate greater awareness and sensitivity to the situation in intensive care, in particular the importance of including within trials a research outcome reflecting family perspectives.

This thesis project began subsequent to employment of the candidate as Research Coordinator for the NSW Organ and Tissue Donation Service from April 2012 to February 2018. While in that role the candidate was a key member of the COMFORT clinical research team that developed this trial protocol. Her role entailed performing a literature review, writing the original drafts and amendments of the study protocol, designing data collection tools, performing data analysis, preparing reports and writing publications. The candidate completed the national educational training on donation conversations and consulted on choice of appropriate data variables with experts including international expert presenters from the Gift of Life Institute Philadelphia, DonateLife colleagues, medical, nursing, and educational subject matter experts on organ and tissue donation, including from donor family perspectives. The candidate contributed to translation of the concept of a 'designated requester' in NSW hospitals by bringing insights from discussions with intensive care colleagues on the likelihood of adherence to early iterations of a "designated requester model" in NSW.

As Research Coordinator, the candidate undertook Project Manager and study monitor roles, effectively coordinating the multicentre study, ensuring compliance with research ethics and governance requirements. This included preparation of the lead ethics submission, protocol amendments, and annual/final reporting; preparation of local site applications for governance authorisation, and mentoring site staff as needed.

Implementation of the intervention involved presentations to grand rounds meetings at study sites, and other site departmental meetings when required. The

candidate trained site staff, primarily donation specialist nurses, in data collection procedures, completion of the case report forms and use of a data dictionary for consistent interpretation of events. Monitoring visits by the candidate included reviewing the documented and oral history of events with donation nurses who had been involved in each event to ensure the case report form had captured an accurate depiction of events. In some instances, the case report form itself had become a source document.

For study oversight, the candidate was a member and secretary of the COMFORT study management committee. Membership of the committee subsequently included the doctoral principal supervisor (LP) and co-supervisor (RE). The candidate reviewed the databases at the NSW Organ and Tissue Donation Service to track recruitment and prepared monthly reports for each site to assist in maintaining motivation and engagement of intensive care colleagues.

The candidate designed the database, completed data management and consolidation activities; undertook quantitative and qualitative data analysis, interpreted and reported key findings. Thesis completion timelines were adjusted to address the clinical priority of the NSW Organ and Tissue Donation Service to address, analyse and publish the findings for the unregistered subsample for the first three research questions before addressing the other research questions.

Chapter 2: An Integrative Review of Training Methods for Healthcare Professionals to Lead Family Donation Conversations

Chapter Introduction

This chapter sets out an integrative review and summarises findings of the literature on methods for training post registration HCPs working in critical care areas, to lead the request for deceased organ donation in hospitals. Evidence for the effectiveness of the training was also reviewed.

The content of this chapter is based on a publication describing a systemically conducted integrative literature review. It addresses the research questions that underpinned development of the intervention:

- Which training methods for teaching communication skills in relation to HCPs' delivery of news of death determined by neurological criteria or withdrawal of life-sustaining treatments, and/or offer of deceased organ donation, have:
    a) Positively influenced HCPs' learning and practice of specialised communication skills?
    b) Been shown to influence family authorisation/consent for organ donation?

The review was submitted to the journal *Patient Education and Counseling* on 23 July 2020 and was accepted for publication on 16 March 2021 (Potter et al. 2021).

It is cited as:

Potter JE, Elliott RM, Kelly MA, Perry L. Education and training methods for healthcare professionals to lead conversations concerning deceased organ donation: an integrative review. *Patient Education and Counseling* 2021; In press.

Background

As outlined in Chapter One, offering organ donation to families of donor-eligible patients can be one of the most difficult responsibilities for healthcare professionals (HCPs), irrespective of previous experience or practitioner expertise. Leading the end-of-life family meeting in the ICU when organ donation is offered requires skilled communication by the HCP, to facilitate families' decision-making based on their family member's values and wishes. However, critical care physicians and nurses may be poorly prepared to lead donation conversations; may not be adequately trained or skilled in specialised communication (Williams et al. 2003) or supported by experienced mentors (Ahern et al. 2012).

For many families, donation decision-making occurs at a time of intense grief and emotion. Typically, family members function as substitute decision makers because patients infrequently leave explicit wishes and frequently lack capacity to make informed decisions. Families' donation decisions have been shown to be open to influence, including by the timing, approach and communication skills of the HCPs offering donation (Simpkin et al. 2009); families' perceptions of treatment and care, the quality of information received, and the level of support and consideration shown them by HCPs (Lopez et al. 2018; Sque et al. 2018).

Effective communication for organ donation conversations requires specialised skills including recognition of grief reactions, understanding of cultural needs, sensitive exploration of attitudes and understanding of donation, and the ability to care for families (Matesanz et al. 2011; Simpkin et al. 2009; Vincent & Logan 2012). This can be underpinned by guiding principles such as "patient-centeredness" (Jakimowicz, Perry & Lewis 2017). The ideal outcome from such skilled approaches is a family donation decision based on the patient's wishes and sufficient information, without any sense of pressure (MacDonald & Shemie 2017).

Specialised communication training for critical care HCPs in conducting donation conversations has been recognised as a key factor in enhancing family satisfaction with care and increasing consent rates for deceased donation (Simpkin et al. 2009; Vincent & Logan 2012). The characteristics of such training programs have not been systematically examined. This is important for informing contemporary learning strategies to enhance conversations with bereaved families and facilitate informed donation decisions that are not subsequently regretted.

The aim of this review was to identify and summarise the evidence for communication learning and skills training to prepare HCPs to offer deceased organ donation to families of donor-eligible patients in the critical care setting.

The research questions were:

Which training methods for teaching communication skills in relation to HCPs' delivery of news of death determined by neurological criteria or withdrawal of life-sustaining treatments, and/or offer of deceased organ donation, have:

a) Positively influenced HCPs' learning and practice of specialised communication skills?
b) Been shown to influence family authorisation/consent for organ donation?

Methods

This was an integrative review using systematic methods. Review methods followed the reporting requirements of the PRISMA statement for systematic reviews (Moher et al. 2009), applied to a systematic search that sought heterogenous studies, date-limited for currency (Grant & Booth 2009).

Data Sources and Search Strategy

The electronic bibliographical databases searched for papers were: MEDLINE (via PubMed), Cumulative Index to Nursing and Allied Health Literature (CINAHL) (EBSCO), Excerpta Medica (Embase, (OVID) and ProQuest Dissertations & Theses Global. Key words and Medical Subject Headings (MeSH) relating to the Population/Intervention/Outcome/Setting (PICOS) framework were identified and combined (see Appendix 2 Table A2.1). Reference lists of relevant full text papers were reviewed to locate additional studies. The search included English language papers published between August 1997 and March 2020.

Eligibility Criteria

Papers considered for inclusion reported studies meeting the following criteria:

a) participants: graduate HCPs working in critical care settings and donation professionals working at OPOs;
b) intervention: communication skills training intending to change skills regarding delivering news of 'brain death', that is, neurological determination of death (NDD), and/or the plan to withdraw life-sustaining treatments and to offer organ donation to families of potentially donor-eligible patients;
c) outcomes: HCPs' communication skills, and/or family experiences and/or rates of family consent to organ donation;
d) time: baseline data (pre-education) compared to post-education, with a minimum of one post-training time point;
e) research design: controlled clinical trials (not necessarily randomised), quasi-experiments, pre and post surveys or observational studies.

Papers were excluded if they:

a) solely described attributes of donation requesters or content of donation training/education programs;
b) focused on communication skills training applied to requests for living organ donation, post mortem tissue donation, performance of donation-related procedures or patient-clinician decision-making about end-of-life care;
c) focused on communication skills for family-clinician decision-making in general, or limitation of life-sustaining treatments, or transitioning from curative to palliative care;
d) were classified as grey literature, letters, editorials, review articles, conference abstracts or qualitative designs; did not evaluate changes in behaviour (actual/simulation).

Study Selection

The titles and citation details of all papers were retrieved from each database and exported to Endnote X8.2™ for screening. Titles and abstracts were screened (JP) to eliminate duplicates and to exclude papers that did not meet the inclusion criteria. If eligibility could not be determined from the abstract, or if the abstract was unavailable, the full text of the paper was obtained. Reference lists of review papers were searched for relevant publications. The full text was obtained for all relevant papers and independently screened (JP and RE). Disagreements were resolved by consensus. A third author (LP) adjudicated when consensus could not be reached.

Data Extraction and Coding

Extracted data for eligible papers included descriptions of the study, participants, intervention and outcomes. Data for each study included: publication year, country, setting, recruitment period and research design. Participant characteristics included age, gender, and work designation. Study interventions included details of the training program – training strategies, content, duration and intensity, group size/s, assessment methods (self-assessment/external assessors), and main findings with measurements of statistical significance, when mentioned.

To identify communication skills, text was tabulated and organised into units of meaning, arising from text containing a key word or phrase, then allocated a category

(Graneheim & Lundman 2004). Categories were comprised of pre-defined behavioural groups derived from a review of communication skills taught to clinically experienced physicians (Hulsman et al. 1999). In general, *receptive behaviours* are described as useful when opening the conversation, to help build rapport and facilitate active participation of the family members in the conversation. *Information behaviours* are intended to promote family members' understanding of complex medical information, ensure that family members and HCPs use the same language and have a shared understanding of topics. *Interpersonal and affective behaviours* are explained as expressing receptive behaviours at a deeper level, particularly focusing on the effect of strong emotions (Hulsman et al. 1999). Categories are not mutually exclusive, and some behaviours may overlap with others.

Definitions

Training programs were defined as the entire communication skills training program or course/workshop. Training strategies were defined as various techniques or approaches employed to teach communication skills to HCPs within a program. Examples were role-play and oral presentations (Berkhof et al. 2011). In this review, 'simulated participants' (Lewis et al. 2017) refer to trained human role players variously referred to as "actors", "standardised family members (SFM)", "standardised patients" and "standardised parents", reflecting the inconsistent use of terms across included studies.

Quality Assessment

The methodological quality of included full text papers was appraised using the Medical Education Research Study Quality Instrument (MERSQI) (Reed et al. 2007). This 10-item instrument has been validated to assess the methodological quality of experimental, quasi-experimental and observational studies of medical education (Reed et al. 2008). The MERSQI six domains include: study design, sampling, type of data (subjective or objective), validity of evaluation instrument, data analysis and outcomes. The maximum score for each domain is three with total scores ranging from 5 to 18 (Reed et al. 2007). The quality appraisal was performed independently (by JP and RE), with any discrepancies resolved by discussion and consensus, with reference to a third author (LP or MK) as needed.

Data Analysis / Synthesis

Heterogeneity of the designs, settings, and outcome measures of the included studies precluded meta-analysis. In order to integrate the wide range of study designs a narrative synthesis was performed. Data synthesis involved a variety of elements, notably developing an initial description of studies, tabulation, and content analysis (Popay et al. 2006).

The conceptual framework adopted for analysis of outcomes was Kirkpatrick's four-level training evaluation model, a sequential design in which outcomes increase in value from learner satisfaction to evidence of workplace outcomes (Kirkpatrick 1998). We applied and refined the framework to better describe the diversity of outcomes by expanding to five categories, similar to previous reviews (Hammick et al. 2007; Issenberg, McGaghie & Petrusa 2005). These entailed:

Category 1 – Reaction (to the program): learner preferences for scheduling, topic content, quality of instructors, and/or quality of the case scenarios and actors;

Category 2A – Learning: changes to perceptions, attitudes (comfort, confidence);

Category 2B – Learning: improving knowledge (*theory test*) and increasing (communication) skills (*performance test*);

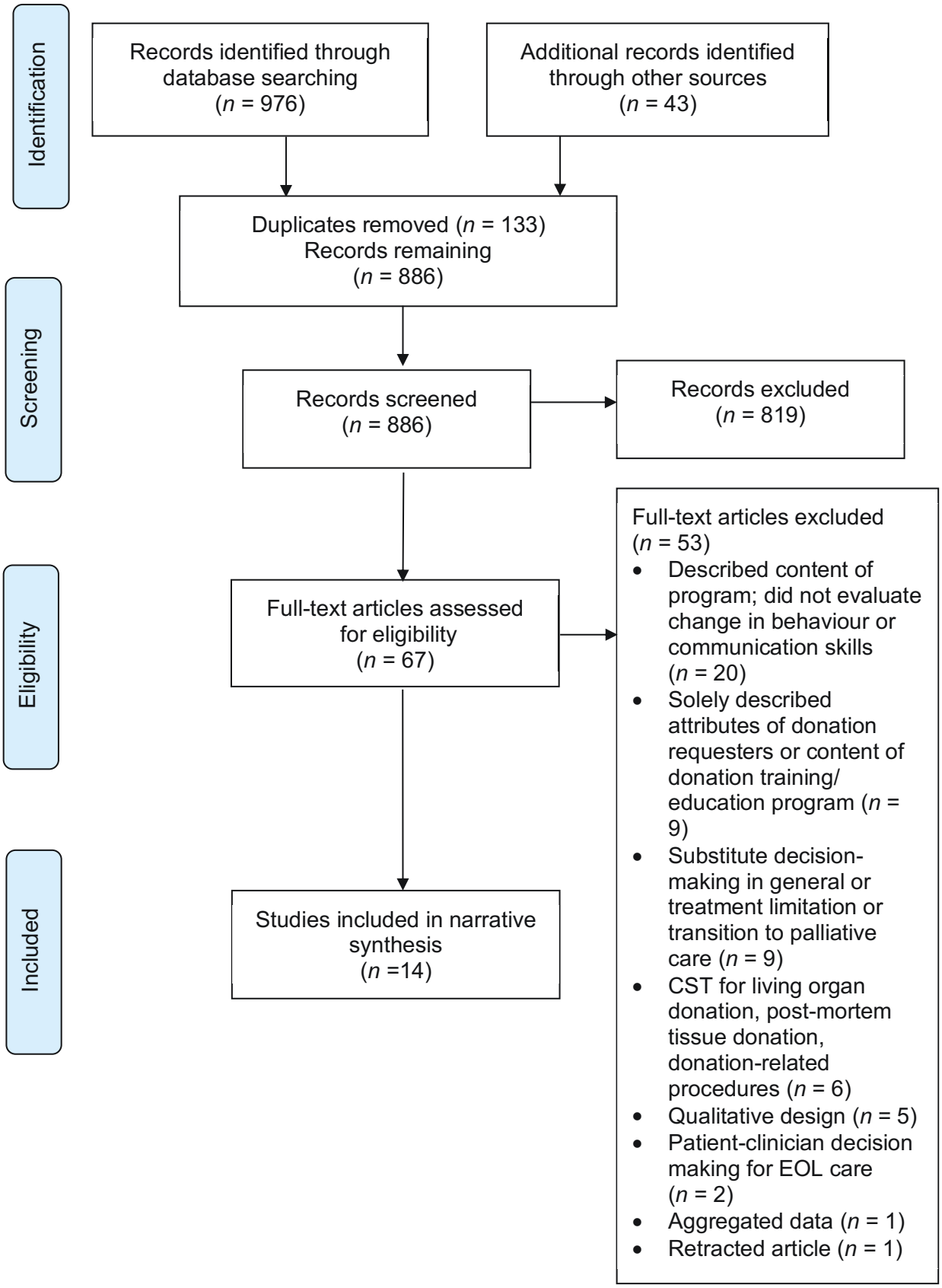
Category 3 – Behaviour: transfer to the clinical setting (attitudes, knowledge & skills);

Category 4 – Results: benefits to patients/family-centred outcomes.

For this review, we reported on learning outcomes measured at category 2A to category 4, to focus on the effect of training on learning new attitudes, knowledge and skills (competence), and their transfer to the clinical setting.

Results

The search resulted in 1019 potentially relevant papers. Title and abstract were read and reviewed, duplicates removed, and 819 ineligible papers excluded. After reading and reviewing the full text of remaining papers, 53 met exclusion criteria and 14 studies were retained for inclusion. (see Figure 2.1).



Note. CST = communication skills training; EOL = end-of-life.

Figure 2.1

Flow Diagram of Study Identification, Screening and Inclusion

Study Characteristics

Characteristics of the 14 included studies are shown in Table 2.1. Most studies were undertaken in North America. Over half (n = 8, 57%) used a single group pre/post design, with three studies using a randomised controlled trial (RCT). Nine (64%) studies evaluated continuing education for OPO coordinators, or for inter-professional groups of HCPs working in paediatric or adult intensive care units (ICU) (Blok et al. 2004; Fico & Feeley 2019; Hales & Hawryluck 2008; Marogna et al. 2018; Meyer et al. 2009; Morton et al. 2000; Potter et al. 2018; Siminoff et al. 2009; Siminoff, Traino & Genderson 2015). Four training programs were integrated within academic programs/curricula designed to meet objectives of specialist medical colleges (DeVita, Arnold & Barnard 2003; Downar et al. 2012; Johnson et al. 2017; Tobler, Grant & Marczinski 2014).

Table 2.1

Characteristics of Included Studies

First author (year)	Setting (country)	Study design	Sample size (*n*)	Age mean (*SD*) (years)	Female *n* (%)	Participants
Vaidya (1999)	A tertiary paediatric ICU (US)	Single group, pre-test/post-test	7	NR	2 (28)	Paediatric intensive care fellows
Morton (2000)	ICUs in 20 hospitals (England)	RCT	64 IG: 32 CG: 32	IG:38 (7.2) CG:40 (9.4)	IG:18 (56) CG:16 (50)	Intensive care consultants and ICU nurses (50:50)
DeVita (2003)	Tertiary care hospital (US)	Single group, pre-test/post-test	7	NR	NR	Critical care medicine fellows
Blok (2004)	7 workshops, 40+ hospitals (NL) 22 workshops, ICUs in 20 hospitals (UK)	RCT	188 NL,IG: 71 NL,CG: 61 UK,IG: 29 UK,CG: 27	NL: 33 (NR) UK: 39 (NR)	NL: NR UK: 26 (50)	Intensive care doctors and ICU nurses. Doctor/total, nurse/total: NL: ~26/132, 106/132 UK: 28/56, 28/56
Hales (2008)	A university and selected hospitals (Canada)	Single group, pre-test/post-test	36	NR	NR	Intensive care doctor, nurses, social workers, respiratory therapist, clinical nurse educator, missing
Meyer (2009)	A tertiary paediatric hospital (US)	Single group, pre-test/post-test	110	35 (8.6)	74 (74)	Physicians (41%); nurses (43%); social workers, chaplains or psychologists (16%), missing (n=3)
Siminoff (2009)	An OPO with 17 hospitals (US)	Non-randomised repeated measures	22	39 (8.6)	16 (73)	OPO coordinators
Downar (2012)	A university (Canada)	Single group pre-test/post-test	51	NR	17 (33)	Critical care medicine trainees
Tobler (2014)	A university (Canada)	Single group pre-test/post-test	39	NR	NR	Residents in paediatric general and emergency medicine programs

Table 2.1

Characteristics of Included Studies

First author (year)	Setting (country)	Study design	Sample size (*n*)	Age mean (*SD*) (years)	Female *n* (%)	Participants
Siminoff (2015)	Nine OPOs (US)	Parallel group RCT	273 IG: 55 CG: 218	40 (9.4)	103 (74)	OPO coordinators
Johnson (2017)	A paediatric hospital (US)	Single group pre-test/post-test	38	NR	20 (53)	Paediatric critical care medicine fellows
Marogna (2018)	A hospital, 60 workshops (Argentina)	Controlled before and after study	IG: 435 CG: NR	NR	250 (57)	Doctors, nurses, other
Potter (2018)	ICUs in 9 hospitals (Australia)	Controlled before and after study	IG: 164 CG: 25	IG: 45.2 (22.1) CG: 43 (NR)	48 (29)	Per case: intensive care doctors, ICU donation specialist doctors, donation specialist nurses, social workers, fellows.
Fico (2019)	9 OPOs (US)	Single group pre-test/post-test	95	41 (11.2)	72 (76)	OPO coordinators

Note. CG = control group; ICU = intensive care unit; IG = intervention group; NL = Netherlands; NR = not reported or unclear; OPO = Organ Procurement Organisation; RCT = randomised controlled trial; UK = United Kingdom; US = United States.

Quality Assessment

MERSQI domain scores for the 14 papers are shown in Table 2.2. The average total MERSQI score was 13.0 (*SD* = 2.7). Four studies with high MERSQI scores of 15.5 or greater (Reed et al. 2007) used a randomised controlled design, and/or were multi-institutional and used objective evaluation methods (Morton et al. 2000; Potter et al. 2018; Siminoff et al. 2009; Siminoff, Traino & Genderson 2015).

Participant Characteristics

The number of participants per study ranged from 7 to 435; 2 of the 14 included studies reported fewer than 10 and five studies reported >100 participants. Participants (*n* = 1361) were medical doctors (*n* = 507, 37%); nurses (*n* = 386, 28%), and OPO coordinators (*n* = 390, 29%). Of the doctors, *n* = 365 (72%) were intensive care specialists (intensivists) or physicians, *n* = 103 (20%) advanced trainees (fellows) training in paediatric or adult critical care medicine, and *n* = 30 (8%) were junior medical officers (residents). Demographic data were often inadequately reported or absent. From 10 studies reporting participant gender (*n* = 1141), over half were female (*n* = 614, 54%). Seven studies reported participants' age, with means between 33 and 46 years (see Table 2.1).

Table 2.2

Methodological Quality of the Included Studies Based on MERSQI Domain and Item Scores

First author (year)	Study design[a]	Sampling		Type of data[d]	Validity of evaluation instrument[e]			Data analysis[f]		Out-comes[g]	Total score
		Institutions[b]	Response rate[c]		Internal structure	Content	Relationship to other variables	Appropriate	Complex		
Vaidya (1999)	1.5	0.5	0.5	3	1	1	1	1	2	1.5	13.0
Morton (2000)	3	1.5	1.5	3	1	1	0	1	2	1.5	15.5
DeVita (2003)	1.5	0.5	0.5	3	1	1	0	1	1	1.5	11.0
Blok (2004)	3	1.5	1.5	1	1	1	1	1	2	1	14.0
Hales (2008)	1.5	0.5	1	1	0	1	0	1	2	1	9.0
Meyer (2009)	1.5	0.5	1	1	0	1	0	1	2	1.5	9.5
Siminoff (2009)	1.5	1.5	1.5	3	1	1	0	1	2	3	15.5
Downar (2012)	1.5	0.5	1.5	3	1	1	1	1	2	1.5	14.0
Tobler (2014)	1.5	0.5	1.5	3	1	1	0	1	2	1.5	13.0
Siminoff (2015)	3	1.5	0.5	3	1	1	1	1	2	3	17.0
Johnson (2017)	1.5	0.5	1.5	1	0	0	0	1	2	1	8.5

Table 2.2

Methodological Quality of the Included Studies Based on MERSQI Domain and Item Scores

First author (year)	Study design[a]	Sampling		Type of data[d]	Validity of evaluation instrument[e]			Data analysis[f]		Out-comes[g]	Total score
		Institutions[b]	Response rate[c]		Internal structure	Content	Relationship to other variables	Appropriate	Complex		
Marogna (2018)	2	0.5	1.5	3	0	0	0	1	1	3	12.0
Potter (2018)	2	1.5	1.5	3	0	1	1	1	2	3	16.0
Fico (2019)	1.5	1.5	0.5	3	1	1	0	1	2	3	14.5

Note. MERSQI = medical education research study quality instrument.
[a]Study design: 1 = single group cross-sectional or single group post-test only; 1.5 = single group pre-test and post-test; 2 = nonrandomised, 2 groups; 3 = randomised controlled trial.
[b]Institutions: number: 0.5 = one site; 1 = two sites; 1.5 = more than two sites.
[c]Response rate, %: 0.5 = <50 or not reported; 1 = 50-74; 1.5 = ≥ 75.
[d]Type of data: 1 = assessment by study participant; 3 = objective measurement.
[e]Validity of evaluation instrument: 0 = not reported; 1 = each for reported internal structure, content, relationship to other variables.
[f]Data analysis: 0 = inappropriate for study design or type of data; 1 = appropriate for study design or type of data; and complexity 1 = descriptive analysis only; 2 = beyond descriptive analysis.
[g]Outcomes: 1 = satisfaction, attitudes, perceptions, opinions, general facts; 1.5 = knowledge, skills; 2 = behaviours; 3 = patient/health care outcomes.

Training Program Characteristics

All training programs included specialised communication skills for conducting family meetings for news of death or end-of-life decisions. Table 2.3 shows the training strategies used in each program. Programs incorporated an average of six training strategies within a framework inclusive of theory and practice with multimodal interventions evident throughout. Theory was provided as readings, oral presentations and instructional videotapes. Application of theory was demonstrated in instructional videotapes, web-based case scenarios, instructor modelling (in-person) and in the observer role. Skills practice involved role-play with peers, facilitators, and opportunities to rehearse conversations with a simulated family where trained actors played the roles of SFMs or peers. The simulated family interviews were video-recorded in six studies and were used for video-assisted debriefing in four studies (Marogna et al. 2018; Meyer et al. 2009; Potter et al. 2018; Siminoff et al. 2009).

Table 2.3

Training Strategies Used in Each Study

First author (year)	Written information	Oral presentation	Instructional videotape	Discussion	Web-based instruction	Self-reflection	Modelling (instructor)	Role-play	Observer role	Feedback/ debriefing	Interview practice with SFM (actors)	Clinical rotation	Total strategies per study (*n*)
Vaidya (1999)	✓							✓		✓	✓[a,b]		4
Morton (2000)	—	✓	✓	✓		✓		✓	✓	✓	✓[b]		8
DeVita (2003)	✓	✓	✓	✓		✓		✓	✓	✓		✓	9
Blok (2004)	—	✓	✓	✓		✓		✓	✓	✓	✓		8
Hales (2008)	✓[c]		✓[c]	✓	✓[c]	✓		—	✓	✓	✓[d]		8
Meyer (2009)	✓[c]	✓	✓	✓		✓		—	✓	✓	✓[b]		8
Siminoff (2009)		✓		✓				✓		✓	✓[b]		5
Downar (2012)	✓	✓		—		—		—	—	✓	✓		4
Tobler (2014)	✓[c]	✓	✓	✓		✓	✓	✓	✓	✓	✓		10
Siminoff (2015)	—				✓			✓		✓	✓		4
Johnson (2017)	✓[c]	✓		✓		✓	✓	✓	—	✓	✓		8
Marogna (2018)	—	✓					—	✓	—	✓	✓[b]		4
Potter (2018)	—	—	—	—	✓	✓	—	✓	✓	✓	✓[b]		6
Fico (2019)	—	—	✓	—	✓	✓	—						3

Note. SFM = standardised family member; ✓ = reported; — = unclear.

[a]Simulated participants (parents) played by real parents and paediatric healthcare professionals (volunteers).

[b]Video-recorded.

[c]Pre-reading.

[d]Simulated participants (colleague and SFM) played by actors.

Table 2.4 shows summaries of program content, assessments and findings. Training was delivered in intensive mode for short duration ranging from two hours to three and a half days. Sessions comprised small groups of three to 16 participants. Content was delivered within contextual real-life or hypothetical and realistic common clinical case scenarios of varying duration. Many studies provided general statements of the essential communication skills training content. Nine programs highlighted specialised communication skills in offering organ donation (Blok et al. 2004; DeVita, Arnold & Barnard 2003; Fico & Feeley 2019; Hales & Hawryluck 2008; Marogna et al. 2018; Morton et al. 2000; Potter et al. 2018; Siminoff et al. 2009; Siminoff, Traino & Genderson 2015). Four studies indicated inclusion of communication skills but provided no detail of the content (Blok et al. 2004; Fico & Feeley 2019; Marogna et al. 2018; Morton et al. 2000). In six studies, an outline of skills taught was indicated in an assessment instrument/checklist (DeVita, Arnold & Barnard 2003; Downar et al. 2012; Johnson et al. 2017; Meyer et al. 2009; Morton et al. 2000; Vaidya et al. 1999). Communication 'frameworks' were specified in five studies (DeVita, Arnold & Barnard 2003; Downar et al. 2012; Johnson et al. 2017; Meyer et al. 2009; Tobler, Grant & Marczinski 2014), frequently the six-step Setting, Perception, Invitation, Knowledge, Emotions, Summary and Strategy (SPIKES) (Baile et al. 2000) protocol (Downar et al. 2012; Johnson et al. 2017; Meyer et al. 2009; Tobler, Grant & Marczinski 2014). One study (Downar et al. 2012) included the Value (family members' comments), Acknowledge (family members' emotions), Listen (to family members), Understand (the patient as a person), Elicit (family members' questions) (VALUE) framework, validated for ICU family meetings regarding withdrawal of life-sustaining treatments (Lautrette et al. 2007).

Table 2.4

Characteristics of the Content, Assessments and Main Findings

First author (year)	Content (case scenarios)	Dose, frequency	Size of small group	Assessment points	Assessment methods	Main findings
Vaidya (1999)	Two realistic and common case scenarios, each 30-min, where SPs simulated anger, frustration, denial, self-blame and grief. 1. An infant, 6-months, with severe pneumococcal meningitis 2. A girl, 13yrs, critical injuries from road trauma.	1-day, NR	NR	Day of the workshop.	External Videotaped recordings scored retrospectively by a single rater, blinded to session order. Instrument: an investigator developed 26-item checklist of 5 categories: (1) communication skills; (2) content issues; (3) support systems; (4) interventions; (5) PPQ (*validated* 7-item 5-point Likert scale (1 = poor, 5 = excellent))	Significant improvement in 1/5 categories, being the PPQ scores (M = 35.2, SD = 14.4) points (p = .02) Category combined score showed significantly improved scores by M = 18.1, SD = 5.2 points (p = .007) with significant improvement from the 2nd session (p = .002) (post feedback from SP)
Morton (2000)	Case scenarios (hypothetical) with two SFM encounters: poor prognosis with plan for brain stem death testing (10-mins); breaking news of NDD and donation request (10-mins). SFMs emotions: pre-test sadness; post-	1-day, once; control group attended after the study	12-16	Pre-test 3 – 4 weeks before the workshop; post-test 4 – 6 weeks after the workshop; 6-month follow up	External Videotaped recordings scored retrospectively by three research assistants, blinded to scenario order. Validated instrument for communication skills: 6-point scale (0 = absent, 3 = not poor/not good, 5 = very good; doctors and nurses scored separately.	Overall, NS improved mean scores for BBN and the OD request for doctors and nurses. At post-test: intervention group doctors significantly improved BBN, pre-M = 2.6, SD = 0.8), post-M = 3.2, SD = 0.9 (p < .05) and acknowledging families emotional and other needs,

Table 2.4

Characteristics of the Content, Assessments and Main Findings

First author (year)	Content (case scenarios)	Dose, frequency	Size of small group	Assessment points	Assessment methods	Main findings
	test anger; follow-up guilt.					pre-*M* = 2.4, *SD* = 0.8, post-*M* = 3.1, *SD* = 0.8 ($p < .05$).
DeVita (2003)	Participant-determined case scenarios (previous actual interactions). *Communication tool:* NURSE	Four 2-hour sessions and a 2-week rotation, academic year	NR	Before and after a 2-week palliative care rotation (time NR)	Self-assessment Preparedness (confidence) for discussing EOL care. Instrument: investigator-developed 5-point scale (1 = poorly prepared, 5 = very prepared). External 20-question palliative care cognitive test.	Mean exam scores improved by 11%; fellows perceived increased preparedness to perform EOL activities with median (range) scores of pre- 3 (2-4), post 4 (3-4).
Blok (2004)	Two hypothetical scenarios: breaking news of NDD; organ donation request.	1-day, once; control group after the study	12-16	Pre-test before intervention (start of workshop); post-test (time NR); 6-months follow up	Self-assessment Self-efficacy. Instrument: investigator developed with 12 statements (6-knowledge, 6- performance) on a 10 cm VAS-scale 'disagree' to 'agree'; perceived difficulty requesting OTD on two 10-point scales (1 = no problem, 10 = extremely difficult).	Post and 6-month doctors in the intervention group significantly improved self-efficacy scores for BBN (death), requesting organ donation and dealing with grief reactions ($p < .001$); perceived difficulty in requesting organs decreased significantly ($p < .05$).

Table 2.4

Characteristics of the Content, Assessments and Main Findings

First author (year)	Content (case scenarios)	Dose, frequency	Size of small group	Assessment points	Assessment methods	Main findings
Hales (2008)	Six hypothetical case scenarios (45 min stations) highlighting ethical and legal issues for substitute SDM for EOL decisions and offering organ and tissue donation.	1 day, NR	3-6	Completed on day of the workshop.	Self-assessment Comfort, confidence, attitudes and knowledge. Instrument: investigator-developed (pre-8 questions and post-15 questions); forced choice and 5-point Likert scales (1 = very uncomfortable, 5 = very comfortable).	Comfort levels in 10 of 11 EOL topics, excepting cultural issues, significantly improved ($p <$ .05).
Meyer (2009)	Two hypothetical case scenarios: a male, 5-yrs, (near-drowning); a female, 17 yrs, (cancer). *Communication tool:* SPIKES	1 day, NR	10-15	Completed on day of the workshop. 5-month follow up.	Self-assessment Preparation, communication skills, relationship abilities, confidence, anxiety. Instrument: investigator-developed 5-point Likert scales (1 = poor/not at all, 5 = very good/very).	Improved communication skills and confidence to engage in difficult conversations (by one or more ratings on the Likert scales) in 98% and 95% of respondents, respectively. Anxiety reduced in 82% and to 74% at follow up.
Siminoff (2009)	Three hypothetical case scenarios, two of NDD and one DCD. Illustrative of dysfunctional families,	1 day, NR	NR	CG: Jan-Aug 2004; IG: Dec 2004-Sep 2006	Self-assessment Comfort levels, time discussing OD with each family; number of donation topics mentioned (from 14).	Comfort levels increased (NS); comfort answering questions increased mean 6.4 to 6.6, $p = 0.01$); donation topics increased

Table 2.4

Characteristics of the Content, Assessments and Main Findings

First author (year)	Content (case scenarios)	Dose, frequency	Size of small group	Assessment points	Assessment methods	Main findings
	cultural differences, and family conflict. Actors adjusted response dependent on trainee behaviour.				Instrument: (*validated* comfort level scale on a 7-point Likert scale, greater comfort with higher scores. External Rate of actual family consent to OD.	by mean 1.1 (p = .03); time in donation discussion significantly increased by 33.1 mins (p < .001); OD consent rates increased by 9.2% (p = .07) (from 46.3% to 55.5%).
Downar (2012)	Four hypothetical case scenarios (45-min stations) with SDM: 1. Intractable conflict (SDMs opposing patient's wishes). 2. Discordance between SDM wishes and Advance Directive. 3. Grief and inner conflict affecting a SDM's decision-making ability. 4. Conflict between two equally ranked SDMs. *Communication tools:* CLASS, SPIKES, VALUE	Half-day, start of each academic year	NR, 4 trainees per scenario	Completed on day of the workshop. 1-year follow-up.	Self-assessment Comfort facilitating SDM and mediating conflict situations using an investigator-developed instrument with 9 questions, each scored on a 5-point Likert scale; self-evaluation of scenario performance on similar instrument as SFM & facilitator (not reported). External Ethical and legal knowledge test (11 questions); scenario performance by facilitator and SFM using investigator-developed instrument on	Comfort scores discussing 8 of 9 topics significantly increased (p < .001), and knowledge scores from 61% to 82% (p < .001). Scenario performance: general trend to improved mean scores over 3 scenarios (NS).

Table 2.4

Characteristics of the Content, Assessments and Main Findings

First author (year)	Content (case scenarios)	Dose, frequency	Size of small group	Assessment points	Assessment methods	Main findings
					communication and inter-personal skills with 16 items, each scored on a 10-point Likert scale.	
Tobler (2014)	Three hypothetical case scenarios, each 75-min, beginning with a clinical crisis event then two 10 min SP encounters, each followed by ~10 min debrief. SPs varied emotional reactions per scenario. 1. An infant, 5-months, near drowning and died (NDD). 2. An infant, 4-months, non-accidental brain injury. 3. A child, 11-months, traumatic brain injury. Communication tool: SPIKES	5-hours, delivered 3 times over 18 months	3 or 4	Randomised to 1 of 2 OSCE stations before or 3-6 months after workshop.	Self-assessment Confidence in communicating 13 BBN skills scored on a response scale (1 = strongly disagree, 5 = strongly agree). External Analysis of videotaped recordings from OSCE stations on BBN by four reviewers (experts and parents) blinded to OSCE station order, using a standard 17-item communication process skills instrument, scored on a 3-point Likert scale (0 = not done, 2 = good).	Confidence in abilities to perform nine aspects of BBN significantly increased ($p < .009$); assessors scores for performance in OSCEs of 14 of 17 communication skills significantly improved with an overall average of $M = 25.30$, $SD = 5.33$ to $M = 27.82$, $SD = 8.33$ ($p = .004$).

Table 2.4

Characteristics of the Content, Assessments and Main Findings

First author (year)	Content (case scenarios)	Dose, frequency	Size of small group	Assessment points	Assessment methods	Main findings
Siminoff (2015)	Program from Siminoff (2009) modified for online delivery. Group 1: four hypothetical case scenarios of NDD cases. Group 2: addition of face-to-face hypothetical case scenarios of NDD cases. SFM adjusted response dependent on requester behaviour.	1 round at each OPO	NR (online)	CG: Jan to Dec 2009; IG: Jun 2010 to Mar 2012	Self-assessment Online instrument measuring comfort levels on a 7-point Likert scale, greater comfort with higher scores. External Actual family decision makers' (n = 1603) perception of request quality and of the requesters' communication skills (24-items) 5-point response scale (1 = never, 5 = always); 12-item instrument on relational communication skills, scale NR-derived from reference-scored on a 7-point scale (1 = strongly agree, 7 = strongly disagree); list of 17 donation topics; actual consent rates for OD.	Relational communication skills significantly improved with an overall mean of $M = 5.80$ to $M = 6.12$ ($p < .05$) by families; overall no change to the total number of donation topics discussed and consent rate of 84% decreased to 83%.
Johnson (2017)	Three hypothetical case scenarios.	3-days, 2nd yearly	4-5	NR	Self-assessment Confidence / preparedness levels in communication skills 5-point Likert scale (1	Self-preparedness in 10 communication skills improved (mean difference 0.8 to 1.4). In 2014 (n=10),

Table 2.4

Characteristics of the Content, Assessments and Main Findings

First author (year)	Content (case scenarios)	Dose, frequency	Size of small group	Assessment points	Assessment methods	Main findings
	1. An infant, out-of-hospital cardiac arrest, hypoxic brain injury. 2. A child with cancer, multiple organ failure. 3. Adolescent, road trauma with traumatic brain injury (NDD). Communication tool: SPIKES				= not well prepared, 5 = very well prepared).	significantly increased self-preparedness in 11 of 12 communication skills ($p <$ .05).
Marogna (2018)	Hypothetical case scenarios. Communication tool: Not specified	4-hours, NR	NR	CG: Jun 2012 to Nov 2014; IG: Dec 2014 to May 2017	External Multiple choice test; procurement indicators, rates of refusal for OD.	Refusals for organ donation after NDD and DCDD decreased by 10.8% and by 8.5%, respectively.
Potter (2018)	Authentic case scenarios of de-identified actual cases. Actors adjusted response dependent on trainee behaviour.	Total 3.5 days, NR & an online refresher	NR	CG: Nov 2012 to Jul 2014; IG: May 2013 to Jul 2016	External Rate of actual family consent to OD.	No improvement to consent rates. Consent rate of 56% (before) decreased to 53% (after).

Table 2.4

Characteristics of the Content, Assessments and Main Findings

First author (year)	Content (case scenarios)	Dose, frequency	Size of small group	Assessment points	Assessment methods	Main findings
Fico (2019)	Actual 'positive deviance requesters' discussing positive deviance behaviours; families' perceptions of those behaviours and of donation requests.	On-site at each OPO ~6.5 hours, once (Mar – Aug 2015) & an online refresher	NR	Pre-test before intervention, post-test 6-months on-site after online refresher (Mar-May 2016)	Self-assessment Self-efficacy requesting donation. Modified 10-item instrument with a 10 cm VAS-scale 'disagree' to 'agree'. Active-empathic listening scale. Modified 11-item instrument with a 7-point scale (1 = never true, 7 = always true). Greater self-efficacy and perceived successful listening with higher scores. External Rate of actual family consent to OD.	No improvement to self-assessed communication skills and consent rates. Overall, requesters' mean quarterly authorisation rate of 53.69% (SD = 4.54).

Note. BBN = breaking bad news*;* CLASS = Context Listening Skills Acknowledge Strategy Summary; DCD = donation after circulatory death; EOL = end-of-life; ICU = intensive care unit; NDD = neurological determination of death; NURSE = Name Understand Respect Support Explore; NR = not reported or unclear; NS = non-significant; OD = organ donation; OPO = organ procurement organisation; OSCE = Observed Structured Clinical Examination; PPQ = Patient Perception Questionnaire; SC = standardised colleague; SDM = substitute decision maker; SFM = standardised family member; SP = standardised parent; SPIKES = Setting Perception Invitation Knowledge Emotions Summary and Strategy; VALUE = Value Acknowledge Listen Understand Elicit; VAS = visual-analogue scale.

For category 1 – reaction: learners' evaluations of the programs were positive; the usefulness and appropriate level of complexity of the topics were rated highly, particularly the fidelity of the hypothetical case scenarios and professionalism of actors (see Table 2.5).

Communication Skills

Specific communication principles and skills relating to the assessed behaviours are shown in Appendix 2 Table A2.2. Skills taught at most workshops included empathy (DeVita, Arnold & Barnard 2003; Downar et al. 2012; Hales & Hawryluck 2008; Johnson et al. 2017; Meyer et al. 2009; Potter et al. 2018) and managing families' strong emotions (DeVita, Arnold & Barnard 2003; Downar et al. 2012; Meyer et al. 2009; Morton et al. 2000; Siminoff et al. 2009; Tobler, Grant & Marczinski 2014). Other frequently taught skills included: religious/culturally appropriate communication (Downar et al. 2012; Fico & Feeley 2019; Hales & Hawryluck 2008; Johnson et al. 2017; Siminoff et al. 2009); use of silence (Fico & Feeley 2019; Meyer et al. 2009; Potter et al. 2018; Tobler, Grant & Marczinski 2014; Vaidya et al. 1999); using plain language when discussing medical information (DeVita, Arnold & Barnard 2003; Downar et al. 2012; Meyer et al. 2009; Tobler, Grant & Marczinski 2014; Vaidya et al. 1999); and HCP self-reflection (Blok et al. 2004; Downar et al. 2012; Fico & Feeley 2019; Hales & Hawryluck 2008; Morton et al. 2000). In offering organ donation, ideally all the aforementioned communication behaviours should be incorporated, with the addition of some specific skills (DeVita, Arnold & Barnard 2003; Fico & Feeley 2019; Hales & Hawryluck 2008; Morton et al. 2000; Potter et al. 2018; Siminoff et al. 2009; Siminoff, Traino & Genderson 2015).

Research Question A: Healthcare Professionals' Communication Skills

The majority of papers (n = 11, 78%) demonstrated changes to communication skills evaluated at the level of learning (Blok et al. 2004; DeVita, Arnold & Barnard 2003; Downar et al. 2012; Fico & Feeley 2019; Hales & Hawryluck 2008; Johnson et al. 2017; Marogna et al. 2018; Meyer et al. 2009; Morton et al. 2000; Tobler, Grant & Marczinski 2014; Vaidya et al. 1999), with few evaluating behaviours (practice change) in the clinical setting (Siminoff et al. 2009; Siminoff, Traino & Genderson 2015) (see Table 2.5). Investigator-developed and validated instruments measured HCP outcomes

by self-assessment (Blok et al. 2004; DeVita, Arnold & Barnard 2003; Downar et al. 2012; Fico & Feeley 2019; Hales & Hawryluck 2008; Johnson et al. 2017; Meyer et al. 2009; Siminoff et al. 2009; Siminoff, Traino & Genderson 2015; Tobler, Grant & Marczinski 2014) or by external assessors, for example facilitators and simulated participants (Downar et al. 2012), or blinded raters scoring video-recorded simulated interviews from workshops (Morton et al. 2000; Vaidya et al. 1999) or examination stations (Tobler, Grant & Marczinski 2014) (see Table 2.4). Table 2.1 shows evaluation of instrument validity. Most evaluations were completed by participants at the workshop conclusion.

Table 2.5

Outcome Categories Based on a Modified Kirkpatrick's Classification

First author (year)	Category of Evaluation				
	1, Reaction [a]	2A, Learning[c]	2B, Learning[d]	3, Behaviour[e]	4, Results[f]
Vaidya (1999)			Yes (smn)		
Morton (2000)	Yes[b]		Yes (smn)		
DeVita (2003)	Yes	Yes (NR)	Yes (NR)		
Blok (2004)		Yes (+)			
Hales (2008)	Yes[b]	Yes (+)			
Meyer (2009)	Yes	Yes			
Siminoff (2009)				Yes (smn)	Yes (-)
Downar (2012)	Yes	Yes (+)	Yes (smn)		
Tobler (2014)	Yes[b]	Yes (+)	Yes (+)		
Siminoff (2015)				Yes (smn)	Yes (smn)
Johnson (2017)	Yes[b]	Yes (smn)			
Marogna (2018)			Yes (NR)		Yes (NR)
Potter (2018)					Yes (smn)
Fico (2019)			Yes (-)		Yes (-)

Note. (+) = statistical significance; (-) = non-significant; (smn) = some variables with significance; (NR) = not recorded.
[a]Category 1 – scheduling, topic content, quality of instructors.
[b]Included quality of the case scenarios and actors.
[c]Category 2A – change perceptions, attitudes (comfort, confidence).
[d]Category 2B – improve knowledge *(theory test)* and increase (communication) skills *(performance test)*.
[e]Category 3 – transfer to the clinical setting (attitudes, knowledge & skills).
[f]Category 4 – benefits to patients (families' final organ donation decision).

Studies indicated that between four and 10 strategies per program were employed to teach specialised communication skills, and that learning significantly improved regarding participants' self-reported comfort, confidence and scores on performance tests.

Category 2A: Learning

HCPs' perceptions and attitudes improved after training. In post-test findings intensivists and ICU nurses reported significantly improved self-efficacy in breaking news of neurological death determination (Thuong et al. 2016), requesting organ donation and dealing with grief reactions, and that they perceived decreased difficulty in requesting organs (Blok et al. 2004). Nurses and fellows described significantly improved comfort levels discussing end-of-life topics (Downar et al. 2012; Hales & Hawryluck 2008), with fellows (n = 10) reporting significantly increased sense of preparedness in core communication skills (Johnson et al. 2017) and self-preparedness to discuss end-of-life (DeVita, Arnold & Barnard 2003). Residents reported significantly improved confidence in their abilities to break bad news (Tobler, Grant & Marczinski 2014). Multidisciplinary participants reported improved self-assessed communication skills and confidence, with concomitant reduced anxiety discussing end-of-life (Meyer et al. 2009) (see Table 2.4).

Category 2B: Learning

Healthcare professionals' knowledge and performance were tested in four studies. In post-tests fellows scored significantly higher in "patient perceptions" of communication skills (Vaidya et al. 1999); intensivists improved breaking news of neurological death determination and acknowledging families' emotional and other needs, but nurses' skills remained unchanged (Morton et al. 2000). Residents significantly improved communication performance (Tobler, Grant & Marczinski 2014), and fellows scored higher on average for communication and inter-personal skills (Downar et al. 2012) (see Table 2.4).

Learning Retention. Four studies evaluated learning retention at 12-months (Blok et al. 2004; Downar et al. 2012; Meyer et al. 2009; Morton et al. 2000). At five to six months, HCPs' self-reported communication skills, confidence and self-efficacy

improved, with reduced anxiety in discussing end-of-life, and in perceived difficulty about offering organ donation (Blok et al. 2004; Meyer et al. 2009). At six months intensivists from both groups retained improvements only for "responding adequately to family member's questions" (Morton et al. 2000). At 12 months, fellows (n = 14) increased their mean communication score in scenario performance compared with the initial scenario (Downar et al. 2012).

Category 3: Behaviour

Changes to communication attitudes, knowledge and skills were evaluated in clinical practice in two studies. OPO coordinators reported spending significantly more time with families discussing more donation topics (Siminoff et al. 2009). Comfort levels in answering families' donation-related questions were significantly increased (Siminoff et al. 2009; Siminoff, Traino & Genderson 2015) (see Table 2.4).

Research Question B: Benefits to Patients (Family Consent for Organ Donation)

Category 4: Results

The effect of communication training on changes to actual consent rates for organ donation was evaluated in five studies (Fico & Feeley 2019; Marogna et al. 2018; Potter et al. 2018; Siminoff et al. 2009; Siminoff, Traino & Genderson 2015). Increased consent rates were described in two studies, but these were either not significantly different (Siminoff et al. 2009) or inferential analyses were not reported (Marogna et al. 2018). Consent rates decreased in three studies (Fico & Feeley 2019; Potter et al. 2018; Siminoff, Traino & Genderson 2015). In one study 5% to 13% of actual family decision makers were interviewed at two to three months after the organ donation request, revealing significantly improved perceived quality of the request and of requesters' relational communication skills (Siminoff, Traino & Genderson 2015) (see Table 2.4).

Discussion

The aim of this review was to identify programs that enhanced communication skills of HCPs in family donation conversations, and to determine program effects in relation to changes in HCPs' skills, family decisions and organ donation rates. Our findings revealed that common training strategies used in 10 or more studies for teaching communication skills included small group role-plays and interview practice with simulated participants, with feedback and debriefing incorporated in all stages. Nearly all studies demonstrated improvements in participants' self-reported learning of specialised communication skills, and observer-rated performance. Behavioural change in transferring new learning to the clinical setting was shown in two reports of OPO coordinators (Siminoff et al. 2009; Siminoff, Traino & Genderson 2015). Training influenced HCPs' confidence in communication capabilities when offering organ donation, with conflicting evidence of the independent effect of training on increased organ donation consent rates. However, only one study confirmed first-hand substitute decision-makers' perspectives (Siminoff, Traino & Genderson 2015).

All programs involved multiple training strategies; this made evaluation of the effectiveness of individual strategies difficult but all programs demonstrated at least one positive outcome, similar to findings of an overview of systematic reviews (n = 12) of core training for patient-physician communication (Berkhof et al. 2011). Our findings supported those of this other review, that learner engagement in small group discussions, and skills practice with feedback using role-play with simulated participants, delivered in (at a minimum) a one day program, were effective strategies (Berkhof et al. 2011). Our findings of passive training strategies such as written information/oral presentation used in combination with experiential learning strategies, such as role-play with feedback, support findings by Berkhof et al (2011) which also showed some positive benefits. Other strategies that featured, and have demonstrated usefulness in other studies, included small group dynamics, typically described as enabling more intimate exploration of practice concepts and enhanced engagement in learning (Kalaian & Kasim 2017). Feedback and facilitated debriefing, featuring in 13 studies in this review, have been demonstrated to enhance reflection on and about practice and increase the incorporation of new learning into subsequent practice (Garden et al. 2015).

In critical care, communication frameworks are well established to guide use of specialised communication skills for physicians leading the ICU team-family meeting regarding withdrawal of life-sustaining treatments (Lautrette et al. 2007; Oczkowski et al. 2016). We found communication tools such as SPIKES and VALUE were an integral part of ICU fellow and multidisciplinary team training programs (Downar et al. 2012; Johnson et al. 2017; Meyer et al. 2009; Tobler, Grant & Marczinski 2014). Studies in our review did not examine these tools for behavioural changes in the clinical setting, but other researchers have done so, showing ICU multidisciplinary team training using the SPIKES protocol linked to family member satisfaction with decision-making at approximately 30 to 60 days after discharge or death (Shaw et al. 2014). Curricula for critical care fellows have also included the SPIKES protocol for communication training for withdrawing life-sustaining treatments and offering organ donation (Roze des Ordons et al. 2017).

In this review, five studies (Fico & Feeley 2019; Marogna et al. 2018; Potter et al. 2018; Siminoff et al. 2009; Siminoff, Traino & Genderson 2015) assessed outcomes of changes to family organ donation consent rates. Studies suggested between three to six strategies each for teaching specialised communication skills, with role-play, feedback/debriefing and interview practice alongside simulated participants commonly used (Marogna et al. 2018; Potter et al. 2018; Siminoff et al. 2009; Siminoff, Traino & Genderson 2015). While studies in this review did not find significant increase in organ donation consent rates, other studies linked advanced communication training for ICU nurses with increased organ donation consent rates (Jansen et al. 2011; Witjes et al. 2020). However, the training strategies employed were not reported. Subsequent adaptation to online delivery of a program in this review (Siminoff et al. 2009) that was evaluated positively by families (Siminoff, Traino & Genderson 2015), showed no overall increase in requesters' self-reported authorisation rates (Siminoff et al. 2020). However, analysis of requester tenure showed significant increases in family consent rate for requesters who had been employed for 12 months or less and for requesters employed for 36 months or more (Siminoff, Traino & Genderson 2015). Despite analyses only including half the requesters (n = 139; 51%; those who had completed a minimum of one case pre-and post-intervention (Siminoff, Traino & Genderson 2015)), findings showed the benefits of communication training early in employment and the importance of ongoing education. The need for ongoing training to improve requester

self-efficacy and stem "learning decay" over time has been described in a longitudinal study of (n = 253) OPO coordinators (Siminoff et al. 2020).

Future research could explore the effect of specific HCP training on substitute decision-maker outcomes and evaluate translation of behavioural change in clinical practice. Outcome measures need to include family-centred perspectives (Kentish-Barnes et al. 2019). Combinations of training strategies, duration and exposure to donation conversations should be evaluated to determine optimal curricula and dosage to facilitate HCPs' communication skills regardless of level or experience. Reporting the types and range of communication skills taught will enable comparisons between studies (Berkhof et al. 2011; Johnson & Panagioti 2018). For example, in our review, *observation* was used as a specific strategy in half of the included studies yet was infrequently described in publications after 2014. Observers and observing others' performances with facilitated feedback or reflection has been identified as key to learning new behaviours, and may be equally effective as performing the activity (Boud et al. 2019).

Healthcare professionals responsible for offering organ donation should consider undertaking communication training involving simulated participants in scenarios based on real cases, reflecting actual clinical practice (Potter, Gatward, et al. 2017). Policy makers should consider the need for high-fidelity simulation such as this for HCPs to develop and master the specialised communication skills required in this sensitive situation. This strategy is now recommended in updated guidelines for critical care, anaesthesia and emergency medicine (L'Her et al. 2020).

Strengths of this review include use of a comprehensive search strategy, a rigorous approach in the review process and adoption of an educational evaluation framework. Included articles were restricted to publications in the last 20 years for relevance to current practice.

Limitations of this review reflect the limitations of the source papers, including the predominance of observational and single-site studies. Study outcome measures mainly focused on HCP self-reported variables or observer-rated checklists and were measured immediately after training. Few studies examined sustainability, translation of improved confidence and skills to clinical practice or sought opinions of substitute decision makers. The paucity of high quality randomised controlled trials precluded meta-analysis, limiting the strength of our findings and therefore the ability to determine the optimal number or combination of training strategies for improved outcomes. It was

not possible to test for any relationships between methodological quality and number of strategies or whether any strategies exerted greater influence on substitute decision-makers' decisions. The lack of studies with high-quality methodology is typical of interventional research performed to assist HCPs to increase organ donation (Witjes, Jansen, et al. 2019).

Conclusion

This review determined that programs assisting HCPs to raise organ donation with families were based on practical application of key communication skills complemented with theoretical aspects. Most programs offered a variety of experiential learning, enabling self-reflection, opportunity to role-play and interact with simulated participants, incorporated feedback and facilitated debriefing. The advantage of this approach is the opportunity to rehearse the donation conversation and receive feedback from experts and peers, shown to increase the likelihood of incorporating new learning into practice. Limitations included the need for release from the workplace to attend training, although most programs had compressed training to one day to facilitate this issue. Feasibility was affected by the availability of resources, in particular funding for simulated participants or appropriate specialist simulation settings. Retention of communication skills varied according to individuals' experiences. There was weak evidence that organ donation rates might subsequently increase following bespoke communication skills training.

Practice Implications

All programs included in this review were evaluated positively, indicating that HCPs value as well as perceive they benefit by additional support to enhance communication skills for donation conversations. These important findings can inform HCP education curricula, service policy and practice improvement strategies, flag and direct opportunities for future research. This information supported development of the intervention which is described and evaluated in the next chapter.

Chapter 3: Development and Evaluation of the Intervention

Chapter Introduction

This chapter sets out the development and preliminary evaluation of the evidence-based intervention of the study. The content of this chapter is based on a publication that describes the methods employed to develop and deliver the intervention, and to address the preliminary evaluation question that asked:

- How acceptable for HCPs is implementation of the intervention: what are health professionals' experiences and perceptions of core elements of the intervention, including training?

This development and evaluation component has been published in the journal *Progress in Transplantation* where it is cited as:
Potter JE, Gatward JJ, Kelly MA, McKay L, McCann E, Elliott RM, Perry L. Simulation-based communication skills training for experienced clinicians to improve family conversations about organ and tissue donation. *Progress in Transplantation* 2017;27(4). This article is provided in its published form as Appendix 3.

Background

As previously noted, conversations with donor-eligible families can be one of the most difficult clinical activities, irrespective of practitioner expertise or prior experience. Interactions playing out during these discussions can trigger raw emotions for family members, and may influence opinions about organ donation. Evidence reviews have indicated that using specially trained and experienced HCPs, and a "collaborative" donation request to families that included a specialist donation nurse/OPO coordinator and the managing team together, positively influenced family consent rates (Simpkin et al. 2009; Vincent & Logan 2012). However, in Australia, raising the topic of organ donation has historically been the responsibility of the intensivist managing care of the donor-eligible patient (ANZICS Death and Organ Donation Committee 2013). Many intensivists have believed that the relationship or rapport that they developed with family members during the ICU stay was helpful when raising organ donation (Potter & O'Leary 2013). Consequently, intensivists often only introduced the donation specialist nurse to families after they have agreed to consider organ donation.

Various approaches have been used to prepare managing clinicians and donation specialists to lead the donation conversation. In Australia, as previously noted, clinicians develop their approach and repertoire from observing colleagues' interactions with families, but opportunities to lead organ donation conversations occur only a few times per year for many intensivists (Mullins, Simes & Yuen 2012). Education for HCPs raising deceased donation or caring for donor-eligible patients in the ICU has comprised attendance at a one-day donor awareness program, that included some communication education, and was mandatory training for ICU fellows (Potter & O'Leary 2013). This requirement was amended in 2014, replacing mandatory donor awareness training with specialised communication training provided in the national educational core workshop (College of Intensive Care Medicine of Australia and New Zealand 2014).

The designated requester (DR) role was introduced in NSW in 2012. This role is undertaken by an experienced HCP who has undergone specialised communication training to develop expertise to offer donation sensitively with the aim of improving decision making (NSW Ministry of Health 2012). To prepare HCPs for the new role, specialised communication training for designated requesters comprised completion of

the national Professional Education Package (PEP) (Grallelis, Van Weerdenburg & Mehakovic 2017), and the NSW Simulation Program. The national educational training introduced an Australian "balanced approach" for specialised donation communication, to help families of donor-eligible patients in acute grief make organ donation decisions that were informed, proactive and enduring (Mulvania et al. 2014). The PEP training took place in two educational workshops outside the workplace. Training strategies included small mixed professional groups of HCPs seated together, presentations of theory and opportunity for HCPs to practice the family donation conversation using role play with peers (Grallelis, Van Weerdenburg & Mehakovic 2017). These workshops had commenced in October 2011 (Mulvania et al. 2014) independent of this study, and were ongoing. Evaluation of the PEP training was conducted elsewhere by the Organ and Tissue Authority (OTA) and used HCP attendee feedback post-workshop, consultation with professional organisations, and data from the DonateLife Audit (Mulvania et al. 2014). This evaluation also entailed a commissioned report and a multicentre observational study of donation conversations from hospitals (n = 15) over a year (Lewis & White 2015; Lewis et al. 2015).

Having donation conversations led independently of the managing team was not previously routine practice in NSW. A structured intervention based on best practice was developed to guide the implementation and evaluation of an independent designated requester (this current study). However, providing education alone, whether in workshop format (Forsetlund et al. 2009) or as e-learning (Vaona et al. 2018), has been reported as insufficient to transfer learning and effect behavioural change in the clinical setting. However, in the US, workshops of between four- and eight-hours duration were designed for HCPs to learn relational and communication skills for "challenging" EOL conversations in an interprofessional environment (Bell et al. 2019). Set in simulation laboratories, this training included enactment of realistic EOL scenarios (paediatric), with simulated participants to increase authenticity of the encounters, and formal debriefing. At three months post-workshop, participants described improved interactions with interprofessional colleagues, suggesting education in realist scenarios with simulated participants could support translation of specialised communication skills to the clinical setting (Bell et al. 2019).

The NSW Simulation Program was developed to prepare intensivists, donation specialist nurses, and social workers to undertake the designated requester role. Commenced in January 2013, the program afforded participants an opportunity to

rehearse the study intervention while in the designated requester role, interacting with simulated participants in realistic clinical scenarios in a safe learning space. In particular, feedback and facilitated video-enhanced debriefing used in the scenario evaluation, have been demonstrated to enhance reflection on and about practice and increase the incorporation of new learning into subsequent practice (Garden et al. 2015).

Thus the aim of this study was to evaluate the NSW Simulation Program of the family donation conversation (FDC) regarding health care professionals' perceptions of its contribution to their preparedness and confidence to undertake the designate requester role.

Methods

Design

We conducted a post-test evaluation of an innovative simulation program with the specific aim of increasing the preparedness and confidence of clinicians undertaking the DR role.

Setting

The study was conducted in NSW in simulation clinical laboratories equipped with full audio-visual (A-V) capabilities in a university health faculty in Sydney, Australia. The setting was a simulated ICU family meeting room, similar to rooms available in most ICUs. The composition of the simulation teams was also arranged to reflect normal practice in NSW, where accredited intensivists manage patients, set and review treatment goals/plans, and registered nurses (RN)s perform the majority of direct patient care.

In Australia, the provision of intensive care services is structured to optimise the management of patients with potential or actual life-threatening injuries or illnesses. Staffing includes but is not limited to an interprofessional team comprising accredited intensivists, senior RNs as supernumerary team leaders, and, for direct patient care, sufficient RNs for a minimum RN: patient ratio of 1:1 for mechanically ventilated patients. Allied health professionals such as physiotherapists, social workers/Aboriginal liaison, and pastoral care staff are included, dependent on the size of the unit (College of Intensive Care Medicine of Australia and New Zealand 2011).

Population

Participants were eligible for this study if they were an experienced, practicing ICU clinician or donation specialist; had completed the national PEP core and practical workshops, and selection as a DR was confirmed by their ICU department head (or delegate). Invitations to participate in the simulation program were emailed from the NSW Organ and Tissue Donation Service.

Ethical Considerations

Informed Consent

Evaluation material provided data for ongoing review of teaching and content of the simulation program. The relevant Human Research Ethics Committee (HREC) advised that their approval was not required for this educational activity. The HREC advice was to notify participants of the use of their completed evaluation forms for publication and provide them an opportunity to decline use of their deidentified data. All participants had previously volunteered their names on the evaluation forms and investigators emailed individuals information enabling them to provide informed consent. No participant declined the inclusion and use of their evaluation material in the study. All participants signed a confidentiality agreement and consent for A-V recording before each workshop. Actors signed a confidentiality and media agreement annually.

Participant Potential Discomfort or Distress

Participants may experience potential discomfort or distress from working with emotionally charged material and having their performance observed. To mitigate these events, facilitator interventions and exit points were integrated into the simulations. In addition, participants could have halted proceedings at any time and either paused for ‘time out’ or taken up the option to withdraw entirely. All participants could access additional support or access to workplace-based counselling as preferred.

Intervention

The simulation program was developed by a team of organ donation, intensive care medicine and simulation training experts. For practice-based professions meaningful learning is best if it is situated within authentic environments, is contextually based and incorporates interactions with peers and experts; concepts that lent themselves to simulation activities (Lave & Wenger 1991). The program design incorporated educational strategies to increase learning: active participation and formative feedback (Ellermann, Kataoka-Yahiro & Wong 2006), aligned with concepts from *socio-material educational frameworks* (Hopwood et al. 2014; Schatzki 2012). Additional meaning was constructed through interactions between and with others, and with environmental materials (artifacts). The specific environment for the FDC was authentically represented in a simulation laboratory with arrangements of furniture; patient scenarios based on deidentified real cases presented contextual materials critical for participant engagement (see Appendix 3, supplemental material). Interactions were planned with experts and peers (facilitators) and 'family members' portrayed by professional actors. After appropriate briefing, actors were able to realistically portray family member conversations and elicit meaningful engagement of participants resulting in socially constructed learning (Hopwood et al. 2014). Subsequent video-assisted and facilitated debriefing helped focus on specific areas and assisted with reflection and active co-construction or refinement of clinical practice (Rudolph et al. 2007).

Workshop Preparation

Before the workshop, actors were provided a: debriefing guide; scenario synopsis; character outline including family background, personality, current state-of-mind; the level of emotional intensity expected could be varied in response to the participant. Actor briefing included the participant's experience level so they could tailor their questions and reactions. The actors prepared in a separate area to participants.

Two weeks before the workshop participants received the program outline, workshop expectations, an assessment guide and a confidentiality agreement. At the beginning of the workshop, the facilitator reviewed this material with all participants. Those who took on the DR role in the simulation were advised to assume their usual

work role (intensivist, donation specialist nurse, or social worker), although few donation specialist nurses had initiated the topic of organ donation before. Participants were encouraged to take their time, to use the skills learned in the PEP, and not offer organ donation until they believed the family was ready.

Procedures

The three-part simulation workshop ran for four hours or a half-day. Each workshop catered for two participants; one enacted the role of requester while the other observed. These people swapped roles to experience or observe a different patient case scenario. Two simulation laboratories ran concurrently so that two half-day workshops accommodated eight participants per day.

Minimum personnel requirements for each workshop included two professional actors, one health care simulation expert (facilitator) and another subject expert. The subject expert often played the role of the bedside nurse. A minimum facility requirement was a simulated ICU family meeting room equipped with A-V recording equipment and visual access for two observers: the facilitator, who made notes or annotated the recording while observing, and a participant observer (Box 3.1).

Box 3.1

Workshop Minimum Personnel and Resource Requirements

Personnel	Facilities and equipment
• One workshop coordinator: to brief the actors, facilitate the timetable, welcome and organise participants. • Professional actors experienced in playing patient roles and debriefing: roles of two family members. • Managing team: roles of an intensivist (played by the facilitator), and a bedside nurse. • Two participants (learner 'designated requesters'). • Two experts: a health professional facilitator and a subject expert in the FDC module content. • Staff for scene setup and take down; sourcing appropriate props. • One simulation technician to run the A-V system including playback; subsequent minor editing.	• Separate area with a table for the facilitator to brief participants as a group at the beginning and debrief after the workshop. • Separate area for actors to create backstories, rehearse and get into character in preparation for their roles. • Simulation laboratory with a viewing room for the participant observer to watch the scenario in real time. • Scenario props: a three-seat sofa, two armchairs, a coffee table, tissues, water and glasses. • A-V system with essential features of real time viewing, replay, digital file copying facilities; optionally, editing with annotation.

Note. A-V = audio-visual; FDC = family donation conversation.

The facilitator provided an overview of the patient scenario to the 'DR' and managing team. Each scenario commenced when the family had been informed either of the inevitable death or the death determined by neurological criteria ('brain death') of their loved one.

Part One: Planning Meeting

The 'DR' participant met the managing intensivist and 'bedside nurse' to gather information and plan the FDC. They specified the manner of their introduction to the family; for example, either by stating they work in organ donation or by using general terms such as an "end-of-life specialist". A short debrief of this part followed (see Box 3.2 Part 1).

Part Two: The FDC

The scenario and A-V recording began when the 'bedside nurse' brought the family into the simulated meeting room and joined the conversation. The 'intensivist' facilitator brought the 'DR' participant into the room and introduced the family in the manner determined in Part One, then left the room to observe and make notes. The DR participant led the FDC using the balanced approach, raising organ donation when appropriate. At the conclusion of the conversation the A-V recording was stopped and a three-stage debriefing process was facilitated (Rudolph et al. 2007). The actors and nurse debriefed immediately, in and out of character (Box 3.2 Part 2).

Part Three: Facilitated Debriefing of The Conversation

The video recorded conversation was viewed and discussed between the facilitator, subject expert, observer, and participant, guided by annotations or notes (Box 3.2 Part 3).

Box 3.2

The Debriefing Process

Debriefing	Activity
Part 1 Planning meeting debrief.	After the planning meeting, an informal discussion led by the facilitator reflects on the team plan and conduct of the meeting. Any information missed by the DR participant is raised at this point. If the participant has not specified how they would like to be introduced to the family, this is established.
Part 2 End of the FDC debrief.	When the FDC is ended, the facilitator enters the room. Feedback is sought from the family in character, to garner initial reactions and emotions, and the participant is encouraged to question the family. Then, at the discretion of the facilitator, the family and nurse are directed to come out-of-character and offer further feedback. Once the initial debrief is complete the actors leave the room.
Part 3 Facilitated video-reflexive feedback.	The observer and the subject matter expert enter the debriefing area. A final facilitated debrief uses a video-reflexive technique to trigger participants' insight and reflection on practice. Annotations/notes on the A-V recording are used as discussion points between the facilitator, subject matter expert, observer, and participant. Standardised criteria are used to guide achievement of key learnings from the national FDC workshops. A digital file of the video recording is provided for the participant's personal ongoing reflection.

Note. A-V = audio-visual; FDC = family donation conversation.

Facilitator Exit Points

Potential facilitator intervention and exit points were integrated into the simulations to ensure the workshops ran smoothly for 'DR' participants and family members. For example, if a participant felt the family needed a break and would normally divide the conversation, the participant drew the conversation to a temporary halt and left the room. The actors were briefed that time had elapsed, another meeting was scheduled, and a second donation conversation was initiated from where the first was left. The simulated conversations were expected to take approximately one hour; the facilitator could intervene to bring it to a close if the conversation was not progressing.

Data Collection

Participants were invited to complete evaluation forms at the conclusion of each workshop. A Simulation Training Evaluation Form was created for the program (EM and MK), because there were no existing evaluation methods that aligned with this type of initiative. The form comprised eight items with five forced choice responses and three open-ended questions. Three items with "yes or no" response options and space for free text comments sought participants' views whether the workshop complemented or built on the PEP; its value as additional or essential training for the 'DR' role; if participants felt more confident undertaking the role after the workshop. Two items with Likert-scaled response options, from poor to outstanding recorded participants' expectations and overall opinions of the workshop. Respondents were asked what they liked best and least, and suggestions for future developments.

Data Analysis

Quantitative and qualitative methods of analysis were used. Simple descriptive statistics (percentages and frequencies) reported quantitative data. Free text responses were transcribed verbatim and content analysis was used for systematic interpretation (Graneheim & Lundman 2004). Two authors (experienced intensive care nurses: JP and RE) who were not involved in the development or delivery of the program performed the primary analysis. The items and responses were read repeatedly. Initially, common content within the responses was identified and coded using keywords. Similar or related words were confirmed in a thesaurus and grouped into categories manually by

one researcher (RE) and using NVivo 10 for Windows (©QSR International) by another (JP). Responses were reread and the frequency that each category occurred was counted. Responses and keywords were reread some days after the initial content analysis to check for inconsistencies; none were found.

To reduce potential for bias, the analysts were blinded to respondents' designation and gender. To support credibility of the analysis, the selection of categories was identified independently and then discussed and agreed, with any disagreements settled in consultation with a third author (LP).

Results

Twenty-five simulation workshops were conducted between January 2013 and July 2015. Eighty-six health professionals were invited and participated, 82 (95.3%) returned an evaluation form, with few (two to four) incomplete responses. Respondents were practicing health professionals; more than half (*n* = 44; 53.7%) were intensivists (denoted as 'M'), nurses ('N') or social workers ('SW') (Table 3.1). The majority attended a single workshop.

All workshops were delivered without any participant withdrawing from any component. The simulated donation conversations were on average 40 minutes in duration; most were effectively managed by the DRs with a few requiring facilitator input to bring the conversation to a timely close.

Table 3.1

Characteristics of Workshop Evaluation Respondents

Characteristic	Total	
	n	%
Female	41	50
Intensivist	44	54
Intensive care nurses and social worker[a]	38	46
Attended workshop on one occasion	66	80
Attended workshop twice	13	16
Attended workshops three or more times	3	4

Note. Respondents *n* = 82.
[a]Only one social worker attended.

Quantitative evaluation was overwhelmingly positive. The respondents rated the simulation workshop highly (78/81; 96.3%) and agreed that it complemented and built on the PEP. Nearly all (78/79; 98.7%) agreed that it was valuable or necessary training for the DR role. Most (76/78; 97.4%) subsequently felt more confident to be a DR. Expectations of the training were well met and it was rated as outstanding (63/80; 78.8%) or good (17/80; 21.3%).

Qualitative evaluation was predominantly positive. Three respondents disagreed that the simulation workshop built on national training but commented that it "…stands alone in its own right" (M), and "may be helpful for someone starting out but not for experienced clinicians" (M). Personal insights from the simulation workshop included that:

> …It is possible that the CORE and Practical sessions affected my practice in some ways. I think I will be more self-conscious of my performance after the simulation session (M).

Three respondents who did not respond to the value of simulation training commented positively (two respondents) and the other stated a preference for mentorship by experienced clinicians: "A single session in isolation is interesting, but a larger group forum with senior colleagues would be more useful" (M). One respondent, whose confidence did not improve, felt they had learnt a lot about communication.

All respondents gave examples of what they liked most. The main categories identified were feedback, use of professional actors, and realism (Table 3.2).

Table 3.2

Categories of Elements Liked Most in the Simulation Workshop

Category and Subcategory	Count[a]
Feedback: person providing it; quality; topic; debriefing; video playback	55
Use of professional actors	47
Realism/high fidelity scenarios	44
Opportunity to practice/usefulness	20
Setting: organisation; safe learning environment	10

Note. [a] Count equals the number of times referred to.

For the 'feedback' category the value of the actors' feedback was specifically highlighted: "The FB [sic] from the actors both in character and out of character was exceptional" (M & N). The quality of feedback overall was rated as good to excellent: "Good feedback, very helpful debriefing sessions and ability to relate to peers" (M). Respondents valued this feedback because of their respect for the experts providing it: "Excellent feedback from experienced educators" (M). The topics covered included key elements of the national education, for example: "…the use of certain language or expansions" (M, SW). Participants appreciated the constructive manner in which it was delivered: "Peer debriefing was safe and constructive" (N). Personal insights were gained from feedback with video playback: "Debrief with video. Really unnerving seeing myself in action. Will make me think" (M).

For the category for use of professional actors, their ability to portray an actual family's reactions, thereby immersing respondents in the unfolding scenario, was flagged: "The realistic scenario and how you forgot that they were in fact actors but a family going through this conversation" (N); "The actors are exceptionally realistic. I had absolutely no problem engaging with them as if they were a real family. I enjoyed watching the scenarios of others" (M).

For the category of realism, the similarities of the scenarios to real situations was reiterated: "The scenarios were very realistic and the actors were very professional" (M); with tolerance for some loss of fidelity: "…not perfect but as close as you can get!" (M).

Other categories were opportunities to practice and the setting. Opportunities to practice mainly related to skill development: "Excellent realistic practice with good skill consolidation" (M). This allowed practice in responding to displays of emotion: "Realistic, with emotions and tears. Good to practice comments" (M). The workshop setting was a suitable place for learning, "Away from hospital, well set out and well managed as a collegial non-threatening exercise" (M). Seven respondents made similar comments.

Most respondents (66/82; 80.5%) detailed what they liked least (Table 3.3). For many this was nothing, reflecting the overall positive evaluation, but performance anxiety, being watched, and the setting were raised.

Table 3.3

Categories of Elements Liked Least in the Simulation Workshop

Category and Subcategory	Count[a]
Nothing	22
Performance anxiety	13
Being watched by self and others	12
Setting: practical considerations	12
Feedback	3
Actors	2
Processes	2

[a] Count equals the number of times referred to.

Performance anxiety occurred before and during the workshop: "Anxiety and apprehension on my part before participation" (M); "… people around you and observing you is nerve racking" (N). Many disliked watching themselves on video. The inconvenience of locating the workshop in the city and the room design were raised. Personal reactions to criticism were highlighted: "I don't take criticism well, but I understand and value it" (M). Finally, the unpredictability of actor reactions was raised and a few participants had difficulty engaging in the observer role.

Fifty-nine participants (72%) made suggestions for future developments. Half related to providing more sessions such as annual refreshers or repeat attendance. More difficult scenarios that included family disagreement, paediatric cases, and donation after circulatory determination of death were also suggested. Feedback suggestions included providing real-time feedback from a facilitator while watching the alternate scenario and creating a montage of the best aspects discussed at some of the simulations.

Discussion

We developed this simulation program to prepare intensivists, donation specialist nurses, and social workers involved with donation conversations to undertake the DR role. Participants' evaluations were overwhelmingly positive with most agreeing that the program was valuable, that it complemented the PEP and increased their confidence as a DR. Debriefing with actors in and out of character was viewed as powerful and a rare opportunity for appraisal of one's performance during an emotional conversation with a family member in acute grief. The video-reflexive feedback was especially useful in identifying areas for improvement in requesters' body language, phraseology, and pace of conversation. Aspects that were least liked related to performance anxiety, the observer role, and being observed. Overall, these results reveal strong support for the use of simulation training to increase the preparedness of experienced clinicians as DRs.

This study examined participants' opinions of rehearsing the donation conversation using the balanced approach in actual, deidentified potential organ donor scenarios with a comprehensive debriefing process. Other programs have also used feedback from peers and facilitators on performances in role-play of hypothetical scenarios with professional actors, for communication training for multidisciplinary groups of clinicians exposed to difficult organ donation and end-of-life conversations in adult and paediatric populations (Browning et al. 2007; Hales & Hawryluck 2008; Meyer et al. 2009; Morton et al. 2000; Siminoff et al. 2009). Feedback from actors has also been obtained, using questionnaires or rating scales and sought directly during workshops and included in evaluations (Browning et al. 2007; Hales & Hawryluck 2008). As in this study, participants reported simulation resulted in better preparation and greater confidence immediately post training and five-months later (Meyer et al. 2009). Intensive care consultants showed improved sensitivity to relatives' needs when conveying news of death and raising organ donation at six months post training (Morton et al. 2000). In England, videotaped recordings of 64 ICU consultant-nurse pair encounters during hypothetical scenarios were independently rated (Morton et al. 2000). Videotaped recordings have also been used to highlight improvements in communication techniques in a group feedback session (Hales & Hawryluck 2008). A similar program, a one-day educational intervention on communicating about organ donation used real-time critique of videotaped performances of OPO Coordinator

participants and additional expert debriefing of the simulation, has been reported (Siminoff et al. 2009).

Evaluation outcome measures have included consent rates for organ donation. In the US an increase of 9.2% over two years was seen after introduction of a communication education intervention (Siminoff et al. 2009); in Australia, organ donation consent rates have increased by 3% over two-years following introduction of the PEP (Mulvania et al. 2014). Participation in the simulation program, focusing on enhancing communication approaches combined with video-reflexive debriefing may increase the skills and preparedness of specialist requesters and further contribute to increased organ donation consent rates.

Participant evaluations of learning experiences of role modelling and the observer role have varied across jurisdictions. For example, in the European Donor Hospital Education Program workshops (United Kingdom), significantly higher learning was reported by those who actively role-played a doctor or a nurse compared to those who observed. This result contrasted with findings from the Netherlands where there was no difference in learning between those who role-played and those who observed (van Dalen et al. 1999). These differences may have been a result of experiences from previous training or requesting, or an effect of the level of participation ('dose') in scenarios. Preparation of the observer participants and how they contributed to the debriefing was discussed with a view to enhancing observer engagement during the simulation and debriefing. This is a growth area in simulation as the benefits of vicarious learning are clear and worth enhancing in the simulation program (O'Regan et al. 2016; Rooney et al. 2015).

The program had a number of strengths. The authenticity of the experience was universally appreciated; actors' expertise immersed participants in the scenarios. Real-life (deidentified) scenarios based on local case-mix, policies and procedures were fundamental to the authenticity. The simulation program was designed to enhance realism and maximise the time available to rehearse the FDC. The multidisciplinary training approximated the clinical environment and fostered collaboration between disciplines in support of bereaved families.

The program has some limitations. The workshops took place in a university simulation laboratory rather than in a clinical setting, and while the actors' performances were excellent, the realism of the surroundings was not perfect. Inevitably, the actors knew that organ donation would eventually be raised, and it was a

challenge for some to ‘reset’ and remember specific dialogue in each scenario. Evaluation of simulation workshops using self-report questionnaires is open to subjectivity and bias. However, grasping a sense of the impact of the simulation on individuals’ sense of professional practice is important for program evaluation, and this is an established, low-cost approach.

Evaluation of such programs is essential, both in the clinical environment and from the perspective of relatives, who ultimately are most affected by the quality of communication by health professionals. Furthermore, factors affecting participation of experienced health professionals in communication skills training and adoption of alternative requesting approaches require investigation. The addition of a validated rating form such as the multi-rater communication skills instrument with gap analysis may increase the robustness of self-appraisal and enable monitoring of learning over time (Calhoun et al. 2009).

Conclusions

We developed and delivered a highly effective and well-received simulation program that provided an opportunity to refine communication skills and techniques to increase the confidence of health professionals leading the donation conversation. Participants identified that skills learned in this program and the opportunity to rehearse conversations in realistic scenarios greatly enhanced their confidence. Overall, it is anticipated that this specialised and targeted training for DRs will contribute to enhance donation conversations conducted by clinicians with greater skills and confidence, achieving improved family experiences of this difficult situation and subsequently increased consent rates for organ and tissue donation in NSW.

Formal rigorous evaluation of the ability of the intervention to achieve its objectives (enhanced family consent rates and satisfaction with the process) is essential. The methods employed to address this follow in the next chapter.

Chapter 4: Study Methods

Chapter Introduction

This chapter sets out the methods of the study. The content of this chapter uses material previously published in a protocol publication, and in a paper presenting the results of the first three research questions for the unregistered subsample.

In the protocol publication, the end point of research question one is referred to as the 'primary end point' of the study. In this same publication, the end points of research questions 2, 3 and 5 are referred to as the 'secondary end points' of the study.

The study protocol was published in the journal BMC Health Services Research: Potter JE, Herkes RG, Perry L, Elliott RM, Aneman A, Brieva JL, Cavazzoni E, Cheng THA, O'Leary M, Seppelt IM, Gebski V, and the COMFORT study investigators. COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT): protocol for an intervention study. *BMC Health Services Research* 2017;(1):42. This article is provided in its published form as Appendix 1.

Additional details of methods have been published in the following publication: Potter J, Perry L, Elliott R, O'Leary M, Aneman A, Brieva J, Cheng A, Seppelt I, Herkes R and the COMFORT investigators. COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT) intervention: a multicentre pre-post study. *Critical Care and Resuscitation* 2018;(20):4. This article is provided in its published form as Appendix 4.

Study Research Questions

For donor-eligible patients who had not registered their donation preferences, comparing current standard practice to an evidence-based intervention including communication training using interaction with simulated participants for designated requesters ("the intervention"), are there differences in terms of SANOK consent rates for deceased organ donation?

How feasible and acceptable for HCPs is implementation of this intervention: do HCPs adhere to core components of the intervention?

For donor-eligible patients who had not registered their donation preferences and where the intervention was in use, what, if any, characteristics of the decision-making process occurring in hospital predicted the family donation decision?

For all donor-eligible patients where an evidence-based intervention (as above) was in use, what do SANOK report in relation to the rationale for their final decision in hospital, either to consent or decline organ donation?
What proportion of SANOK reported that they regretted their final donation decision, either to consent or to decline donation, at around 90 days after enrolment?

Methods

Research Design

The design chosen for this study came from a position of pragmatism. This approach included the principle of generating "actionable knowledge", achieved by documenting events in real world situations, in this instance, routine practice in critical care settings (Kelly & Cordeiro 2020). Epistemologically, the inquiry process acknowledged that new knowledge was interconnected with previous experience and ways of acting (Kelly & Cordeiro 2020), potentially influencing changes in practice HCPs actually adopted, the effect on desired outcomes, and family experiences.

Accordingly, the research design used multiple methods to accommodate the complex evaluation that was required to address the research questions. Multiple methods can gather more information by enabling use of both quantitative and qualitative approaches. A multi-method evaluation was required to investigate the outcomes of the intervention, the processes affecting the application of the intervention, its uptake, how it varied between sites, over time, and the causes of that variation. Understanding how an intervention works is essential to be able to understand its outcome and is an equally important topic of study. A strength of the approach taken in this study was that it facilitated exploration of the processes underlying any effects of the intervention on donation consent rates, by enabling investigation of HCP adherence to the intervention within routine practice, and exploration of families' donation decisions and the reasons that drove their choices. Limitations of this design included the additional time and skills required to collect, complete and analyse the large, diverse and complex datasets generated by this research design. Additionally, integrating different types of data in the analysis is recognised as time consuming and can pose challenges in terms of aligning findings from different methods, methodologies and paradigms (Tariq & Woodman 2013).

In this project, qualitative data provided confirmatory information for the quantitative data in several areas. Qualitative methods described HCPs' frequency of adherence to practice change in the clinical setting. Qualitative data provided insights into the SANOKs' decision contemporaneously and over time. Qualitative data supported the dichotomous yes/no decision by capturing SANOKs' reasons for that decision prospectively and by exploring whether their donation decisions were sustained over time, or how and why it changed. Quantitative and qualitative data were analysed separately to progressively address the various components of the research aims.

The methodology to address the primary research question (whether the intervention increased family consent rates) entailed before-and-after quasi-experimental design using quantitative methods. This design was chosen as the most rigorous design available to test an intervention within the parameters of this topic and context. This entailed applying only those implementation strategies that were deemed feasible within routine clinical practice, and accommodating the small proportion of people dying in NSW hospitals in a situation where organ donation might be possible. In order to determine the effect of the donation process change intervention on the end point of consent rates.

The quantitative component entailed:

Research question 1: This was addressed using a before-and-after intervention study in nine ICUs in NSW, Australia, between 1 November 2012 and 8 July 2016. Each site included aggregated donation events from a period of six months pre-intervention and an intervention period of varying length.

Research question 2: This investigated which components of the intervention were adopted / applied and entailed analysis of records of the donation conversation process as documented prospectively by study sites, including notifications of donor-eligible patients to the NSW Organ and Tissue Donation Service. This approach was chosen because, while the intervention was standardised, its delivery in the clinical setting was controlled by local investigators who adapted the program to their local context.

Research question 3: This examined which components of the intervention were required to achieve / predict any improvement in consent rates, and entailed analysis of records of the donation conversation process from study sites, and notifications of donor-eligible patients to the NSW Organ and Tissue Donation Service

(as above). This question was designed to ascertain whether individual elements of the intervention were more effective than others in determining an optimal 'dose' to achieve consent.

The qualitative component entailed:

Research question 4: This examined the reasons why the SANOK agreed or declined donation, and probed whether the intervention affected this by analysing records of the donation conversation process as documented by study sites. This involved prospective data collection by HCPs who sensitively asked the SANOK who participated in the donation conversation and/or signed the consent form for organ donation about the reasons for their final donation decision at that time. This approach was chosen to enable collection of rich but also sensitive information contemporaneously by HCPs who had an existing relationship with bereaved families in the clinical setting, during this stressful and exhausting time.

Research question 5: This examined whether the intervention could improve the SANOK satisfaction with their donation decision in the longer-term, and whether their decision was sustained over time, using an exploratory methodology. This entailed qualitative interviewing with the senior next of kin who participated in the donation conversation and/or signed the consent form for organ donation via telephone at 90 days after enrolment. This approach was chosen to enable collection of rich but also sensitive and personal information by interviewers separate from the clinical setting and experienced in bereavement support to be able to care for the interviewee while discussing distressing events.

Settings

Sites included seven metropolitan teaching hospitals, a tertiary paediatric hospital and a major regional hospital. All hospital ICUs admitted medical and surgical patients. Additionally, the metropolitan hospitals included the specialities of neuroscience and trauma, and three offered transplantation services (see Chapter 5 Table 5.1, Table 5.2 and Table 5.3). The NSW Organ and Tissue Donation Service was the database custodian for notifications of donor-eligible patients from NSW hospitals.

Intervention

The COMFORT intervention incorporated six best practice components for offering organ donation in the hospital setting (see Box 4.1).

Box 4.1

Components of the COMFORT Intervention

No.	Description of Each Component of the Intervention
1	Organ donation conversations were the responsibility of a designated requester (NSW Ministry of Health 2012). Primary communication with families regarding end of life management and death remained the responsibility of the managing team.
2	Designated requesters were volunteer intensivists, experienced critical care nurses, or social workers who had been deemed appropriate by the site principal investigator/ICU department head to undertake the role, **and** who had completed mandatory training.
3	The offer of organ donation was separated from end-of-life family meetings (Simpkin et al. 2009).
4	If families mentioned the topic of organ donation prior to it being introduced in a FDC, the conversation was sensitively deferred to the designated requester (Siminoff et al. 2001).
5	Donation conversations were conducted within a structured family meeting. Key features included: a) a pre-conversation multidisciplinary action plan; b) held in a private location; c) led by the designated requester (as above), with the managing intensivist leaving the conversation (at their discretion) (ANZICS Death and Organ Donation Committee 2013; Billings 2011; Billings & Block 2011).
6	The requester used a 'balanced approach' during the FDC, including providing families with information on the benefits of donation for themselves and recipients (Mulvania et al. 2014). Requesters encouraged active participation of family members in the conversation by using communication techniques such as open-ended questions, silence and showing empathy (Lautrette et al. 2007; Siminoff et al. 2009).

Note. ICU = intensive care unit; FDC = family donation conversation; NSW = New South Wales.

Mandatory Training

Regarding intervention component 2, mandatory training for designated requesters entailed completion of the Professional Education Package (PEP) core and practical workshops (Grallelis, Van Weerdenburg & Mehakovic 2017), followed by the NSW simulation-based workshop (half-day) (Potter, Gatward, et al. 2017). The simulation workshop provided designated requesters preparation and opportunities to practice components 3 to 6 of the COMFORT intervention. Subsequent attendance at the simulation workshop was required for annual refresher training for specialist donation nurses and social workers, and every 18 months for intensivists, for the duration of this study. Up to six designated requesters were estimated to be required at each study hospital.

Site Implementation

For the before-and-after intervention study, the NSW Organ and Tissue Donation Service was the study coordinating centre, given its function as referral centre for notifications of donor-eligible patients from NSW hospitals. The study management committee included membership of the NSW Organ and Tissue Service Executive and at least one senior intensivist who was the local project lead at each study site.

As the study intervention was a modification to health service delivery, it was led in each hospital by local donation nurse and medical specialists. Education sessions were delivered as required to colleagues in the departments of emergency medicine, intensive care, neurosurgery and social work to support and provide information and feedback on the implementation process of the new intervention.

Participants

Participants in this study were the families of potential deceased organ and tissue donors (donor-eligible patients) and the HCPs involved in each organ donation event, termed a 'case'. Eligible donor-eligible patients had met all inclusion and no exclusion criteria as detailed below.

Inclusion Criteria

Donor-eligible patients of all ages, managed in the ICU or under the care of ICU HCPs, who were potential deceased organ and tissue donors.

Exclusion Criteria

Donor-eligible patients who had fulfilled one or more of the following criteria:

a) A patient who was not medically suitable for deceased organ donation;
b) A patient who had no SANOK able to participate in donation conversations;
c) An adult patient in the ICU who could have provided first person consent for deceased donation, for example a patient with cervical spine injury;
d) A patient only eligible to donate tissue after death.

To address **research question 1**, the primary end point of the study only, donor-eligible patients must not have registered their donation preferences. Only donor-eligible patients who had not recorded their organ donation preferences, or were aged ≤16 years were included, because evidence suggested that registration was associated with consent (Lewis et al. 2015; Stephens, Pilcher & Opdam 2013). This group of donor-eligible patients is referred to as the *unregistered subsample* in this thesis.

To address **research question 2**, data from all cases were collected by donation specialist nurses by self-report either when participating in the first donation conversation or by liaising with the HCPs who were involved in that process. This procedure was used to track intervention fidelity and to limit missed eligible cases.

To address **research question 3**, data from the unregistered subsample were extracted from data collected for research question 2.

To address **research question 4**, data from all cases identifying the SANOK, or the delegated decision maker, who had participated in the donation conversation and/or signed the consent form for organ donation were included.

To address **research question 5**, data from all cases where SANOK had been offered and had agreed to bereavement aftercare, were invited to participate in an interview from 90 days after enrolment.

End Points

The primary end point for the study was:

- The SANOK consent rate for deceased organ donation where the potential donor had not registered their donation preferences (research question 1).

Secondary end points were:

- HCPs' adherence rates to core elements of the COMFORT intervention (research question 2);
- Identification of predictors of family donation decision (research question 3);
- SANOKs' rationales for their final donation decision at the hospital, per case (research question 4);
- The proportion of SANOK who reported they regretted their final donation decision at around 90 days after enrolment, per case (research question 5).

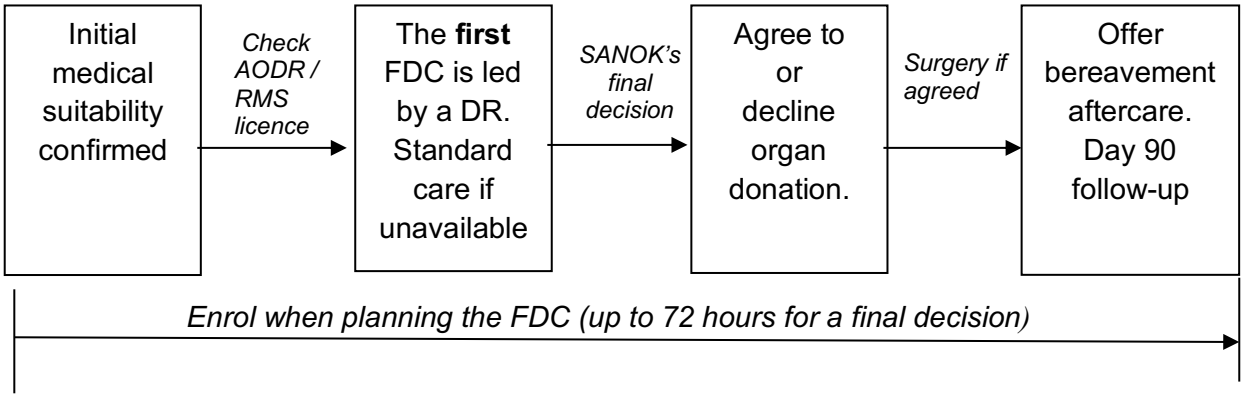
Study Outline

In accordance with usual practice, members of the managing team identified a donor-eligible patient who was apparently medically suitable for organ donation and notified the donation specialist nurse or doctor at the hospital, or the NSW Organ and Tissue Donation Service. The donation specialist coordinators at the NSW Organ and Tissue Donation Service checked the donor registers to find any recorded preference for organ donation, assessed medical suitability, and the availability of suitable recipients.

In the pre-intervention control condition, the donation conversation was managed by the HCP(s) and processes of usual practice in that setting. In the COMFORT intervention condition, the managing team were responsible for delivering the news of death and contacted the donation specialist/designated requester to plan the approach to the family and initiate the donation offer (as above and Figure 4.1).

Figure 4.1

Flow Chart of the Study Outline



Note. AODR = Australian Organ Donor Register; DR = designated requester; FDC = family donation conversation; RMS = Roads and Maritime Services.

A chart of the study design and data collection periods is shown in Figure 4.2. The before-and-after intervention periods for the whole study occurred between 1 November 2012 and 8 July 2016. The control period (1 November 2012 – 29 July 2014) included aggregated donation events from the six months pre-intervention at each site. The intervention period (1 May 2013 – 8 July 2016) began after the site initiation visit at each hospital. The site initiation visit was the point where hospitals crossed over from the control to the intervention condition.

Bereavement support provided by the NSW Organ and Tissue Donation Service Family Support Coordinator was offered to families who participated in the donation conversation regardless of their final organ donation decision. The SANOK or the delegated decision maker who agreed to bereavement aftercare was invited to participate in the follow-up interview from day 90 after enrolment.

Figure 4.2

The Data Collection Timeline for the Pre-Intervention and Intervention Periods.

Time periods in months	Site number						
	9	3	7	4, 6	2, 8	1, 5	OTDS Day 90
Nov 2012	X[a]	X	X	X	X		X
Dec 2012	X	X	X	X			X
Jan 2013	X	X	X				X
Feb 2013	X	X					X
Mar 2013	X	X					X
Apr 2013	X	X					X
May 2013	X	X					X
June 2013	X	X					X
July 2013	X						
Aug 2013	X						
Sept 2013	X						
Oct 2013	X						
Nov 2013	X						
Dec 2013	X						
Jan 2014	X						
Feb 2014							
Mar 2014							
Apr 2014							
May 2014							
June 2014							
July 2014							
Aug –Dec 2014							
Jan – June 2015							
July – Dec 2015							
Jan – July 2016							

Note. OTDS = Organ and Tissue Donation Service.
[a]X = period of no data collection; light grey shading indicates the period of pre-intervention; dark grey shading indicates the period of intervention.

Evaluation: Data Collection and Management

Setting

To characterise and describe the setting, data recorded at the beginning and at completion of the study at each site included: number of hospital and ICU beds; categories (medical/surgical/paediatric) of patients admitted to the ICU; areas of specialty; medical, nursing and allied health staffing establishments and ratios; availability of private meeting rooms; frequency of multidisciplinary communication (ward rounds; and family meetings) (see Appendix 5 for CRF 1).

Current Control

To describe practice for the 'control condition' (i.e., preintervention details of donation events for the period of six months before each site implemented the intervention and joined the program), data were extracted from the NSW Organ and Tissue Donation Service databases. In the notification / referral database, data had been collected prospectively by donation specialist nurses at each hospital and routinely forwarded to the NSW Organ and Tissue Donation Service. To ensure all eligible events had been captured, a record of these cases was compared with the record of deaths in an ICU or Emergency Department and entered in the national DonateLife Audit. NSW jurisdictional Audit data were held by the NSW Organ and Tissue Donation Service; donation specialist nurses had extracted these data on patients aged up to 80 years retrospectively from medical records, and categorised deaths according to the potential for deceased organ donation.

Data characterising the control condition included: medical suitability for deceased organ donation; donor-eligible patient's date of birth, donation intent registered on their driver licence and the Australian Organ Donor Register; initiator of the donation conversation; family final donation decision, and outcome of the donation event.

Intervention Period Screening

A screening log was maintained of notifications of donor-eligible patients who were apparently medically suitable for deceased organ donation during the study intervention period. Donation specialist nurses routinely collected data at each hospital

and forwarded completed notification / referral forms to the NSW Organ and Tissue Donation Service for validation and consistency checks, and entry into the database.

Donation Events (Case)

A unique number was allocated to each donor-eligible patient at enrolment. Data from eligible donation events included donation pathway (that is, neurological or circulatory death), designation of initiator of the family donation conversation, donation intent on a register, and family donation decision. Also noted were characteristics of donor-eligible patients such as: date of birth, gender, ethnicity, religion, primary event/cause of death, dates and times of ICU admission and death, commencement of procurement surgery (CRF 6), and family contact details.

Family Donation Conversation

Adherence to components of the family donation conversation were consecutively recorded for each donation event by self-report from the observations of HCPs who participated in that meeting (CRFs 2-5). Details included key characteristics of the COMFORT intervention implementation:

- Component 1: Role of the ICU HCP who led the initial family donation conversation (termed the 'requester') and their relationship to the managing team (CRF 3);
- Component 2: Requester demographic, training and number of donation conversation experiences in the preceding calendar year (self-report) (CRF 5);
- Component 3: Dates and times of the end-of-life family meeting about news of death or the inevitability of death, and of the start of the first donation conversation (CRFs 2 and 3);
- Component 4: Recording family offers of donation at any time (CRFs 2 and 3);
- Component 5: Features of a structured family meeting including pre-planning with the multidisciplinary team, the location, the requester, details of the transition from the managing team to the designated requester, and time the managing intensivist left the conversation. Also noted were reasons for deviation from the intervention components, such as reasons the managing intensivist did not leave the meeting or another HCP offering organ donation who was not a designated requester (CRFs 2 and 3).

- Component 6: Specific topics discussed in the first meeting indicating use of a balanced approach and whether families raised any topics, showing their participation in the conversation. (CRF 3).

To minimise potential recall bias, HCPs were encouraged to complete study documentation, particularly CRF 3, at the close of the conversation. A consensus approach was used with equal weight given to each HCP's observations. This CRF was expected to be completed within one week.

In CRF 3, HCPs recorded the SANOKs' initial and final donation decisions. Where appropriate and possible, these decisions were graded as 'reactive' or 'in principle'. A 'reactive no' was identified where the SANOKs' initial response to the offer of donation was to decline, and was perceived by the reporting HCP to originate from powerful emotions such as grief reactions. An 'in principle' decision was one based on information and it was determined to be 'proactive' when reflective of the values and wishes of the donor-eligible patient and one that they would have made themselves on an ordinary day, had they been able to (Mulvania et al. 2014). The differentiation of decision responses (as reactive or in principle) was made by the donation specialist nurses; all of whom had completed specialised communication training for offering donation that included identifying and responding supportively to family members' grief reactions. The final donation decision by the SANOK was recorded at conclusion of the conversation (in CRF 3).

In CRF 4, the reasons stated by the SANOK and, where appropriate, HCPs' perceptions of their final decision at that time were noted (see Appendix 1 Additional file 2 for CRFs 2-6).

Follow-up with the Senior Available Next of Kin

Follow-up bereavement aftercare was offered to SANOK as part of the donation conversation process. The NSW Organ and Tissue Donation Service Family Support Coordinator conducted the telephone interviews with next of kin who agreed to bereavement aftercare and had provided consent. Data sought included: bereavement aftercare received; information received regarding organ and tissue donation, and family members' perception as to whether this was adequate for them to make a decision; previous discussions with their relative regarding organ and tissue donation; if they would now make the same donation decision, and their decision rationale. Personal and

demographic information including age, gender, ethnicity, religion and highest education level were asked at the end of the interview (see Appendix 6 for interview schedule, CRF 7).

Framework for Analysis

Research Question 1

The sample to answer this question was the unregistered subsample. The sample size calculation (for the primary end point) was performed using Simon's two-stage design (Simon 1989), requiring 140 eligible donation conversations. This sample had 80% power (95% confidence interval [CI]) to detect a relative increment of 11% in the consent rate of the intervention group. Inferential analysis tests were two-sided with alpha set at .05. All analyses were performed on an intention-to-treat principle. For example, in a case where the intervention was not properly followed, such as the SANOK had organ donation raised by an inappropriate requester instead of a designated requester, the donor-eligible patient remained in the study and was considered to have received the intervention. We did not impute missing values. Where there were missing data, we reported the number of observations used in the analysis.

A flow-chart showed the number of donor-eligible patients and the numbers enrolled from each site (see Figure 5.1). The primary end point was ascertained at the hospital and was available for all donation events. Donor-eligible patient, HCP requester and donation conversation characteristics made up a donation event, termed a case. Findings were reported by case unless specified otherwise.

Categorical data (such as details of gender, religion, ethnicity of donor-eligible patients, cause of death and donation pathway) were summarised using frequencies and percentages. Continuous data such as age, duration and number of donation conversations, and length of stay in ICU, were summarised using the mean and standard deviation or median and IQR, depending on the distribution of data.

To address the primary end point:

- Consent rates provided by the next of kin for organ and tissue donation in the unregistered subsample were calculated.
- The primary end point of consent for donation (agreed or declined) was analysed using the Chi-square test or Fisher's exact test.

Research Question 2

The sample to answer this question was all cases (full sample). Categorical data (such as details of HCP gender, religion, ethnicity, and adherence to core components of the intervention) were summarised using frequencies and percentages. Adherence to core components of the intervention were obtained via the CRF and rates calculated. Continuous data (such as HCPs age, number of years worked in ICU, and number of participants at the donation conversation) were summarised using the mean and standard deviation.

Core Components of the Intervention: Allocation of Points. A summative index (Titler et al. 2009) was derived of HCPs' adherence rates to core components of the intervention. This was defined as HCPs' uptake rates of each component of the intervention with summed scores of intervention components.

Rates were calculated by intervention component as follows:

Designated requester led the donation conversation. Yes/No.

0 = No, led by managing team.

1 = Yes, led by designated requester.

Preparation of the designated requester completed as per protocol. Yes/No.

0 = Requester had completed nil or some communication training.

1 = Requester had completed all mandatory training.

Separation of the donation conversation from news of death. Yes/No.

0 = No separation (mentioned in same meeting).

1 = Separation (news of death before or after the donation conversation).

Family offers of organ donation are deferred to a donation conversation led by a designated requester. Yes/No.

0 = Family raised donation and offer not deferred by HCP, or raised by HCP

1 = Family raised donation and appropriately deferred, or not raised by HCP

Donation conversation occurs in a structured family meeting. The first two subcomponents were summed to obtain the value.

i. Pre-FDC multidisciplinary action plan. Yes/No.

   0 = No action plan.

   0.5 = Yes, action plan with the multidisciplinary team and the DR.

ii. Private location. Yes/No.
0 = Bedside of potential donor or public space elsewhere.
0.5 = Private room or special area for meetings, including telephone.

iii. Led by the designated requester. Not scored here because duplicated element #1.

iv. Transition. Not scored here because the managing intensivist staying or leaving was discretionary.

The requester used a balanced approach and communication tools. Yes/No.

0 = Requester did not use elements of a balanced approach and family did not raise any topics.

0.25 = HCP raised benefits of donation

0.25 = HCP raised the rare opportunity of donation

0.25 = HCP raised knowledge of the donor-eligible patients' wishes

0.25 = SANOK/family raised at least one topic.

Individual intervention components were scored separately and as the sum of components. The total score dependent variable was the sum of components no. 1 + no. 2 + no. 3 + no. 4 + no. 5 + no. 6, producing points ranging from 0 to 6.

Qualitative methods were used to analyse topics discussed in the donation conversation for intervention components 4, 5 and 6. Topics stated by the HCP and/or raised by the family were analysed qualitatively using content analysis (Graneheim & Lundman 2004). Predefined categories based on representative ideas derived from the literature were the basis for this section, with an additional free text option. Statements including the "rare opportunity of donation", and/or the "benefits of donation" indicated the HCP used the balanced approach. For the free text, exact words from the text that captured predefined or new key ideas were highlighted and their frequencies counted. Text was tabulated and grouped into units of meaning arising from text containing the key words. These units were further reduced by condensing the text and then allocating a new code, if needed, that was derived from the data and based on the representativeness of the ideas (Graneheim & Lundman 2004). These categories of topics in the donation conversation were summarised using frequencies.

Topics raised by the family were given precedence when mentioned first, that is before the HCP had introduced the topic in the donation conversation. To support the rigor of the approach, coding and categories determined by *the candidate* (*refer to page*

10) were discussed and agreed with supervisor RE and confirmed with the supervisory team. Categories were compared using the Chi-square test or Fisher's exact test.

Research Question 3

To answer this question, the unregistered subsample was selected. Exploratory analysis using bivariate methods employed the Chi-square test or Fisher's exact test when comparing categorical data. Continuous variables were compared using unpaired Student t-tests or the Mann-Whitney U test, dependent on the distribution of data. Data were tabulated with the top rows presenting normally followed by nonnormally distributed data. Univariate variables with a p-value < .20 were considered for inclusion in the multivariate model. A p-value of < .05 was considered statistically significant for retention in the multivariate model, in addition to theoretically relevant intervention variables. Binary logistic regression was used to explain the impact on the probability of consent of theoretically variables related to the context, donor-eligible patient data, and intervention component adherence. Data were assessed for normality and log-transformed where appropriate. We did not impute missing values.

Research Question 4

The sample to answer research question 4 was all cases (full sample). Responses stated by the SANOK and/or perceived by the HCP at the hospital were analysed qualitatively using content analysis (Graneheim & Lundman 2004). Reasons stated by the SANOK were given precedence when both stated by the SANOK and perceived by the HCP. Predefined categories of reasons for the SANOKs' donation decision at the hospital were based on representative ideas derived from the literature, with a free text option. For the free text, exact words that captured predefined and new key ideas were highlighted and their frequencies counted. Text was tabulated and grouped into units of meaning, arising from text containing the key words or phrases. These units were further reduced by condensing the text and then allocating a category that was predefined or a new category based on the representativeness of the ideas (Graneheim & Lundman 2004). These categories of reasons to consent or decline donation were summarised using frequencies. The reasons were subsequently grouped into themes, derived from previous Australian data (Neate et al. 2015).

To support the rigor of the approach, coding and categories determined by *the candidate* (*refer to page 10*) were discussed and agreed with supervisor RE and confirmed with the supervisory team.

Research Question 5

The sample to answer research question 5 was all SANOK who had both agreed to bereavement aftercare at the hospital and who subsequently agreed to and were interviewed by the NSW Organ and Tissue Donation Service Family Support Coordinator from 90-days after enrolment. The proportion of respondents who reported they regretted their final decision either to consent or to decline donation from 90 days was reported by case.

A flow-chart shows the number of SANOK eligible and the numbers enrolled (see Chapter 6 Figure 6.1). Summary statistics were presented of SANOKs' demographic data (such as details of gender, religion, ethnicity) using frequencies and percentages. Continuous data (such as age, duration of the interview) were summarised using the mean and standard deviation. Categorical data from the forced-choice items such as showing the next of kin's decision opinion, were summarised using frequencies and percentages.

For the qualitative analysis, interviews were initially recorded by interviewer note-taking and subsequently by audio-recording. The audio recordings were transcribed verbatim and combined with those recorded by note-taking for qualitative analysis. Due to the small sample, reasons SANOK regretted or were unsure of their donation decision from 90 days after enrolment were presented as vignettes. These vignettes illustrated the story behind the quantitative findings of the endurance of donation decisions, and transcript excerpts were presented to preserve the full voice of participants.

Overall, for the qualitative analyses a number of measures were used to achieve trustworthiness of data. Three concepts were addressed; credibility, dependability and transferability of data (Graneheim & Lundman 2004). Credibility of the findings was achieved by firstly selecting appropriate participants who had experienced the phenomena (an actual donation conversation); selecting relevant units of meaning abstracted from the interview transcripts, and then by *the candidate* and supervisory

team discussing and agreeing on categories. Representative quotations demonstrated the source of the derived theme or code from abstracted data.

Dependability of data was enhanced by a consistent plan for data collection and by restricting the interviewer to an individual with expertise in supporting bereaved families. The change from data collection by interviewer note taking alone to note taking accompanied by audio-recordings increased the reliability of data collection. In addition, collecting interviewee demography and details of the donation outcome captured changes in donation procedures, such as donor age or donation pathway, over time, enhancing transferability of the findings.

Monitoring

The study monitor/project manager (*the candidate-refer to page 10*) conducted a site initiation visit and subsequent monitoring visits to each study site during the intervention phase to support protocol compliance and adherence to good clinical practice in research. Hospital records, source documents and other study files were accessible at all study sites for auditing purposes. The project manager monitored recruitment contemporaneously by screening notifications of donor-eligible patients to the NSW Organ and Tissue Donation Service.

The project manager (*the candidate-refer to page 10*) and supervisor RE performed source data verification of registered donation preferences for the unregistered subsample in 100% of cases for both study periods. Variations in practice of checking the donor registers meant that registers were not always accessed before the first donation conversation, sometimes delayed until after hospital discharge when accessed by the Tissue Bank staff. In the intervention period, depiction of events was verified contemporaneously in discussions with the donation specialist nurse and requester, so deviations were captured accurately. The study management committee adjudicated cases found to be not medically suitable for organ donation subsequent to the donation conversation.

Ethical Considerations

The study was a pragmatic evaluation “in practice” of adoption of key components of an intervention that entailed adherence to clinical practices based on evidence-based guidelines for end-of-life communication with families. Donation

conversations were conducted according to current best practice by enabling them to be led by HCPs who had received specific training in supporting bereaved families and offering organ donation. As a result, the intervention offered potential benefit and only low risk to next of kin participants, as defined in the National Statement (National Health and Medical Research Council, Australian Research Council & Australian Vice-Chancellors' Committee 2007). As such, certain elements of the study were deemed routine care or routine 'audit' activities by the appropriate Health Authority Human Research Ethics Committee (HA HREC), and usually exempted from their ethical review.

However, for this multicentre study we elected to submit a full "greater than low risk" HREC application. The appropriate HA HREC approved use of data collected routinely for donor-eligible patients who have died in the ICU and their family member(s) had attended a donation conversation. In line with the advice received from the appropriate HA HREC, we did not seek consent from family members to participate in a donation conversation as this procedure occurred as part of normal standard care, determined by the managing clinical team.

We sought and received HA HREC approval to use patient, HCP and family member data to examine adherence to key elements of the intervention that occurred as part of normal standard care. For copies of the HA HREC approval letters and UTS HREC Ratification, see Appendix 8.

The HA HREC had reviewed and approved the research protocol as a whole (see Appendix 9) and study documents including the:

- record of the donation event (CRF) 2-6 (see Appendix 1, additional file 2);
- site details CRF 1 (see Appendix 5);
- CRF completion guidelines (see Appendix 10), poster and fact sheet (see Appendix 11).

For the follow-up (research) phase:

- the cover letter and participant information sheet and consent form (see Appendix 7);
- the interview schedule CRF 7 (see Appendix 6).

HREC Approval

St Vincent's Hospital Sydney Human Research Ethics Committee approved this study (HREC/12/SVH/271) and ratified by the University of Technology Sydney Human Research Ethics Committee (reference no. 2013000133) (see Appendix 8). Separate Research Governance Officer authorisations were also obtained locally from each site subsequent to HREC approvals of protocol amendments and reports.

Informed Consent

The procedure for requesting consent for organ and tissue donation was a routine, although relatively infrequent, component of end-of-life clinical care for ICU HCPs. The study intervention was determined a quality improvement initiative, anticipated to improve usual care for emotionally distressed families where organ donation was being offered. In line with the approval received from the appropriate HA HREC, we did not seek additional (research) consent to use patient, HCP and family data to examine adherence to key elements of the intervention as these procedures occurred as part of usual care. Data collected to monitor adherence to elements of the intervention represented audit data (that is, they represented HCP adherence to best practice) and HCP individuals were not identified, other than by their designation. HCPs elected to provide or withhold demographic data at their discretion.

Consent was sought from senior next of kin to participate in the follow-up (research) phase. An invitation to participate in the follow-up interview and the participant information sheet and consent form were posted to SANOK who agreed to follow-up approximately two weeks before the 90-day post enrolment time point (see Appendix 6 for invitation, participant information sheet and consent form). Written or verbal consent was subsequently sought from the SANOK for the follow-up interview and to audio-record it, although the interviewer took notes rather than audio-recording if participants preferred. This contact procedure was similar to methods used in previous research with families of donor-eligible patients (Neate et al. 2015). Hence the three-stage process for consent to follow-up entailed:

1. Initial verbal consent to offer bereavement aftercare, followed by
2. Provision of written information and written or verbal consent, and
3. Confirmation of consent before conducting the interview, and for audio-recording.

Participant Distress or Harm

As part of routine care, HCPs delivering this intervention were able to access existing psychological supervision for support should they wish. It was possible that contacting bereaved families may have caused families anxiety or distress, and we carefully planned the approach to mitigate that possibility in the following ways:

- Families who agreed to organ donation were routinely offered bereavement aftercare by the donation specialist nurses at the hospital. When the SANOK did not meet the donation specialist nurse the requester, hospital social worker or chaplain offered bereavement aftercare provided by the NSW Organ and Tissue Donation Service Family Support Coordinator.
- Offering bereavement aftercare provided by the NSW Organ and Tissue Donation Service Family Support Coordinator to families who declined organ donation; this was previously not available to them under standard care conditions, but routinely offered to families who agreed to donation.
- As standard care many next of kin received telephone support from the Family Support Coordinator either at the usual 4-week follow-up call or if they initiated contact themselves, using the toll free number supplied by mail in the first two weeks post bereavement.
- An invitation to participate in the Day 90 survey was mailed to SANOK approximately two weeks before the proposed interview so they could review the invitation to participate in the follow-up in their homes and decide at their leisure whether they wished to participate.
- In light of their existing relationship with the family, their counselling expertise and independence from the managing clinicians, the NSW Organ and Tissue Donation Service Family Support Coordinator conducted the Day-90 interview subsequent to family verbal or written consent.
- During telephone contact the participant could discontinue at any time if they experienced or showed signs of emotional distress. In this situation, the interview was interrupted and the participant given the opportunity to discontinue/continue later. Participants were able to change their mind at any time without affecting eligibility for ongoing bereavement support.
- If any medical, psychological or emotional issues requiring follow-up were disclosed during the telephone contact, the participant was referred to

appropriate practitioners. For help with psychological or emotional concerns the interviewer, the Family Support Coordinator, negotiated follow-up support as needed by the next of kin with themselves or another registered psychologist, if that was more convenient for the participant.

Confidentiality

Each donation event (case) comprising donor-eligible patient, family and requester data was de-identified and allocated a coded study number, separate to the medical record number and donor number. The CRF was made reidentifiable by assigning this unique number to each donation event. All data were identified by this number and the donor-eligible patients' initials. This number was used to code next of kin interviews and HCP demography.

This process enabled the CRFs to be reviewed against the original medical record during the study and for the whole of the archiving period as required. The code list at each site was not stored with the paper CRFs. It was stored in a locked cabinet at each site to prevent accidental identification of records. The master list at the NSW Organ and Tissue Donation Service was stored electronically on a secure server, password-protected, with access restricted to designated staff.

The project manager (*the candidate-refer to page 10*) anonymised study data stored in the database by coding cases with the study number and age of the donor-eligible patient. This procedure was performed when data were extracted and electronic files forwarded to the statistician or delegate, at the NHMRC Clinical Trials Centre, for analysis of the unregistered subsample for research question one.

Personal details of senior next of kin or HCPs could have been revealed to individuals contracted to transcribe the audio interviews. These individuals were bound by Australian Privacy laws to maintain confidentiality. Data reported in publications or presentations were non-identifiable and reported in aggregate form.

Potential for Bias in Data

To minimise personal bias from *the candidate* (*refer to page 10*) when monitoring, documentation in the CRF that differed from the source was discussed with the site donation specialist nurse and verified from multiple sources wherever possible to confirm accuracy. This process involved checking messages on mobile phones,

checking back with the intensivist/other doctor who initiated the first donation conversation. Sometimes the CRF itself was the source because of inadequate documentation in the medical records. When screening cases at the NSW Organ and Tissue Donation Service, donation events were checked with the NSW State Donor Coordinators, to check details, timelines and medical suitability criteria and compared with study eligibility criteria. Cases where eligibility could not be resolved were adjudicated by the study management committee.

Storage and Archiving of Study Documents

Hard copy (paper) and electronic files for the study were stored in secure, locked conditions at the NSW Organ and Tissue Donation Service, at each centre and on password protected computers in a secure location within the Organ and Tissue Donation Service. The study electronic database was located on a secure server at the NSW Organ and Tissue Donation Service within the South Eastern Sydney Local Health District; as with all health service data, back-ups are performed nightly to secure servers.

Hard copies of records for the study have been archived and stored securely for seven years following publication of the results of the unregistered subsample before destruction. Data archived at an off-site repository were tracked with other sensitive, patient-related health service data.

Chapter Conclusion

The pragmatic approach taken with the design of study methods was intended to enable evaluation of the uptake and outcomes of a ‘best practice’ intervention. This entailed a framework of evidence-based family conversations led by a skilled ‘designated requester’ convened after the news of the donor-eligible patient’s death had been delivered, to make decisions regarding end-of-life care and organ donation. This was an important initiative to identify ‘what worked’ in usual clinical settings when requesting organ donation in critical care environments, both in terms of what changes in practice HCPs were willing and able to adopt, and what effect this may have on desired outcomes in terms of consent rates, and family satisfaction with the donation decision-making process and the sustainability of the decisions they made.

Chapter 5: Results of the Primary and Care Process Secondary End Points

Chapter Introduction

This chapter sets out the SANOK donation decision results for the unregistered subsample and care process secondary end points of the study and is based on the content of the publication that reports these findings. Study results have been organised into two sections, which reflect the way in which the data were analysed to manage the scope of the work and to address the clinical priority of the NSW Organ and Tissue Donation Service to address, analyse and publish the findings for the unregistered subsample for the first three research questions before addressing the other research questions.

Study Research Questions

This chapter therefore reports findings in relation to research questions 1-3:
For donor-eligible patients who had not registered their donation preferences, comparing current standard practice to an evidence-based intervention including communication training using interaction with simulated participants for organ donation requesters ("the intervention"), are there differences in terms of SANOK consent rates for deceased organ donation?
How feasible and acceptable for HCPs is implementation of this intervention: do HCPs adhere to core components of the intervention?
For donor-eligible patients who had not previously registered their donation preferences and where the intervention was in use, what, if any, characteristics of the decision-making process occurring in hospital predicted the family donation decision?

These primary and selected end points of the study, for the unregistered subsample, were reported in the following publication:

Potter J, Perry L, Elliott R, O'Leary M, Aneman A, Brieva J, Cheng A, Seppelt I, Herkes R and the COMFORT investigators. COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT) intervention: a multicentre pre-post study. *Critical Care and Resuscitation* (2018) 20;(4). This article is provided in its published form as Appendix 4.

Results

Characteristics of the clinical settings including communication and donation conversation practices for these study sites (n = 9) are shown in Table 5.1.

Before the intervention period, only one site had a formal policy for family meetings or updates following ICU admission. For other regular meetings of the multidisciplinary team, two sites met weekly for complex case management and Grand Rounds, respectively. Another two sites had monthly meetings for morbidity and mortality / quality improvement activities. There were no changes to family meeting policy or meetings of the multidisciplinary team after the intervention period.

When allocating registered nurses to care for donor-eligible patients, few sites used specially trained nurses, such as those who had completed donor awareness training. No site reported using a team approach as their model of care.

Before the intervention period, three sites indicated adoption of designated requesters; by the end of the study sites reported an increased uptake of donation specialist nurses and designated requesters to lead donation conversations (see Table 5.1). Approximately three-quarters of sites (n = 7, 78%) had selected five or more designated requesters, comprising 28 – 80% of case requesters per site (see Appendix 13 Table A13.1).

Table 5.1

Characteristics of Communication and Organ Donation Practices

Characteristic	Pre		Post	
	Mo	*Range*	*Mo*	*Range*
Facilities for family				
Waiting rooms, *n*	1	1 – 1	1	1 – 2
Private meeting rooms for family, *n*	2	1 – 6	1, 2[a]	1 – 5
HCP communication				
Multidisciplinary team ward rounds per day, *n*	2, 3[a]	1 – 4	1, 3[a]	0 – 6
Formal multidisciplinary intensivist handover meetings, per week, *n*	2[b]	1 – 14	1[b]	1 – 7
	n	%	*n*	%
Determinants of nurse allocation to POD				
Team leader discretion	4	44	4	44
Experienced nurses (CNS)	4	44	3	33
Special group	1	11	2	22
Donation conversation[c]				
Responsible for introducing organ donation and leading the FDC[d]				
Intensivist (managing the patient)	8	–	9	–
Designated requester	3[e]	–	5[e]	–
DSN	1[e]	–	4[e]	–
Intensivist (as above) and DSN together	–	–	1	–
Donation specialist medical	–	–	1	–

Note. N = nine study ICUs. CNS = clinical nurse specialist; DR = designated requester; DSN = donation specialist nurse; FDC = family donation conversation; *Mo* = mode; POD = potential organ donor.
– = not done.
Total % for some categories will deviate from 100% by ± 0.1% due to rounding.
[a]Equal modes of three instances.
[b]Mode of three instances and multiple modes of two instances: pre- *n* = 1 and *n* = 5 meetings; post- *n* = 1, *n* = 2, *n* = 5, and *n* = 7 meetings.
[c]Responsibility of more than one designation per site.
[d]Missing for one ICU pre-.
[e]If managing intensivist thought appropriate (*n* = 1 ICU pre; *n* = 2 ICUs post).

Selected characteristics of the context including the study ICUs' daily work routines and staffing establishment are shown in Table 5.2. Regarding the shift pattern for RNs, all nine hospitals rostered 8 and 12-hour shifts. However, 10-hour shifts were available in seven hospitals pre- and in six hospitals post-intervention. Characteristics were comparable in the pre and post intervention periods with non-significant differences in site characteristics (data not shown).

Table 5.2

Characteristics of the Context and Daily Work Routines of the Study Sites

Characteristic	Pre			Post		
	M	SD	*Range*	*M*	*SD*	*Range*
Context						
Hospital beds, *n*	545	250	235 – 911	569	264	240 – 919
Funded ICU beds, *n*	24	14	7 – 51	25	13	8 – 51
ICU single rooms, *n*	14	18	1 – 58	15	18	1 – 58
Medical HCPs						
Intensivist FTE/ICU bed	0.39	0.07	0.25 – 0.50	0.40	0.09	0.29 – 0.60
Intensivist working <0.75 FTE / ICU bed, *n*	0.20	0.30	0.02 – 1.00	0.22	0.26	0.00 – 0.88
ICU Registrar FTE/ICU bed	0.69	0.23	0.31 – 1.00	0.63	0.27	0.89 – 1.17
Nurse HCPs						
RN, FTE / ICU bed	5.77	1.21	3.88 – 7.13	5.60	1.14	3.88 – 7.47
RN with critical care qualifications/ICU bed, *n*	3.00	1.30	0.98 – 5.14	2.59	1.23	0.03 – 3.50
Daily work organisation						
Intensivist rostered weekday / ICU bed, *n*	0.13	0.04	0.07 – 0.21	0.13	0.03	0.07 – 0.19
Registrar rostered per weekday/ICU bed, *n*	0.20	0.07	0.13 – 0.31	0.16	0.05	0.09 – 0.27
Facilitation						
Donation specialist medical, FTE/ICU bed	0.03	0.15	0.01 – 0.05	0.02	0.01	0.01 – 0.05
Donation specialist nurse FTE/ICU bed	0.06	0.04	0.02 – 0.14	0.05	0.03	0.02 – 0.13

Note. N = nine study ICUs. FTE = full time equivalent; HCP = healthcare professional; ICU = intensive care unit; RN = registered nurse.

Table 5.3 shows selected context characteristics of the study sites' daily workday staffing establishment in the ICU, regarding support of senior nurses and allied health HCPs.

Table 5.3

Workday Availability of Senior Nurse and Allied Health Staff

Characteristic	Pre		Post	
	Mo	*Range*	*Mo*	*Range*
Nurse and Allied Health HCPs				
Clinical Nurse Consultant during workday, *n*	1	0 – 3	1	0 – 3
Clinical Nurse Educator during workday, *n*	1, 2[a]	1 – 4	1	1 – 4
Nurse Unit Manager during workday, *n*	1, 3[a]	1 – 4	2	1 – 5
Social work, during workday, *n*	1	1 – 3	2	1 – 3
Hospital chaplain, during workday, *n*	1	0 – 9	1	0 – 8

Note. N = nine study ICUs. HCP = healthcare professional; *Mo* = mode.
[a] Equal modes of three instances.

Research Question 1: Senior Next of Kins' Donation Decision for the Unregistered Subsample

Screening and Enrolment in the pre-Intervention Period

In the pre-intervention period, 135 donor-eligible patients were screened, and less than one-fifth (*n* = 25, 18%) met criteria for enrolment in the unregistered subsample. The average age of donor-eligible patients was 43 (range, 0.8 – 77) years. Nearly half (*n* = 12/25, 48%) were male, with Christian beliefs (*n* = 11/19, 58%), and three quarters of Australian or New Zealander ethnicity (*n* = 17/23, 74%). For most of the 25 cases (*n* = 16, 64%) death was determined by neurological criteria, with the primary cause of death intracranial haemorrhage (*n* = 10, 40%), then traumatic brain injury (*n* = 9, 36%).

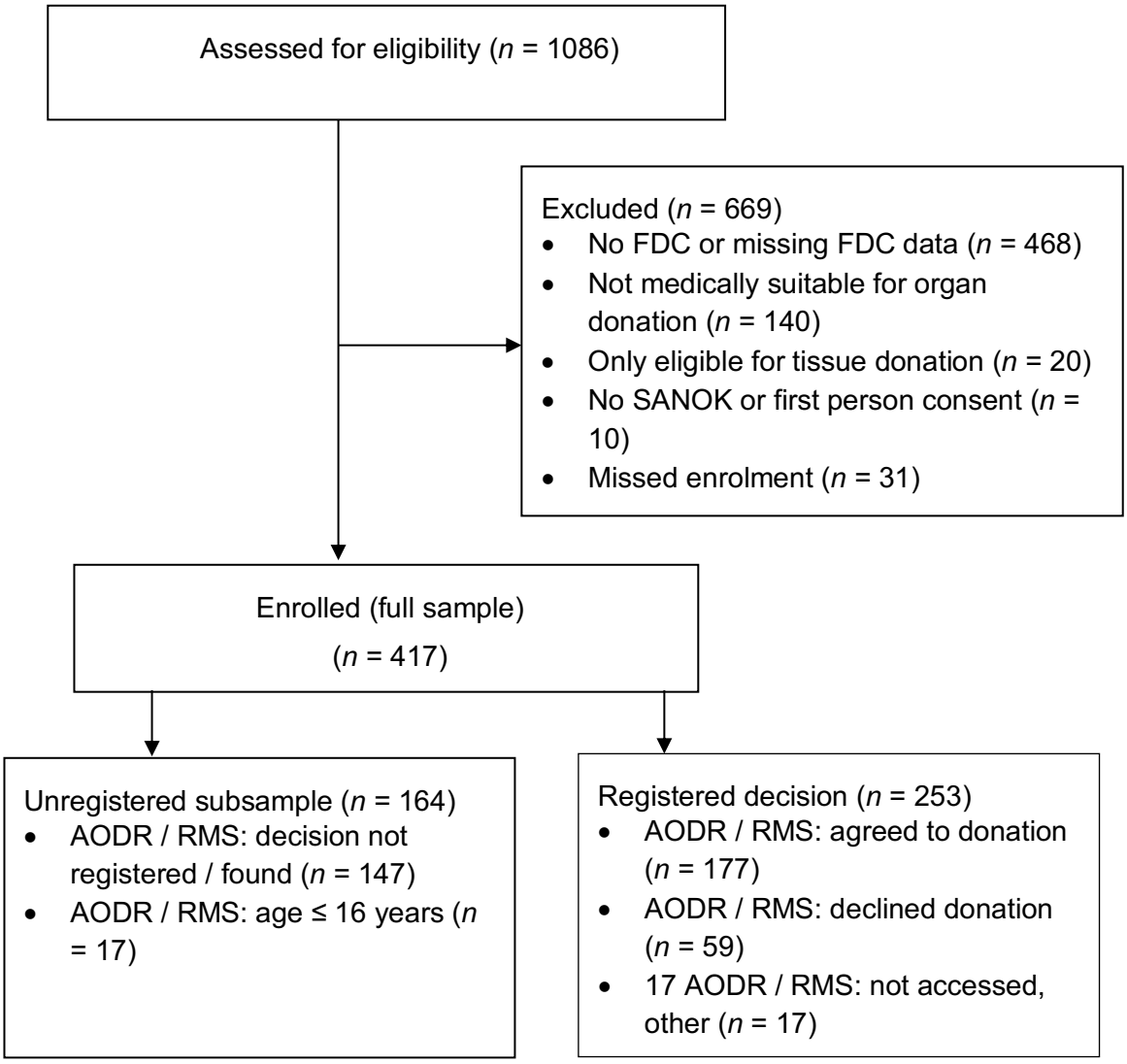
Screening and Enrolment in the Intervention Period

Over the intervention period there were 1086 donor-eligible patients screened with 417 donor-eligible patients (cases) enrolled from nine hospitals in NSW (full sample). The main reasons for exclusion were either a donation conversation had not taken place or details of the donation conversation were missing (*n* = 468, 70%). The

unregistered subsample comprised over one-third (*n* = 164, 39%) of the total cases (see Figure 5.1).

Figure 5.1

Screening and Enrolment of Donor-Eligible Patients in the Intervention Period



Note. AODR = Australian Organ Donor Register; FDC = family donation conversation; RMS = Roads and Maritime Services register; SANOK = senior available next of kin.

Demographic characteristics of donor-eligible patients for the unregistered subsample and the full sample groups, reported by case, are set out in Table 5.4. The average age of donor-eligible patients in the unregistered subsample was 45.2 years (*SD* = 22.1), with the full sample relatively older (*M* = 51.1, *SD* = 18.5); range 0.3 – 88 years in both groups.

Table 5.4

Demographic Characteristics of Donor-Eligible Patients

Characteristics	Unregistered Subsample		Full Sample	
	n	%	*n*	%
Male sex	100	61	244	58
Age (years)				
≤ 16	17	10	17	4
17-70	127	77	350	84
≥ 71	20	12	50	12
Country of birth: Australia	114	70	301	72
Ethnicity[a]				
Australian or New Zealander	96	58	276	66
Aboriginal or Torres Strait Islander peoples	10	6	18	4
Maori or Pacific Islander peoples	6	4	7	2
East Asian	21	13	40	10
Southern and Eastern European	11	7	30	7
Other and mixed ethnicity[b]	20	12	45	11
Religious affiliation[c]				
Christianity	88	54	226	56
No religion	57	35	142	35
Non-Christian religions; non-religious beliefs[d]	17	10	37	9

Note. *N* = 417 for the full sample (*n* = 164 for the unregistered subsample).
Total % for some categories will deviate from 100% by ± 0.1% due to rounding.
[a]Missing for one patient full sample (not admitted to an ICU).
[b]Mixed ethnicity of Australian or New Zealander and another for five patients (ANZ & East Asian *n* = 4, ANZ & North African & Middle Eastern *n* = 1): *n* = 4 in unregistered subsample.
[c]Missing for *n* = 12 donor-eligible patients: *n* = 2 in unregistered subsample.
[d]Includes Baha'i, Buddhism, Druze, Hinduism, Islam, Judaism, Maori faith and Sikh; atheist, humanist.

Characteristics of death and organ donation of donor-eligible patients in the unregistered subsample and the full sample analysed for the intervention period, by case, are set out in Table 5.5. Death was certified by neurological criteria in over half (52%) of the cases in the unregistered subsample. Many of the events/circumstances of death attributed to trauma/violent incidents (see Appendix 13, Table A13.2).

In the full sample, for the cases that proceeded to procurement surgery (*n* = 190, 46%), the average time from written consent to the start of procurement surgery was 20.8 hours (*SD* = 10.8; range, 3 – 110).

Table 5.5

Death and Organ Donation Characteristics of Donor-Eligible Patients

Characteristics	Unregistered Subsample		Full Sample	
	n	%	*N*	%
Determination of death				
Neurological criteria ('brain death')	86	52	205	49
Circulatory criteria	78	48	212	51
Cause of death				
Intracranial haemorrhage	57	35	162	39
Cerebral hypoxia-anoxia	51	31	116	28
Traumatic brain injury	36	22	91	22
Cerebral infarct/other neurological	14	9	35	8
Non-neurological	6	4	13	3
Organ donation outcome				
Actual donor after brain death[a]	53	32	144	34
Actual donor after circulatory death[b]	28	17	86	21
Non donor[c]	83	50	187	45

Note. *N* = 417 for the full sample (*n* = 164 for the unregistered subsample).
[a]Includes *n* = 13 that did not proceed to procurement surgery (*n* = 5 in unregistered subsample).
[b]Includes *n* = 27 that did not proceed to procurement surgery (*n* = 10 unregistered subsample).
[c]Includes *n* = 33 not medically suitable for organ donation due to system and donor/organ reasons (*n* = 10 in unregistered subsample).

In the intervention period, donation conversation clinical characteristics including time to death of donor-eligible patients (by case) for the unregistered subsample and the full sample are set out in Table 5.6. Most final donation decisions were made at the close of the first donation conversation, (mode *n* = 1), with a mode for duration of 30 min, which excludes the time DSN spent with the family after the final donation decision.

Table 5.6

Timing of Donation Conversations and Clinical Characteristics for the Unregistered Subsample and Full Sample[a]

Characteristic	Unregistered Subsample				Full Sample			
	n	*M*	*SD*	*Range*	*n*	*M*	*SD*	*Range*
Duration, first FDC in min	163	:29	:16	1 – 120	416	:32	:16	1 – 120
FDCs to final decision, *n*	164	1.9	0.9	1 – 5	417	1.8	0.8	1 – 6
	n	*Md*	*IQR*	*Range*	*n*	*Md*	*IQR*	*Range*
Time in ICU to meeting about news of death in hours	161	41.0	15.0 – 99.5	0 – 1151.0	403	39.0	16.0 – 96.0	0 – 1148.0
Time, ICU admission to first FDC (*start)* in hours	162	43.5	19.7 – 106.2	0.3 – 1167.0	408[b]	41.0	19.0 – 100.0	0.3 – 1167.0
Time, first FDC *(start)* to final decision in hours	163	1.7	0.5 – 5.7	0.0 – 122.0	416	2.4	0.7 – 5.6	0.0 – 122.3
Time in ICU to certification of death in days	164	2.2	0.9 – 5.0	0.2 – 50.9	416[c]	2.1	0.9 – 5.0	0.1 – 50.9

Note. *N* = 417 for the full sample (*n* = 164 for the unregistered subsample). ICU = intensive care unit; FDC = family donation conversation.

[a]Mode of analysis dependent on distribution of data. Top rows present normally followed by nonnormally distributed data.

[b]Missing for nine patients *n* = 8 donation discussed before admitted to ICU*, n* = 1 missing start time.

[c]Missing for one patient not admitted to ICU.

Consent

In the intervention period, for the unregistered subsample (comprising the primary end point) consent for donation was provided in 87 of 164 (53%) cases 95% CI [0.45, 0.61], and in 14 of 25 (56%) eligible donation events 95% CI [0.37, 0.74] pre-intervention (p = .83). The odds of consent in the intervention period relative to the pre-intervention period were OR 1.13; (95% CI = 0.48, 2.63; p = .78). In donor-eligible patients aged 16 years or less, consent was obtained for 8 of 17 (47%) donation events 95% CI [0.23, 0.72]. The limited number of minors (n = 3) pre-intervention precluded separate reporting of pre- and post- intervention comparisons of consent.

Research Question 2: Healthcare Professionals' Adherence to the Intervention

Adherence to the intervention was evaluated by including the full sample, reported by case. Over the 38 months of the intervention period, HCPs who led the first donation conversation were mostly (n = 283, 68%) male; aged on average 46 years (SD = 7.4) (range, 30 – 68); frequently designated an intensivist (n = 336, 81%), and having worked in ICU an average of 15.2 years (range, 1 – 40). HCPs led an average of seven donation conversations (SD = 5.7; range, 1 – 23) during the intervention period. (See Appendix 13, Table A13.3).

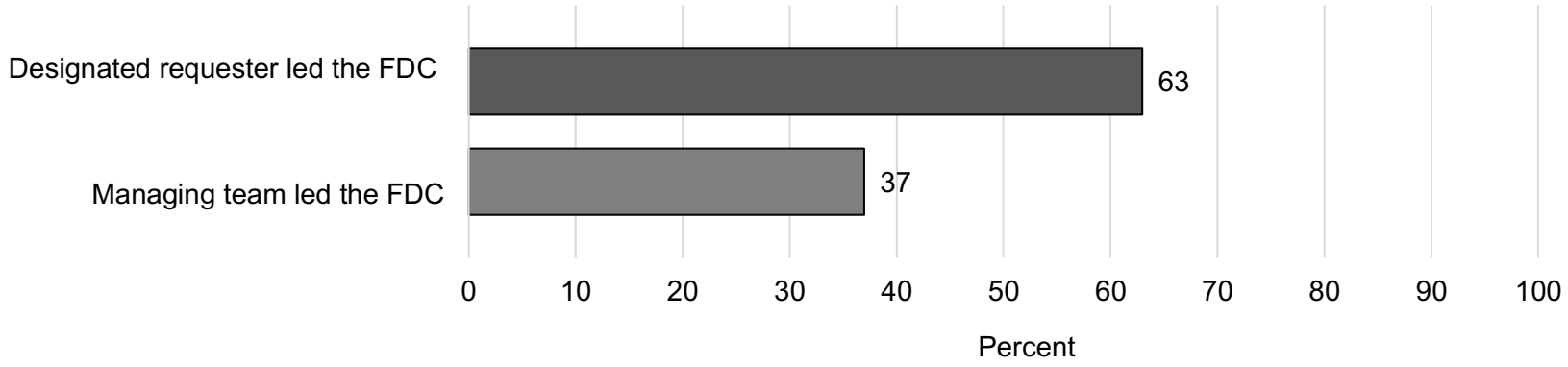
The first donation conversation was attended by mean and mode of three HCPs (SD = 1.3) (range, 1 – 8). Family members and friends attended in groups of three to five in nearly half (n = 204, 49%) of cases (M = 4.9; SD = 3.4), with a range of 1 – 26 individuals (see Appendix 13 Table A13.4). Family member attendees were often the spouse/partner, adult children, adult siblings and their partners or parents (see Appendix 13 Table A13.5). A donation specialist nurse met the family in three-quarters (n = 317, 76%) of cases.

Overall, staff adhered to a median of 4.50 (IQR = 3.00 – 5.50) intervention components, as depicted in Figures 5.2 – 5.7. Reasons supplied for non-adherence in nearly half of donation conversations not led by a designated requester included the managing intensivists' opinion that the designated requester was not deemed necessary or appropriate (n = 31, 24%), or that a designated requester was unavailable (n = 31, 24%). (See Appendix 13, Table A13.6).

For intervention component 1, of designated requesters leading the first FDC see Figure 5.2. One-third (n = 137, 33%) of cases were run independent of the managing team.

Figure 5.2

Intervention Component 1, HCP leading the FDC for the Full Sample

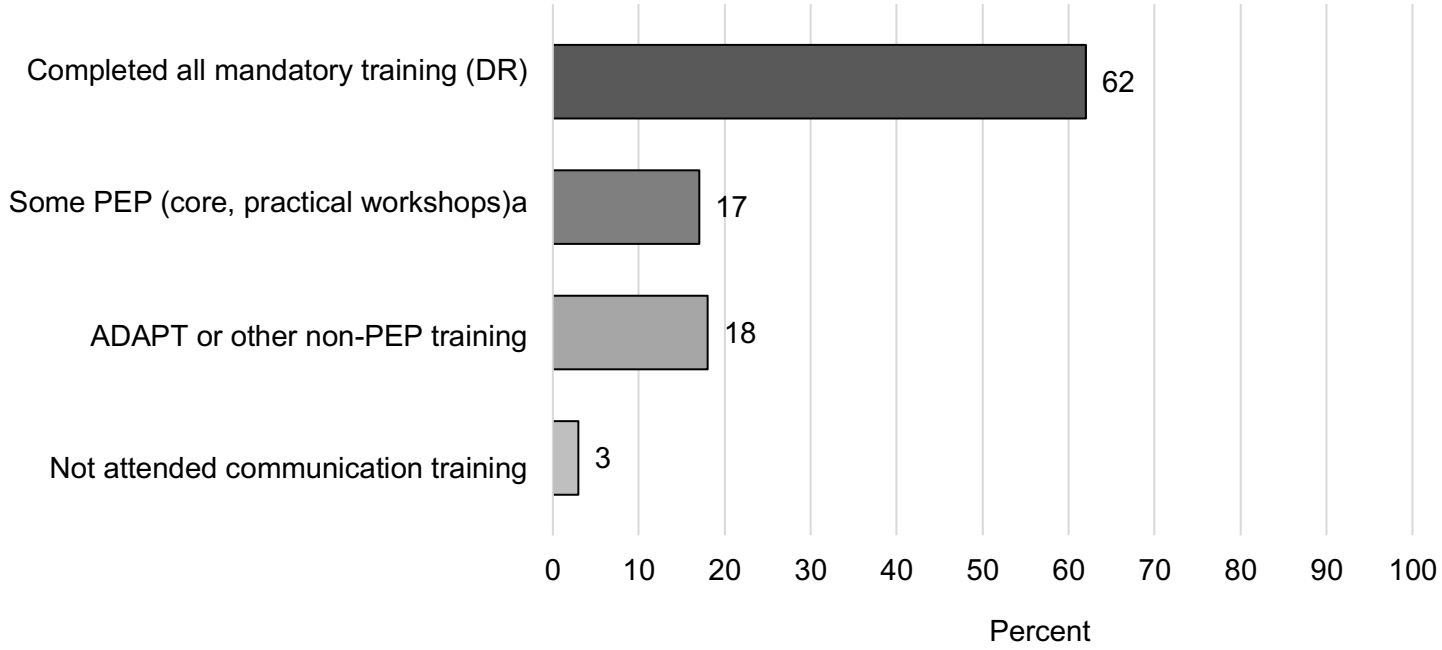


Note. N = 417. FDC = family donation conversation; HCP = healthcare professional.

For intervention component 2, before leading the FDC nearly all designated requesters had completed mandatory training, comprised of the national PEP core and practical workshops and the NSW simulation-based workshop (described in Chapter 3 and Appendix 3), while many managing teams had received some form of donor awareness or other communication training (see Figure 5.3).

Figure 5.3

Intervention Component 2, Training Completed When Leading the FDC for the Full Sample

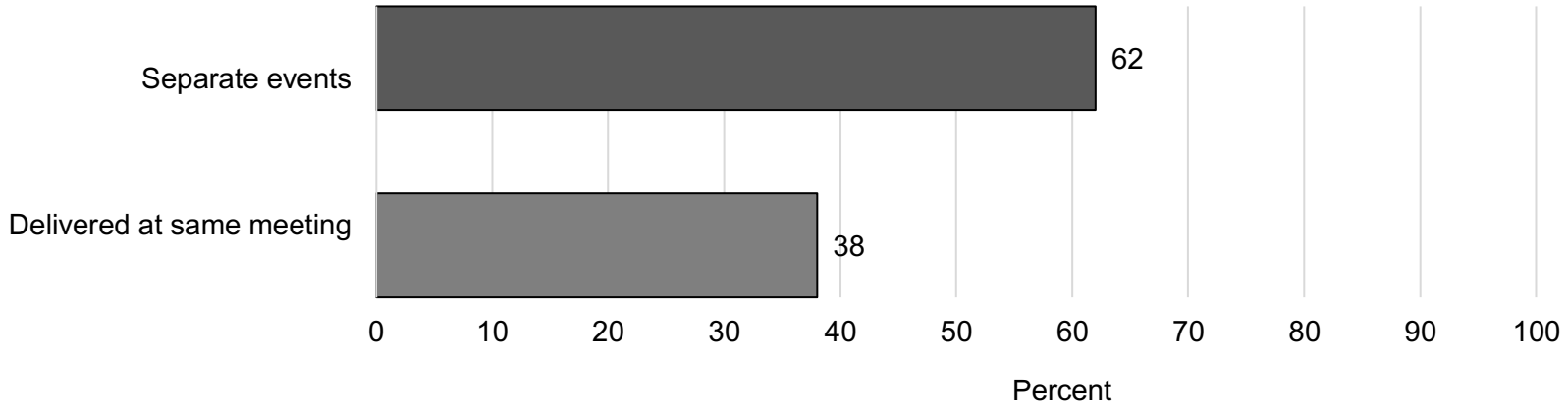


Note. *N* = 417. ADAPT = Australasian Donor Awareness Program; DR = designated requester; FDC = family donation conversation; HCP = healthcare professional; PEP = Professional Education Package.
[a]Some PEP only core workshop, *n* = 54 (54/70) requesters.

Adherence to component 3 (separation of the FDC from the end-of-life meeting) occurred in approximately two-thirds (62%) of cases (see Figure 5.4).

Figure 5.4

Intervention Component 3, Timing of News of Death in Relation to the FDC for the Full Sample

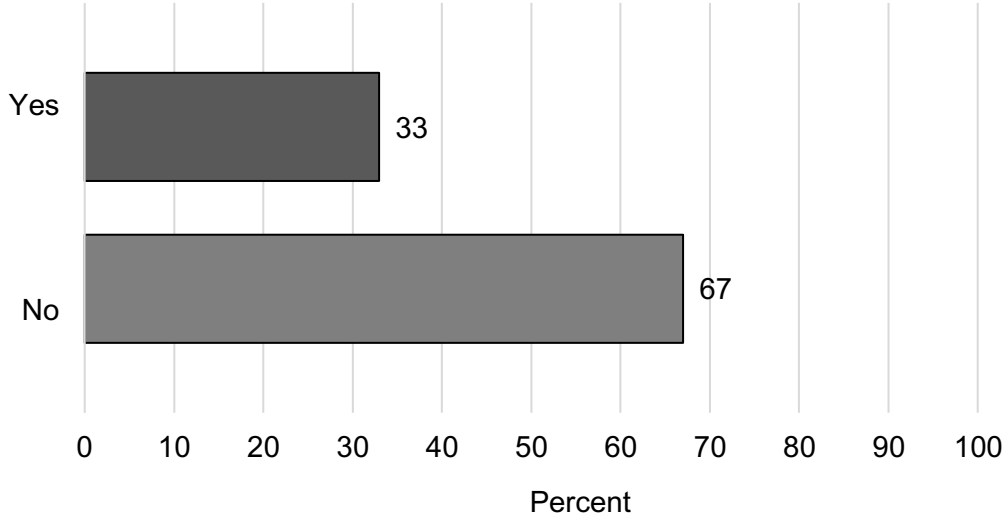


Note. $N = 416$. FDC = family donation conversation; OD = organ donation.

Uptake of component 4 (deferral of family offers of donation) was high. Families offered donation before HCPs introduced the topic in one-third (33%) of cases (see Figure 5.5).

Figure 5.5

Intervention Component 4, Family Offered Donation Before HCP at any Time for the Full Sample

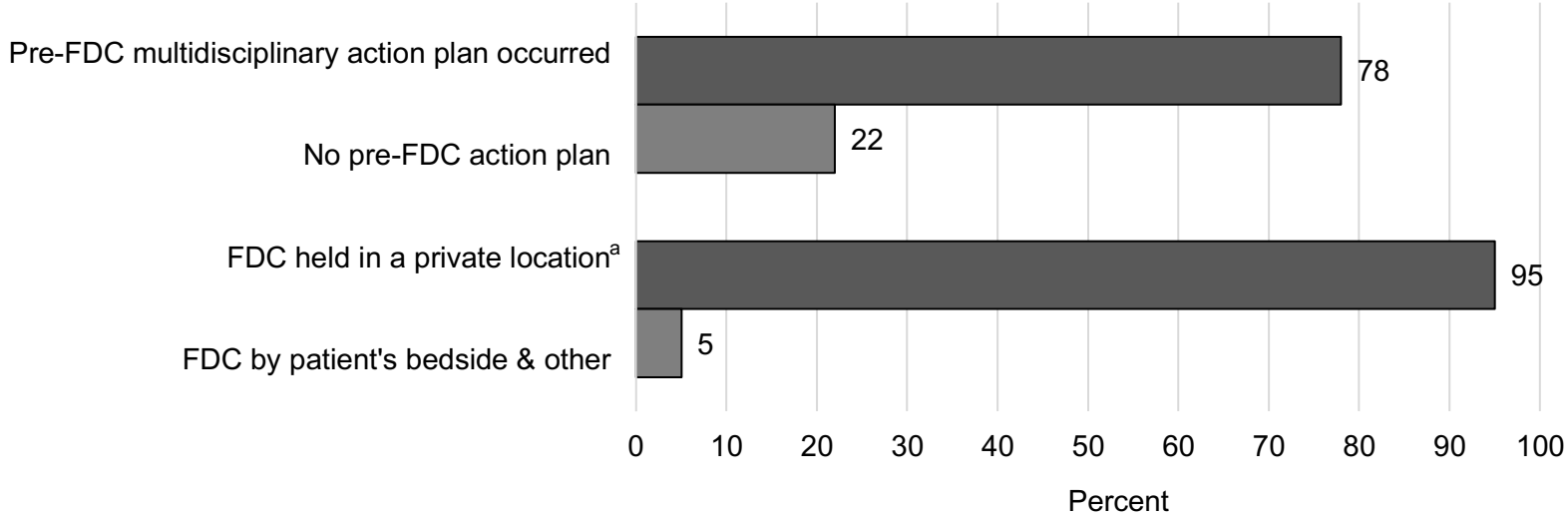


Note. *N* = 417. FDC = family donation conversation; HCP = healthcare professional.

Adherence to intervention component 5 varied, with the highest uptake for meeting in a private location (see Figure 5.6).

Figure 5.6

Intervention Component 5, Structured Family Meeting for the Full Sample

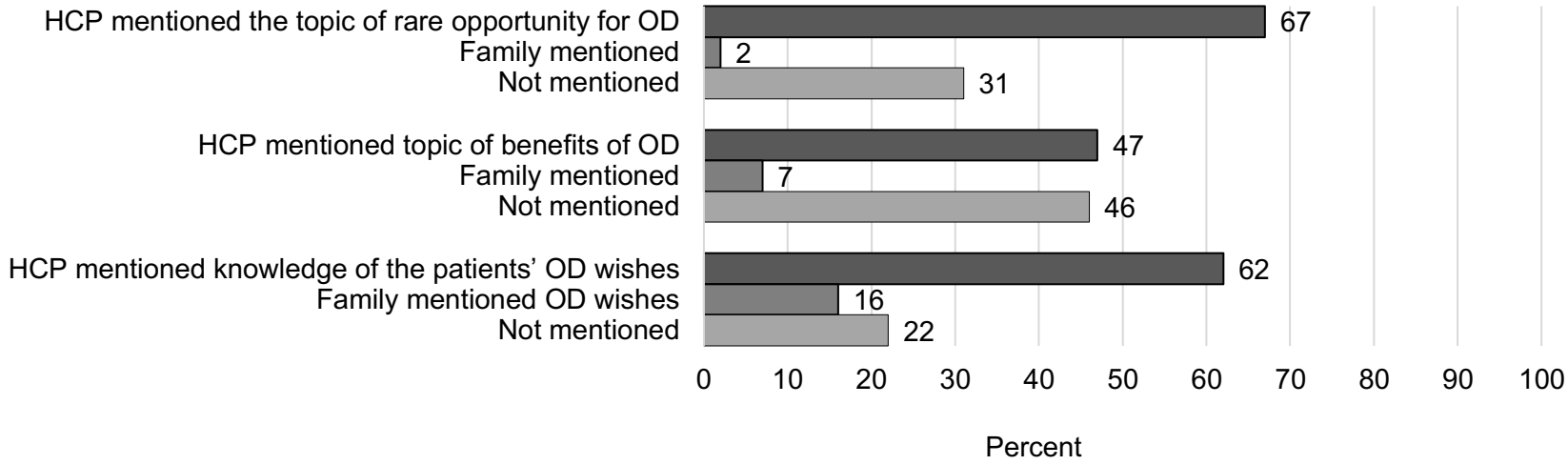


Note. $N = 417$. FDC = family donation conversation.
[a]Missing one case for private location

For intervention component 6, requesters using any language specifically relating to uptake of a balanced approach ranged from less than half (47%) for the benefits of donation, to approximately two-thirds (67%) for the rare opportunity of donation during the first donation conversation (see Figure 5.7).

Figure 5.7

Intervention Component 6, Use of a Balanced Approach by HCP Leading the FDC With the Full Sample



Note. $N = 417$. FDC = family donation conversation; HCP = healthcare professional; OD = organ donation.

Research Question 3: Prediction of the Senior Next of Kins' Donation Decision for the Unregistered Subsample

To answer this question, the unregistered subsample was used because of the influence of the prior registered decision of the donor-eligible patient on the SANOKs' decision. Donor-eligible patient demographic and clinical characteristics associated with donation decisions (per case) in bivariate analyses are set out in Table 5.7. Significantly lower consent rates were associated with patients' ethnicity, X^2 (1, N = 164) = 5.04, p = .025, religious affiliation, X^2 (2, N = 162) = 11.86, p = .003, and circulatory determination of death, X^2 (1, N = 164) = 6.89, p = .009. There were no associations with HCP characteristics (data not shown).

Table 5.7

Association of Donor-Eligible Patient Characteristics With the Donation Decision, Unregistered Subsample

Characteristic	Final Decision				Bivariate Test		
	Agreed		Declined		χ^2	*df*	*p*[a]
	n	%	*n*	%			
Male sex	53	53	47	47	0.00	1	.988
Age in years, mean (*SD)*	43.9	(21.1)	46.7	(23.3)	(…)	162	.439
Born in Australia	60	53	54	47	0.03	1	.872
Ethnicity:					5.04	1	.025
Australian or New Zealander	58	60	38	40			
Other ethnicity[b]	29	43	39	58			
Religious affiliation[c]					11.86	2	.003
Christianity	45	51	43	49			
No religion or non-religious beliefs	37	65	20	35			
Other religions	3	18	14	82			
Certification of death					6.89	1	.009
Neurological criteria (brain death)	54	63	32	37			
Circulatory criteria	33	42	45	58			
Causes of death[d]					1.91	1	.167
Traumatic brain injury	23	64	13	36			
Other neurological	62	51	60	49			

Note. *n* = 164 (*n* = 87 agreed, *n* = 77 declined). FDC = family donation conversation; ICU = intensive care unit.

[a]*p* values were calculated using the chi-square test or Student's t-test as appropriate.

[b]Other includes indigenous cases; and mixed ethnicity of Australian or New Zealander and another for four patients: three in agreed group, one in declined group.

[c]Missing for two patients in agreed group.

[d]Excluded six patients with a non-neurological cause of death.

Donor-eligible patient donation conversation characteristics associated with donation decisions (per case) in bivariate analyses are set out in Table 5.8. Significantly higher consent rates were associated with increasing number of conversations to a final decision and more time taken to make a decision (p <.001).

Table 5.8

Comparisons of Donation Conversation Characteristics With the Donation Decision, Unregistered Subsample[a]

Characteristic	Final Decision								Tests	
	Agreed				Declined				*df*	*p*[b]
	n	*M*	*SD*	*Range*	*n*	*M*	*SD*	*Range*		
Total time, first FDC in min	86	:30	:13	5 – 75	77	:28	:19	1 – 120	161	.414
FDCs to final decision, *n*	87	2.2	0.8	1 – 5	77	1.5	0.8	1 – 5	162	<.001
	n	*Md*	*IQR*	*Range*	*n*	*Md*	*IQR*	*Range*		
Time, FDC *(start)* to final decision in hours	86	4.0	1.9 – 14.5	0.5 – 70.0	77	0.6	0.4 - 1.3	0 – 122.0	(…)	<.001
Time, ICU admission to first FDC (*start)* in hours	86	30.0	17.0 – 107.5	0.3 – 606.0	76	56.0	24.5 - 105.7	2.0 – 1167.0	(…)	.054
Time in ICU to certification of death in days	87	1.9	0.9 – 5.1	0.2 – 27.0	77	2.5	1.1 - 4.9	0.2 – 50.9	(…)	.312

Note. n = 164 (n = 87 agreed, n = 77 declined). FDC = family donation conversation; ICU = intensive care unit.
[a]Mode of analysis dependent on distribution of data. Top rows present normally followed by nonnormally distributed data.
[b]p values calculated using the independent samples Student t-test or Mann Whitney U test, as appropriate.

Intervention components associated with the senior next of kins' donation decision in bivariate analyses are depicted in Table 5.9. When the designated requester was independent of the managing team consent was obtained in 28 of 46 (61%) of cases ($p = .19$). Other components were also associated with significant differences in consent rates: the incidence of consent was lower when the FDC was separated from the end-of-life death meeting, $X^2 (1, N = 164) = 4.34$, $p = .037$, and consent rates increased where families mentioned donation before HCPs, $X^2 (1, N = 164) = 12.67$, $p < .001$.

Table 5.9

Association of Intervention Components 1 - 6 With the Donation Decision, Unregistered Subsample

Component	Final decision				Bivariate test		
	Agreed		Declined		χ^2	*df*	*p*
	n	%	*n*	%			
1. HCP leading the FDC					0.92	1	.337
Designated requester (DR)	55	56	43	44			
Managing team	32	48	34	52			
2. Communication training					1.07	2	.584
Completed all training (DR)[b]	54	56	43	44			
Some workshops (PEP core, practical)[c]	12	44	15	56			
ADAPT, other or nil communication training[d]	21	52	19	48			
3. Separation of end-of-life and FDC					4.34	1	.037
Separate events	46	46	53	54			
Delivered at same meeting	41	63	24	37			
4. Family raised OD before a HCP					12.67	1	<.001
Yes	37	74	13	26			
No	50	44	64	56			
5. Structured family meeting							
Pre-FDC action plan occurred	66	52	61	48	0.26	1	.608
FDC held in a private location	83	52	75	48	(…)		.685
6. 'Balanced' communication							
HCP mentioned the *benefits* of OD	42	53	37	47	(…)		.022
Family mentioned the benefits of OD	10	91	1	9			
HCP mentioned the *rare opportunity* of OD	53	50	54	50	(…)		.364
Family mentioned the rare opportunity	4	80	1	20			
HCP mentioned *knowledge of the patient's OD wishes*	47	52	43	48	0.64	1	.423
Family mentioned knowledge of the patients' wishes	13	62	8	38			

Note. *n* = 164 (*n* = 87 agreed, *n* = 77 declined). ADAPT = Australasian Donor Awareness Program; DR = designated requester; FDC = family donation conversation; HCP = healthcare professional.
Total % for some categories will deviate from 100% by ± 0.1% due to rounding.
[a]*p* values calculated using the Chi-square or Fisher's exact test, as appropriate.
[b]National PEP core and practical workshops and NSW simulation workshop.
[c]One DR completed only the national core workshop.
[d]Nil communication training for six cases: *n* = 2 agreed and *n* = 4 declined.

Multivariate logistic regression analysis revealed six characteristics were independently associated with SANOK consent to organ donation. Where the family raised organ donation before an HCP offer, where the FDC was led by a designated requester independent of the managing team and where more than one FDC occurred, each was associated with increased family consent. Where the patient was of a non-Christian religion, where there was a separation in time between the end-of-life conversation and the FDC, and where the patient spent a longer time in the ICU before the FDC, each was associated with reduced consent rates (Table 5.10). The Hosmer-Lemeshow goodness of fit test showed that the model was well calibrated (p = .47).

Table 5.10

Association of Patient, Context and Intervention Characteristics with the Donation Decision (Multivariate Logistic Regression Analysis)

Characteristics	Odds ratio	95% CI		*p*
		LL	*UL*	
Patient religion: no religion, non-religious beliefs	1			
Patient religion: Christianity	0.59	0.26	1.33	.201
Patient religion: non-Christian	0.18	0.04	0.91	.038
Duration of stay in ICU, admission to FDC (hours)	0.70	0.50	0.98	.037
Number of FDCs to final donation decision	3.35	1.93	5.81	<.001
FDC: intervention components				
1. Managing team leading the FDC	1			
Designated requester leading the FDC (independent of team)	3.84	1.35	10.98	.012
Designated requester leading the FDC (managing team)	1.19	0.47	3.00	.714
3. Separation of news of death and FDC	0.38	0.16	0.89	.026
4. Family offered donation before HCP	4.34	1.79	10.52	.001

Note. n = 164 (n = 87 agreed, n = 77 declined). CI = confidence interval; FDC = family donation conversation; HCP = healthcare professional; ICU = intensive care unit; LL = lower limit; UL = upper limit.

Chapter Conclusion

In this study, examination of implementation of a 'best practice' multi-component intervention, there was no statistically significant difference in SANOK consent rates during the intervention compared to pre-intervention periods.

There was good uptake of components of the intervention that occurred before the donation conversation. Specifically, component 2, with almost all of designated requesters completing mandatory training before leading the first FDC, and for component 5, with most FDCs held in private rooms. However, many 'best practice' components of the FDC itself were often omitted, particularly for a designated requester leading the first donation conversation.

Despite the suboptimal uptake of parts of the intervention we identified components associated with increased probability of consent to donation by SANOK for the unregistered subsample. Significant factors included use of a designated requester independent to the managing team, and holding more conversations per case. Allowing a separation in time between the conversations focused on breaking the news of end-of-life meeting and the offer of donation, and the donor-eligible patient spending a longer time in the ICU before the donation conversation were all associated with decreased probability of consent.

Other influential factors included the donor-eligible patient being of a non-Christian religion, which was associated with reduced likelihood of consent; consent was more likely where the family raised the topic of organ donation before a HCP offered this.

The effect of the intervention on family members' opinions of the decision-making process for deceased organ donation and whether their donation decision endured in the months that followed, are demonstrated in the next chapter.

Chapter 6: Results of Family Secondary End Point

Chapter Introduction

In this chapter the results for family-related secondary end points of the study, responding to research questions 4 and 5, are set out. As these questions relate to clinical practice and to the decision-making rationales of the families of donor-eligible patients, the dataset for these analyses was based on the full sample, not just the unregistered subsample used to address research questions 1 and 3. The full sample was used to address research question 4, with data describing the donation conversation process collected prospectively at the hospital concurrent with the episode of end-of-life care in the ICU. The sample to answer research question 5 comprised SANOK from the full sample who had both agreed at the hospital to bereavement aftercare and subsequently responded positively to the invitation for an interview from 90-days after enrolment.

Study Research Questions

This chapter therefore reports findings in relation to research questions 4 and 5.
For all donor-eligible patients where an evidence-based intervention was in use, what do SANOK report in relation to the rationale for their final decision in hospital, either to consent or decline organ donation?
What proportion of SANOK reported that they regretted their final donation decision, either to consent or to decline donation, at around 90 days after enrolment?

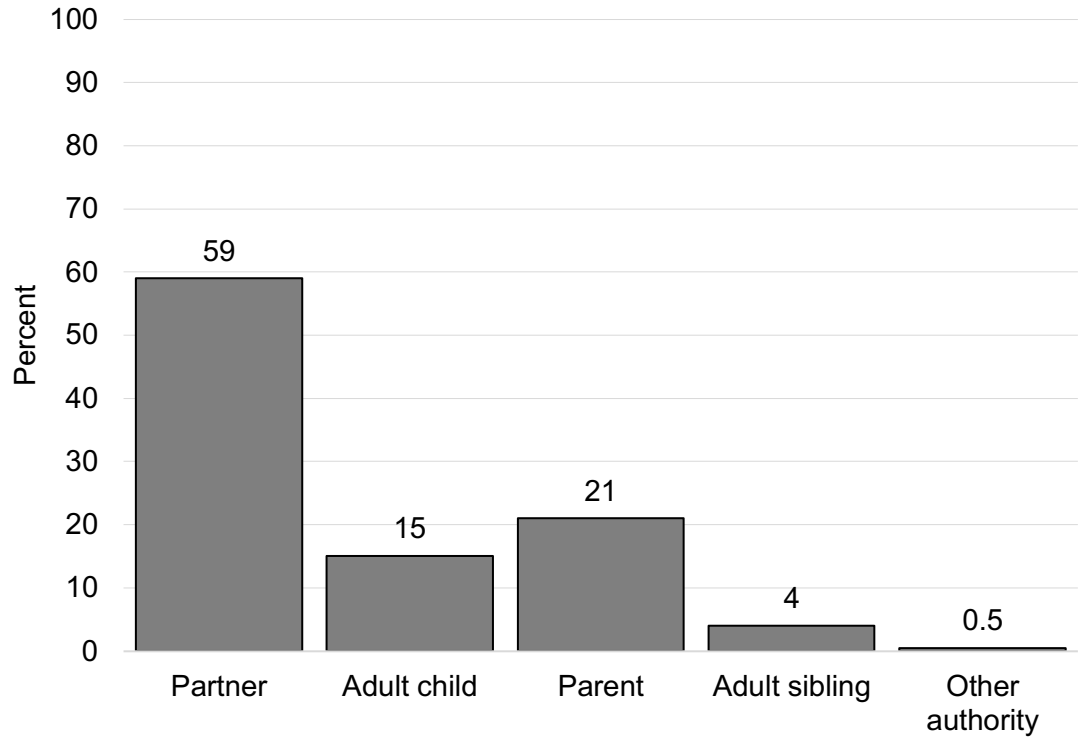
Research Question 4: Senior Next of Kins' Decisions in Hospital

For the full sample, in the majority of cases the SANOK of the donor-eligible patient was their partner (*n* = 248, 59%), followed by a parent (*n* = 86, 21%) (see Figure 6.1). In a small proportion (*n* = 14, 3%) of cases the SANOK delegated decision-making, mostly to an adult child (*n* = 7) or an adult sibling (*n* = 6), or to a parent (*n* = 1).

Revocation of consent for organ donation by families occurred in two cases (*n* = 2, 0.5%), at 18.5 and 54 hours after their provision of written consent for deceased organ donation (see case example 3, pp. 130).

Figure 6.1

Designation of the Senior Available Next of Kin

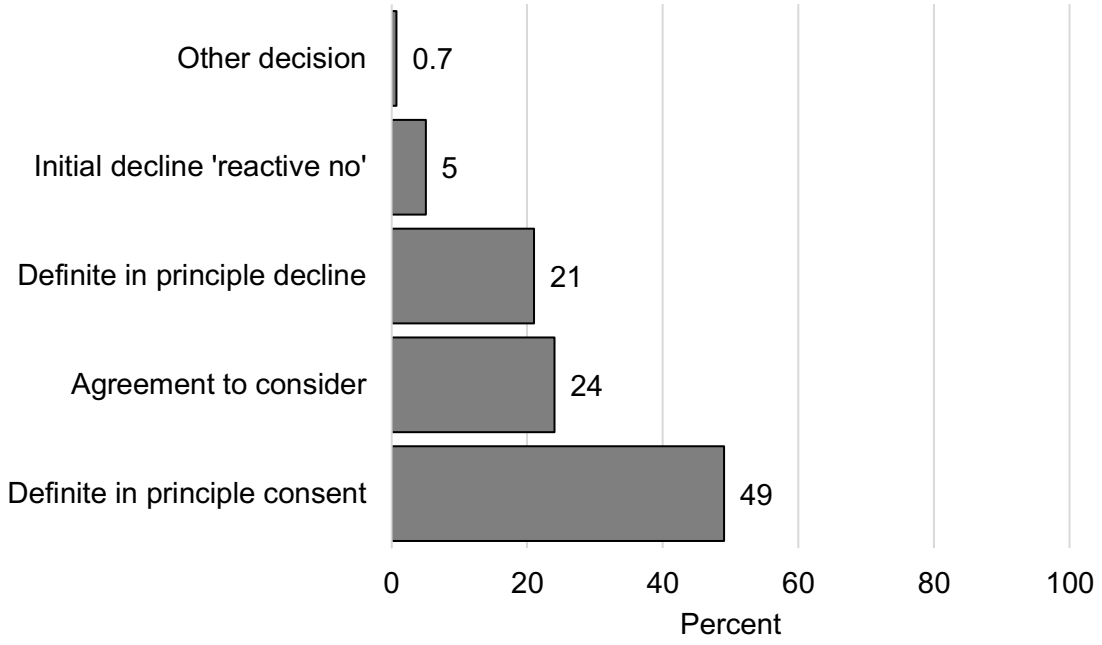


Initial Donation Decision at the Hospital

At the close of the first donation conversation, nearly three-quarters of SANOK (n = 292, 70%) had made a definite 'in principle' decision (i.e., a decision perceived by HCPs as proactive, based on information, reflecting the decision their family member would have made on an ordinary day, had they been able to (Mulvania et al. 2014). Nearly one-quarter (n = 101, 24%) agreed to consider the information and subsequently continue the conversation. A small proportion (n = 21, 5%) responded initially with a 'reactive no' (i.e., a decision perceived by HCPs as originating from powerful emotions such as grief reactions (Mulvania et al. 2014); see Figure 6.2.

Figure 6.2

Senior Available Next of Kin Decision at Close of the First Donation Conversation



Final Donation Decision at the Hospital

At the hospital, for their final organ donation decision *n* = 255 (61%) agreed to donation and *n* = 162 (39%) declined donation. Collected using a pre-populated list of potential reasons for the SANOKs' donation decision at the hospital developed from the literature, with an additional free text option. Reasons stated by the SANOK for their final donation decision at the hospital are shown in Table 6.1 and Table 6.2.

Table 6.1 shows reasons stated by the SANOK for agreeing to organ donation which they provided at the hospital. In most cases (*n* = 252, 99%) the SANOK had provided a reason for their final decision, citing both a mean and mode of three reasons (range 1 - 7) per case; on average (the mode) three reasons were supplied by *n* = 67 (26.6%) of SANOK.

An overarching theme emerged which suggested that SANOK agreed to donation because of the beneficial outcome countered the disaster /pain / darkness of the situation. This theme was underpinned by two major themes, of: the desire to help themselves or others (altruism), and knowledge of the donor-eligible patients' values and donation wishes (see Table 6.1). The ability to derive benefit from the awful situation was based on either comfort for the donor family by an altruistic act which they were able to play a part in, or by someone else gaining life through organ transplantation. They also appeared to perceive personal benefit derived from the satisfaction of being able to carry out the donor-eligible patients' wishes.

Three-quarters of SANOK (*n* = 186/252, 74%) declared that they knew their family member would have wanted to help others through organ donation. This also allowed them an opportunity to express, and feel the good of, the positive values held by the family member they were losing, as someone motivated by altruism and the desire to be of use to others, even in their death. For some SANOK, the fact their family member had never expressed an objection to donation was sufficient indication of their wishes.

Table 6.11

SANOKs' Reasons for Agreeing to Organ Donation Provided at the Hospital

Theme	Count[a]	Category	Example quote
Helping self or others	186	Donor would have wanted to help others	"He would have been the type to help others before substance abuse changed him." (02008, sister)
	121	Enabling someone else to live a better life	"Great believer in karma." (06049, parent)
	118	Opportunity for something positive to come out of a tragedy	"Wished for her life to end on a high note." (07017, husband)
	31	Part of a relative living on in someone else	—
	27	Previous personal experience with donation	"A friend refused to donate her 24 year old son's organs and regrets her decision. They don't want to regret not donating." (05005, son)
	14	What other donor families have shared	—
	8	Personal experience with transplantation	"They have a family member that received a transplant." (06042, wife)
	2	Choose specific organs or tissue to donate	"Family friend died of liver disease a year ago, only wanted to consider liver donation." (01008, brother)
Knowing the values and wishes	165	Knew donor's wishes from previous discussion	—
	99	Knew donor's wishes from donor registry / driver licence	"I knew she was a donor on her driver licence." (03013, sister) "Mother was a giving person, wanting to help others." (03013, children)
	17	The donor had never said "no"	—

Note. $n = 252$ cases provided a reason.
[a]Count equals the number of times referred to.

Table 6.2 shows reasons stated by the SANOK for declining organ donation which they provided at the hospital. In most cases (n = 156, 96%) the SANOK had provided at least one reason for their final decision. A mean of two reasons (range 1 - 9) were provided per case, with a mode of one reason (n = 58, 37.2%). Dissatisfaction with the patient's treatment in the ICU was not mentioned. There were three main themes for decisions to decline: knowledge or uncertainty of the donor-eligible patients' wishes; social, religious or cultural beliefs; and the donation process (see Table 6.2).

The main theme related to the wishes of the donor-eligible patient, their family member, expressed by n = 65/156 (42%) of SANOK. This theme reflected SANOKs' knowledge of or uncertainty of their family members' donation wishes. Many SANOK declared they knew exactly what their family member would have wished, citing previous discussions or awareness of their registered decline on the RMS. Senior available next of kin who supported donation themselves had sometimes expressed surprise when learning of the donor-eligible patients' registered decision to decline. However, in this situation they upheld that registered decision in the absence of any recent conversation indicating a change of mind. Where donation had never been discussed, the resultant uncertainty led the SANOK to believe that their family member had not wanted to donate. When family members expressed differing opinions on donation without achieving consensus, the SANOK defaulted to declining donation (see case example 1 pp. 127). Some families overruled the donor-eligible patients' registered agreement to donation; where this occurred, it was in the context of lack of consensus between family members on their decisions, or followed expressions of surprise when organ donation had been offered (see case example 4 pp. 132).

For the theme of 'cultural, religious or social', reasons indicated beliefs expressed by the teachings of local religious leaders, and pre-existing social beliefs requiring protection of the integrity of the cadaver by maintaining it "whole". Some cultural beliefs overlapped with 'process' considerations; this was particularly the case in terms of not understanding, or not recognising or regarding patients certified under NDD criteria as actually dead. This was also illustrated in case example 3 (see pp. 130).

For the theme of the 'donation process', reasons indicated that families felt that the time spent waiting within the process was too long for SANOK to accommodate. Senior available next of kin also were concerned that the donor-eligible patient had experienced enough suffering, and that they did not want them to have to continue ICU

treatment or to continue waiting for 'brain death' to enable organ donation (see case example 4 pp. 132).

Table 6.12

SANOKs' Reasons for Declining Organ Donation Provided at the Hospital

Theme	Count[a]	Category	Example quote
Wishes of the donor-eligible patient	45	Knew patient's wishes from previous discussion	"He and his wife had discussed donation and they did not believe in it." (02006, husband)
	40	Uncertainty regarding the patient's donation wishes	"Patient had never expressed intention to donate." (06034, husband)
	20	Knew patient's wishes from donor registry / driver's licence	—
	14	Disagreements among the family group	"Patient's second eldest daughter was quite distressed about organ and tissue donation, eldest daughter, brother and mother very supportive. Patients' husband needed a family consensus to agree. He was not aware that his wife was registered on AODR, but could not agree if their daughter was so distressed even though he agreed." (02007, husband)
	10	Upheld patient's wishes (registered 'no') from donor registry / driver licence (no recent conversation)	" …surprised that he was a registry refusal but they had never talked about donation, family very supportive of organ and tissue donation." (02045, de facto wife)
	6	Family believed the patient did not want to donate	"(*name*) is a type of person who would have spoken up and told me about his wishes regarding organ donation." (01011, wife)
Cultural, religious, social	50	Not wishing surgery to the body/concerns regarding disfigurement of the body	Shared belief between siblings "We enter this world whole and should leave this world whole." (05008, adult sibling)

Table 6.12

SANOKs' Reasons for Declining Organ Donation Provided at the Hospital

	30	Religious/cultural reasons	Not endorsed by local (*suburb*) Grand Mufti, who "greatly discouraged organ donation as not "whole" for the afterlife." (06061, son)
	12	Longstanding negative views on organ donation	"(I'm) supportive of donation in principle. (She) had longstanding negative views on donation." (01103, husband)
The donation process	33	Thought that the patient had suffered enough	"Surprised about (his) wishes. Felt that (he) has been through enough and wanted him to be in peace." (07021, wife)
	23	Dissatisfaction with duration of the donation process	"Felt that unfair to prolong intubation and had already waited over 24 hours to see if the patient would progress to brain death." (06020, sister-in-law)
	20	Emotional exhaustion of family	"Family unable to watch her like this any longer." (03025, daughter)
	13	Family had decided on their own that organs would not be suitable	—
	9	Concerns over delay to funeral/burial process	"…Want to repatriate body back to China…" (06023, son)
	5	Family were unable to accept death, lack of understanding of brain death	"Not dead as believed in Chinese law still alive while heart beating." (06003, husband)
	1	Concerns regarding integrity of process e.g. unfair organ allocation, organ selling	—
The donation	4	Other	"No, definitely not-don't want to discuss further." (09011, grandmother)
convers-ation	1	Dissatisfaction with the patient's treatment in other areas of the hospital	—

Table 6.12

SANOKs' Reasons for Declining Organ Donation Provided at the Hospital

Note. n = 156 cases provided a reason AODR = Australian Organ Donor Register; NOK = next of kin.
[a]Count equals the number of times referred to.

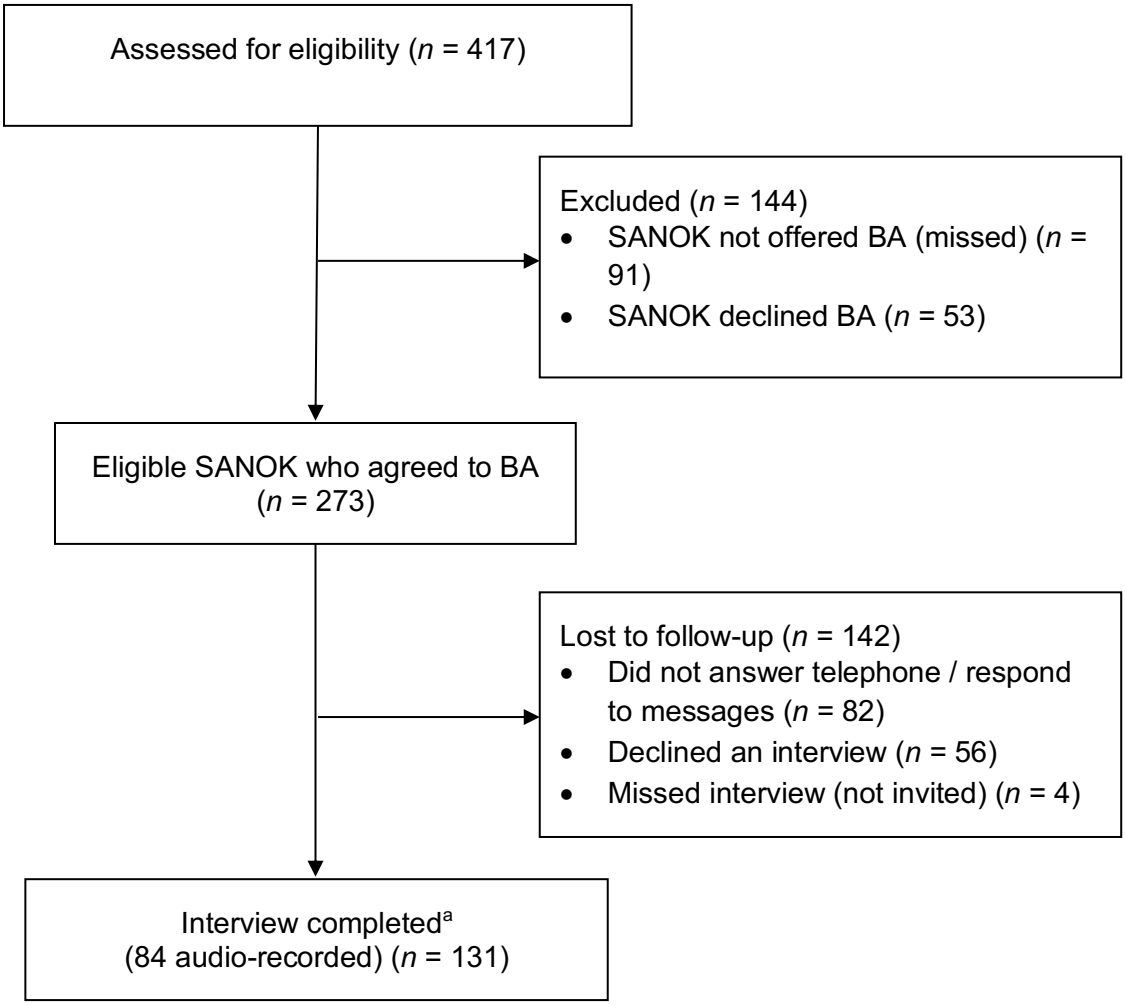
Research Question 5: Regret of Final Donation Decision at Around 90 Days

During the follow up period from day-90, of eligible cases (n = 273) nearly half (n = 131, 48%) of SANOK were enrolled and completed a follow up interview (see Figure 6.3). The designated SANOK who had either signed the consent form or who had declined donation at the hospital were contacted. A maximum of four attempts at contacting SANOK, including using different modes such as phone and email, were made by the NSW Organ and Tissue Donation Service Family Support Coordinator (interviewer), before categorising the case as lost to follow-up (n = 82). For six cases which included more than one interview with senior next of kin of equal rank, the first completed interview was used for these analyses.

The interviews (n = 131) occurred at a median 102 (IQR 84 to 213) days after enrolment in this study (i.e., when the first donation conversation was planned). This corresponded with a median 101 (IQR 92 to 114) days after certification of death. The interview duration was a mean 19 (SD = 10), ranging 6 – 60 min. One interview used an interpreter (for Portuguese) to speak to the family of a donor-eligible patient who lived overseas.

Figure 6.3

Screening and Enrolment of Senior Next of Kin for Follow up



Note. BA = bereavement aftercare; SANOK = senior available next of kin

[a]One designated SANOK interview per case; excludes another seven interviews from additional family members for six cases.

Characteristics of the Senior Next of Kin Interviewees

Demographic characteristics of the designated SANOK (interviewees) are set out in Table 6.3. Nearly half of these senior next of kin (46%) were the partner of the deceased (previously termed the donor-eligible patient in this thesis). Interviewees were aged on average 52.1 (*SD* = 13.3), range 19 – 79 years. Of those who had lived with the deceased (*n* = 81, 62%), the duration was an average 23.4 (*SD* = 14.2), ranging 1 – 56 years.

Previous discussions with the deceased about organ donation were reported by nearly two-thirds of interviewees (*n* = 82, 63%); in two cases (1%) this was not applicable as the deceased was a child. At the hospital most (*n* = 124, 95%) interviewees had agreed to donation, only a few (*n* = 7, 5%) declined the offer.

Table 6.13

Characteristics of Senior Next of Kin Interviewees [a]

Characteristic		Value	
	N (total)	*n*	%
Female sex	131	87	66
Country of birth	129		
Australia		101	78
Ethnicity	131		
Australian or New Zealander		104	79
North-West European		10	8
East Asian		5	4
Oceanian: Maori		1	1
Other and multiple ethnicity		11	8
Religious affiliation	131		
Christianity		74	56
No religion		50	38
Non-Christian religions; non-religious belief[b]		7	5
Relationship to the deceased	131		
Partner		60	46
Adult child		22	17
Parent		36	28
Adult sibling		10	8
Other relationship		3	2

Note: Total % for some categories will deviate from 100% by ± 0.1% due to rounding.
[a]Interview from one designated senior available next of kin per case.
[b]Includes Baha'i, Buddhism, Hinduism, Islam, spiritual.

Educational Characteristics of the Senior Next of Kin Interviewees

The highest educational level attained by the interviewees was provided for almost all cases (*n* = 130, 99%). A few (*n* = 3, 2%) completed their education at primary school level. Many (*n* = 52, 40%) reported they had completed some or all of their high school education, while over half (*n* = 73, 56%) were completing or had attained technical or tertiary qualifications. Overall, *n* = 57 (44%) had completed or were studying a university degree, and a few (*n* = 2, 1%) had completed other educational courses.

Characteristics of the Interviewees' Deceased Family Member

Characteristics of the interviewees' deceased family members are set out in Table 6.4. Nearly two-thirds (*n* = 82, 63%) of cases had death determined by neurological criteria, with the remaining cases (*n* = 49, 37%) certified by circulatory criteria.

Table 6.14

Donor Registration and Donation Outcome of the Deceased Family Member

Characteristics	Value	
	N (total)	%
Decision on donor register (RMS and AODR)		
Agreed to donation	79	60
Declined donation	6	5
Registers not accessed	1	1
Not registered/found (unregistered subsample)	45	34
Cause of death		
Intracranial haemorrhage	57	44
Cerebral hypoxia-anoxia	33	25
Traumatic brain injury	28	21
Cerebral infarct/other neurological	11	8
Non-neurological	2	1
Organ donation outcome		
Actual donor after NDD[a]	82	63
Actual DCD[b]	36	27
Non donor[c]	13	10

Note. $N = 131$. AODR = Australian Organ Donor Register; DCD = donation after circulatory death; NDD = neurological determination of death; RMS = Roads and Maritime Services register.
Total % for some categories will deviate from 100% by ± 0.1% due to rounding.
[a]Includes $n = 4$ that did not proceed to procurement surgery.
[b]Includes $n = 11$ that did not proceed to procurement surgery.
[c]Includes $n = 8$ not medically suitable for organ donation due to system or donor/organ reasons.

Bereavement Aftercare

All interviewees (*n* = 131) received some form of bereavement aftercare. Many (*n* = 121, 92%) received two forms of written information on bereavement. Most (*n* = 116, 88%) received follow-up phone calls from both the donation specialist nurse and the Family Support Coordinator, while *n* = 2 (1%) did not receive any phone call. Almost all received written information in the form of a booklet (*n* = 130, 99%) or a pamphlet (*n* = 122, 93%). Almost all (*n* = 129, 98%) had a follow-up phone call, typically from the Family Support Coordinator (*n* = 126, 96%) or a donation specialist nurse (*n* = 122, 93%). In one instance the Family Support Coordinator did not speak with the interviewee but had talked with his wife. Calls from a social worker were rare (*n* = 3, 2%). Occasionally (*n* = 5, 4%), interviewees received a home visit, from a donation specialist nurse, a midwife, a research nurse and a member of the police; in one case from a retired nun, on a number of occasions.

Does the Decision Endure?

In response to the question "*Thinking back to the decision you made regarding organ and tissue donation 3-months ago, would your decision today remain the same*?": interviewees overwhelmingly (*n* = 127, 97%) agreed their organ donation decision had endured at three months after the death of their family member. The remaining interviewees were unsure (*n* = 3, 2%) or stated 'possibly' no (*n* = 1, 1%).

Comparison with Interviewees' Donation Decision at the Hospital. At 90-days, a higher proportion (*n* = 1/7, 14%) of interviewees who had declined donation at the hospital would probably not have made that decision had the situation been different, compared with those who had agreed (*n* = 3/124, 2%). The candidate (*refer to page 10*) has not completed analysis exploring interviewees' reasons for their donation decision enduring and will complete in post-doctoral analyses.

Exploration of the Interviewees' Reasons for Their Donation Decision not Enduring

In three cases (case examples 1-3, from 2014, 2015 and 2016 respectively), each interviewee stated they were unsure they would repeat their donation decision made at the hospital; in another case from 2014, they reported they would probably not make the same decision (case example 4). The following are verbatim transcriptions of example

responses to the interview question "*Can you tell me a little bit more about the reasons for your original decision (and if appropriate) why your decision has changed?*"

Case Examples: Enduring Decision 'Don't Know'

Case example 1: 2014 – ID 03009:

The donor-eligible patient was male, aged 36 years with no religious beliefs and in the unregistered subsample group. He was admitted to the ICU on a Monday just after midnight and died 8.6 days later. Death was certified by circulatory criteria and caused by an intracranial haemorrhage.

The end-of-life and donation conversation meetings were separated by approximately 50 min, 8.5 days after ICU admission. The 20 min donation conversation took place in a private location after midday on a Tuesday; attended by HCPs (n = 2) and one family member (patient's mother), (not SANOK). The requester was the managing intensivist (a DR). Topics raised by HCPs included withdrawal of life-sustaining treatments, and of the rare opportunity and benefits of donation. The mother's initial decision was to decline. A subsequent meeting occurred with the partner (SANOK), who was informed of her mother-in-law's decision from the first meeting, and the partner declined donation (at 50 min from the start of the first meeting). She stated two reasons for her decision: not wanting surgery to the body or concerns of disfigurement, and uncertainty of the patient's wishes. Additionally, the donation specialist nurse perceived the SANOK wanted to uphold the mother-in-law's decision.

Interview at 90+ days later

The interview was with the wife, who was aged 34 years, had Christian beliefs, and had lived with her husband for 17 years. She was completing a university qualification. The interview duration was 15 min.

She had wanted her mother-in-law to be involved in the donation decision. "I had been making all the decisions up until then and I wanted my mother-in-law to be involved too. She spoke with [*husband's*] brother and sister about it (organ donation) and they didn't want it".

She wanted him ..."whole. We had never really had a conversation and I wanted to respect my mother-in-law's wishes."

Case example 2: 2015 – ID 08005:

The donor-eligible patient was male, aged 22 years with Christian beliefs and in the unregistered subsample group. He was admitted to the ICU late Friday afternoon and died 11 days later. Death was certified by circulatory criteria and caused by hypoxia-anoxia.

The end-of-life and donation conversation meetings were separated by approximately 44 hours, 7.9 days after ICU admission. The 45 min donation conversation was set in a private location, mid-morning on a Monday, attended by HCPs (n = 3) and immediate family members (n = 3). The requester was the managing intensivist (a donation specialist medical/DR). Topics raised by HCPs included withdrawal of life-sustaining treatments, circumstances of death, and of the rare opportunity and benefits of donation. The SANOK initially decided to consider donation; all family members attended a second meeting and provided written consent (at 6.5 hours from the start of the first meeting). Three reasons were mentioned for their decision: enabling someone else to live a better life, the opportunity for something positive to come from a tragedy, part of their family member living on in someone else. Procurement surgery occurred 25 hours after signing consent.

Interview at 90 + days later

The interview was with the mother, who was aged 61years, had Christian beliefs and had lived with her son for 22 years. She had completed a university qualification. The interview duration was 25 min.

She was unsure whether she would make the same decision because they had been challenged by the multiple issues of the decision, by: 1) its short timing and pressure, 2) not understanding what was happening, 3) wanting to avoid another painful procedure for the donor, 4) lack of family consensus, 5) organ recipient death.

"Well I don't know because ...at the end he had, he had to get another painful procedure and also with the two-minute timing of it, that seemed, it just put a lot of pressure on everybody and I didn't understand why they had to do it. Because I wanted, I didn't know if I was certain that what had happened had happened and there wasn't time to think about, did it definitely happen or not, we just had to leave."

"I didn't realise they'd have to draw blood and everything...so that would have been extra pain and trauma for him right up at the end..."

Knowing her son as a person, helped her feel certain about the decision.

"But he was a very giving person so, and very generous... I felt kind of bad, at the same time knowing that if [*son*] was asked, he would have said yes."

There was not consensus between the parents.

"But I think once, once we decided to go ahead then we, then we definitely had to go ahead with ...that was the hard part because his dad especially was still not wanting to do it."

However, discovering the organ recipient had died added to her grief "yes that was very disheartening...so (I) felt bad for their family as well."

Case example 3: 2016 – ID 01113:

The donor-eligible patient was male, aged 41 years with no religious beliefs and in the unregistered subsample group. He was admitted to the ICU late one Sunday night and died 22 days later. Death was certified by circulatory criteria and caused by an intracranial haemorrhage.

The family had raised donation and the conversation had been deferred. The end-of-life and donation conversation subsequently occurred in the same meeting, 441 hours (18.4 days) after ICU admission. The 15 min donation conversation was set in a private location on a Friday morning, attended by HCPs (n = 6) and extended family members (n = 4). The requester was the managing intensivist who had completed the core workshop but had not initiated a multidisciplinary action plan before the FDC. Topics raised by HCPs included withdrawal of life-sustaining treatments and the possibility of organ donation. The SANOK (wife) had initially decided to consider the information and provided written consent at the third conversation (at 6 hrs from the start of the first meeting), when introduced to a donation specialist nurse. Not all family members attended every meeting. One reason to consent was mentioned: knowing her husband's wishes from a registry (*no record found)*.

Revocation of consent subsequently transpired (21:00 hours) at 54 hours after signing consent. Reasons perceived by the HCP were: "complicated, understanding of donation/grief/unhappy with neurosurgery care." Death was certified 5 hrs later.

Interview at 90 + days later

The interview was with the wife, who was aged 35 years, with no religious beliefs and had lived with her husband for 17 years. She was completing a university qualification. The interview duration was 45 min.

She knew her husband's wishes explicitly.

"I knew that he never wanted to be in a vegetative state...because of his underlying condition... We had talked about donation... he (had) said "when I'm gone what does it matter to me you know".

She experienced multiple delays throughout the decision process.

"[*husband*] was in intensive care for three weeks and my initial questions about organ donation came very early in the piece, and I was told by the social

worker that we would not at that point make that decision...therefore we were not going to have that discussion…when I wanted that information".

When donation was discussed much later, she felt rushed and under pressure.

"I found towards the end that there was a lot of pressure to make a lot of decisions very quickly…I even had [*donation specialist nurse*] tracking me down in the car park of [*hospital*] urging me to make a decision".

She also felt that she was given insufficient information about other donation activities in NSW that had delayed her time frames.

"We went through the process of making the decision and filling out all the paper work...then [*husband*] had to wait, another twelve hours... I can't remember the exact details but we were made (to) wait while that other person was going through the (donation) process."

The decision to withdraw consent appears to have been the right thing to do.

"…at the end of the day [*husband*] wasn't a prime candidate for organ donation…and I wasn't aware of all these time frames…that certain organs were going to shut down, that they were no longer going to be eligible…"

She felt people were not aware of the "two types of death" required to enable organ donation and was confused by the legal criteria for NDD.

"being told by the neurologist that this person (had) …no chance of ever recovering any cognitive function" (she understood) "…they are brain dead to the point that they are not going to have any brain function, but at the same time they're not brain dead enough (for) that option of organ donation… but they have to go through …circulatory death..."

Case Examples: Enduring Decision No

Case example 4: 2014 – ID 06014:

The donor-eligible patient was female, aged 58 years with Christian religious beliefs and registered 'yes to donation' on the RMS and AODR. She was admitted to the ICU late one Saturday night and died 9.6 days later. Death was certified by circulatory criteria and caused by a cerebral infarction.

The end-of-life and donation conversation meetings were separated by approximately 3 hours 50 min, 1.6 days after ICU admission. The 30 min donation conversation was set in a private location on a Monday afternoon; attended by HCPs (*n* = 4) and two family members. The requester was the managing intensivist who had completed the core workshop. Topics raised by HCPs included circumstances of death, withdrawal of life-sustaining treatments, organ donation processes, the rare opportunity and benefits of donation, and knowledge of the patients' donation wishes. SANOK initially opted to take some time to consider the information. A subsequent meeting was attended by both children, resulting in a final decision to decline donation (at 1.5 hours from the start of the first meeting). Five reasons were stated for their decision: they held longstanding negative views on organ donation; they did not wish for surgery, as this would cause disfigurement of the body; they had decided themselves that the patient's organs were not suitable; they thought the patient had suffered enough; and finally, they were uncertain about the patient's wishes. The donation specialist nurse never met the family.

Interview at 90 + days later

The interview was with the daughter, who was aged 26 years, had Christian beliefs and had not been living with her mother. She had completed a technical qualification. The interview duration was 45 min. it was noted by the interviewer that her response to whether she would make the same decision today was, 'possibly no but undecided'.

The decision process felt rushed, and their memory was that the news about her mother having died was immediately followed by the organ donation offer.

"...it would have been better to have a break between conversations. They needed time to adjust to the news of her death. It was a shock to both her brother and herself to hear the words "organ donation".

They had wanted to protect their mother.

"...seeing her lying there in ICU she looked so young in comparison to the other people in ICU – we didn't want her to be touched."

She was unsure how her mother would have felt about their donation decision.

"As time passes, I wonder if she would have been disappointed that we didn't follow her wishes? But I wouldn't have wanted her heart to be taken. The heart is the spirit of the person... I'm not sure that we made the right decision, but the timing wasn't right, we needed more time to understand (that she had died) and accept the fact that the life support was going to be turned off."

In this case there was a discrepancy between the contemporaneous record of events and the families' recollection of when organ donation was raised. It is possible the managing intensivist raised donation in the earlier meeting regarding the inevitability of death and had not documented that conversation. Alternatively, perhaps the family had not understood at that meeting that death was inevitable, so when donation was raised in the second meeting, they were not ready to hear or consider that information.

Summary of Results

In summary, nearly three-quarters (70%) of SANOK had made their decision about organ donation by the end of the first donation conversation in the hospital. The reasons they gave for their final decision to agree to donation were often related to seeing some benefit from the situation, for themselves and/ or other people (altruism). SANOK who declined donation frequently stated either that they had known or were unaware of their family members' donation wishes.

Nearly half of these SANOK participated in a follow up interview. Overall, they were well educated, with nearly half of interviewees studying towards or holding tertiary qualifications. For the overwhelming majority of interviewees, their donation decision had endured. Only a few (n = 4) interviewees described uncertainty regarding regret for their decision made at the hospital. All were SANOK of donor-eligible patients whose death had been certified by circulatory criteria; all indicated difficulty making decisions in that situation.

Exploration of reasons for their uncertainty found this related to their experiences of the donation conversations and challenges imposed by requirements of donation processes. While many of their reasons were similar to their reasons stated for their final decisions at the hospital, some differences were expressed. For the donation conversation, reasons concerned perceived pressure to make decisions quickly and the timing of the conversation; where, for example, HCPs offered organ donation before the family were ready for that information, not having accepted impending death. For the donation process, there was confusion about eligibility for organ donation and problems with insufficient information on processes and inadequate communication regarding time frames. After experiencing the procedure of treatment withdrawal in the operating theatre, one SANOK recalled how difficult the situation was, with insufficient time for her to understand that her family member had died.

Chapter Conclusion

This chapter described the reasons SANOK gave for their final donation decision at the hospital, and then examined whether that decision endured three months later. This study found few relatives had changed their final donation decision over time. Prior knowledge of the donor-eligible patients' wishes was frequently mentioned as the reason for the senior next of kins' donation decision at the hospital.

The decision process was obviously stressful but findings indicated some components of the donation process and some circumstances around the event where HCPs have opportunities to ameliorate this stress and distress for families. This was, in part at least, the purpose of the COMFORT intervention.

Discussion of the findings and considerations of their implications in relation to national and international literature and according to the study research questions, follows in the next chapter.

Chapter 7: Discussion

Chapter Introduction

This chapter sets out discussion of the overall findings according to the thesis research questions. The content includes published material from the discussion section of the study protocol (Potter, Herkes, et al. 2017), and from the publication of findings of the unregistered subsample (Potter et al. 2018).

The discussion opens by considering the context of the thesis, that of the topic of HCP preparation to initiate and lead the donation conversation, using a new approach to offering organ donation to bereaved families in the ICU. The principal findings are then discussed in response to each research question.

Background

The intervention delivered for this study was designed to improve the support provided to families when considering organ donation and to better manage this situation, which has been shown to result in both immediate (short-term) and longer-term distress for some families. To do this, the study targeted the quality of HCP communication and support for families making end-of-life and donation decisions in the ICU, shown to have long-term effects on families' bereavement (Lautrette et al. 2007).

Multiple factors have been implicated as increasing family members' distress. Family members of critically ill patients have reported adverse symptoms of anxiety and traumatic stress during the ICU stay (McAdam et al. 2010) and from 90-days (Sundararajan et al. 2014). In the US, a secondary analysis of surrogate decision-makers (n = 306), of adult ICU patients (n = 224) who had been mechanically ventilated for a week minimum, found families' negative perceptions of their relative's comfort (pain management) and emotional support had reported increased traumatic stress symptoms at 90-days (Wendlandt et al. 2019). Distressed family members have difficulty understanding detailed medical information (Eyler & Jeste 2006), and the quality of HCP communication is therefore particularly important when conveying complex EOL information such as brain death. Increased risk of traumatic stress has been described in donor family members who felt the donation experience was negative, such as

confusion about brain death, when interviewed an average of 37 (range, 3 – 60) months after death (Merchant et al. 2008).

Bereavement Symptoms and Complicated Grief

Factors increasing family member's distress can influence their bereavement intensity and symptoms of complicated grief. In this study, many donor-eligible patients had died due to a traumatic (violent) event. In NSW, a prospective study of bereaved family members (n = 78) demonstrated that at six months after death, higher bereavement intensity remained where the circumstances of death were violent, death was drawn out, or families had perceived greater suffering (in ICU) than anticipated (Buckley et al. 2015). Further, lower preparation for the death contributed to families' bereavement intensity (Buckley et al. 2015). Factors such as difficulty accepting death, particularly misunderstanding brain death and family conflict at end-of-life have been found to increase the risk of complicated grief (Kentish-Barnes et al. 2018; Mason, Tofthagen & Buck 2020). These experiences of distress are equally likely to affect both senior next of kin who consent and decline donation. A multicentre longitudinal study examining the experience of families of donor-eligible patients (n = 202) found that families who had declined donation reported lower quality communication during the organ donation process, but grief symptoms not significantly different to donor families three and nine months later (Kentish-Barnes et al. 2018). These factors flag opportunities for intervention in the care provided by HCPs over the period of the FDC and decision-making.

However, many critical care HCPs find end-of-life and bereavement a difficult situation to deal with effectively and sensitively. Surveys of physicians and nurses have described their familiarity with providing emotional support to bereaved families in the ICU, recognising the importance of family discussions early in the ICU stay. However, some have reported difficulties supporting families experiencing intense emotions, and found it difficult knowing what to say to comfort them, particularly when they have not accepted the patient's impending death (Kalocsai et al. 2020). For this high stress situation, the best possible preparation for HCPs is warranted to ensure families have the best experience possible given the potential for enduring harm and distress if not handled well.

Specialist Requesters and Donation Conversations

Informed consent for donation by the donor-eligible patient's legally authorised representative underpins the donation process at end-of-life. The donation conversation is a pivotal point in this process with families making decisions based on factors such as the level of emotional support and type of language used by HCPs. Evidence reviews have indicated that an approach to families using specially trained and experienced HCPs and that included a specialist donation nurse/organ procurement organisation (OPO) coordinator, positively influenced families' experiences and their donation decisions (Simpkin et al. 2009; Vincent & Logan 2012).

Various approaches have been used for a trained donation specialist to lead the initial donation conversation. Internationally, HCPs trained in specialised communication for donation may be intensive care doctors working in a dual role of donation specialist and treating clinician, or an individual independent of the managing team, such as an OPO coordinator designated requester (Kentish-Barnes et al. 2017; Shemie, MacDonald & Canadian Blood Services-Canadian Critical Care Society Expert Consultation Group 2014). Donation conversations with the treating clinician and a specialist donation nurse together, termed "collaborative requesting" (Vincent & Logan 2012) have been recommended in best practice guidelines (Consent/Authorisation Best Practice Development Group 2015; Organ and Tissue Authority 2017). In the US, participation of OPO coordinator designated requesters has been recommended during contact with bereaved family members when donation is offered (Kotloff et al. 2015). In NSW in 2012, a government plan was outlined to trial specially trained HCPs identified as "designated requesters" to selected hospitals to lead donation conversations independently of the managing team (NSW Ministry of Health 2012). The need for additional preparation for this role was identified.

Educational Preparation for the Designated Requester Role

To prepare HCPs for the new role, specialised communication training for designated requesters included completing the national Professional Education Package on offering organ donation. Training methods included presentations of theory, and opportunity to practice the family donation conversation using role play with other participants in a workshop setting (Organ and Tissue Authority 2014b). These workshops commenced in October 2011 (Mulvania et al. 2014) – independent of this

current study – and were ongoing. These educational workshops used interprofessional learning, which has anecdotal benefits from training together diverse professionals who also work together, albeit the evidence for these benefits remains unclear (Reeves et al. 2013).

Having donation conversations led independently of the managing team was not previously standard practice in NSW. A structured intervention based on best practice was developed to guide the implementation and evaluation of an independent designated requester (this current study). The NSW simulation program was developed to prepare intensivists, donation specialist nurses, and social workers to undertake the designated requester role. Commenced in January 2013, the program afforded participants an opportunity to rehearse the study intervention, while interacting with simulated participants in realistic clinical scenarios in a safe learning space (Potter, Gatward, et al. 2017). In particular, feedback and facilitated video-enhanced debriefing used in the scenario evaluation have been demonstrated to enhance reflection on and about practice and increase the incorporation of new learning into subsequent practice (Garden et al. 2015). Within this context, the principal findings of the research are expanded below and are set out in response to each research question.

Research Question 1: Senior Next of Kin Donation Decisions for the Unregistered Subsample

For donor-eligible patients who had not registered their donation preferences, comparing current standard practice to an evidence-based intervention including communication training using interaction with simulated participants for designated requesters ("the intervention"), are there differences in terms of SANOK consent rates for deceased organ donation?

A multi-component complex intervention including designated requesters was implemented to support SANOK donation decision-making. Implementation of this 'best practice' multi-component intervention was examined in the before-and-after study, to evaluate its impact for SANOK and their donation decisions. No statistical difference was found in family consent rates after the intervention had been introduced compared to the pre-intervention time periods.

There are a number of possible sources of confounding for these findings. In the pre-intervention period, sources included problems with data quality, the donation

pathway and duration of data collection. First, despite the rigorous approach to collection, extraction and verification of data, it is possible that not all donation conversations were identified in routinely collected data. All donation conversations were believed to have been retrieved, including where the SANOK had declined donation, and cases had been excluded based on system or donor/organ reasons of medical suitability criteria. However, SANOK decisions to decline donation were more likely to have not been recorded than consent decisions, and this may have resulted in an overestimation of the consent rate. This was particularly a risk when the donation specialist nurse was not informed of the case, increasing the likelihood that the HCP offer of donation was not documented in the patient's hospital record. Such circumstances also may have limited the ability to time the donation conversation in relation to confirming donor eligibility status, with donation conversations occurring for donor-eligible patients who ultimately had not met medical suitability criteria (Waller et al. 2020). This may have occurred particularly when donation was first raised by families.

The consent rate was higher than anticipated in the pre-intervention control cohort, having increased from 29% in NSW from 2011 for unregistered cases, contributing to an overall annual rate of 51% for all cases in that year. The sample size was based on an annual rate of 29% derived from routine data collection (not dedicated research data) (Potter, Herkes, et al. 2017) and hence any problem with determining consent rates from routine data will have impacted sample size calculation (and the study may thereby have been under-powered. In Victoria, (the next highest populated state to NSW in Australia), a consent rate of 56% for unregistered donor-eligible patients was also described over a similar timeframe as the pre-intervention period (Marck et al. 2014), perhaps implicating the earlier routine data used for sample size calculation as a more likely source of error.

Donation Pathway, Study Timeline and Donor Pool

Next, the donation pathway included a higher proportion of NDD cases (64%) in the pre-intervention period than in the intervention period (49%). This discrepancy may be an important explanation of the findings in the current study, reflecting results from a medical record audit report from the UK in which there was a higher consent rate for NDD compared to DCD cases (Prescott et al. 2019). This was also found in the

intervention period in the current study, supporting the experiences reported in other Australian states (Marck et al. 2014).

Another potential source of confounding arose from the study timeline. The pre-intervention timeframe of six months may have been too short, given the documented tendency of donation activity to cluster (*unpublished NSW Organ and Tissue Donation Service data*), with multiple concurrent referrals (Waller et al. 2020). Perhaps a 12-month timeframe might have improved accrual, captured any potential seasonal variations (Cignarella, Redley & Bucknall 2020), and demonstrated more truly representative preintervention results. Further, limited resources (time) were available to embed the new practice before it was evaluated.

Finally, possible sources of confounding during the intervention period included the characteristics and increased size of the donor pool, improved data quality, and the potential impact on the consent rate of the nationally delivered educational program. In NSW from 2010 - 2015, observational data revealed that the number and complexity of patients referred for consideration of organ donation had increased over time, with only a modest increase in actual donors (Waller et al. 2020). Patients had a higher burden of comorbidities and significantly increased age (Thomson et al. 2019), possibly due to an amendment in June 2014 that increased the upper age limit from 65 to 70 years for a potential DCD donor (Office of the Chief Health Officer 2020). Overall consent rates in NSW increased over time, from 58% in 2010 to 65% in 2015 (Waller et al. 2020), possibly reflecting increased opportunities from the enlarged donor pool, in part due to technological advances enabling additional organs to be transplanted from DCD doors, such as hearts (Macdonald et al. 2015). However, cases with a registered decline of donation had been excluded, (important because of the change to the *Human Tissue Act* in 2012), and the number of cases with a registered agreement to donation, and donation pathways, were not reported.

Data quality improved in the intervention period, corresponding with the change from paper-based to electronic data capture of referrals to the NSW Organ and Tissue Donation Service in 2013, improving record keeping (Thomson et al. 2019). Additionally, once the study commenced *the candidate* (*refer to page 10*) screened all referred patients prospectively and followed up missing or incomplete data related to donation conversations (see Figure 4.2, pp 70).

Another potential source of confounding that affected both study periods was the national education workshops continuing independent of this current study. The core

educational workshop, commenced in 2011, subsequently became mandatory training for intensive care fellows in 2014 (College of Intensive Care Medicine of Australia and New Zealand 2014). It was completed by (*n* = 70) 17% of cases led by the managing team in the full sample in the intervention period (see Figure 5.3 pp 94). Requester attendance at this training was unable to be accurately determined in the pre-intervention period, although it is likely that donation specialists would have been early attendees at the national workshops.

Altogether, the effect of these incremental modifications to donor selection and uptake of the national core workshop for consent rates is unknown. Usual practice may have been shifting towards and diluting any effect of the intervention, particularly affecting medical and nurse donation specialists who were designated requesters in this current study. Strengths of this study included prospective screening of donor-eligible patients and recording donation events with minimal loss of data in the intervention period; however, design and other potential limitations of the pre-intervention period may mean that the study was underpowered. On balance, it is possible these findings may have obscured the effects of the intervention on consent rates.

Research Question 2: Healthcare Professionals' Adherence to the Intervention

How feasible and acceptable for HCPs is implementation of this intervention: do HCPs adhere to core components of the intervention?

This research question was addressed in the before-and-after study and reported using the data showing uptake of the intervention components with the full sample. Findings revealed that in the intervention period, most HCPs adopted key components of the intervention that are required to be conducted before the donation conversation. For example, for component 2, with (*n* = 258) 99% of designated requesters had completed mandatory training when leading the first FDC (*n* = 263); for component 5, (*n* = 396) 95% of FDCs were held in private rooms. However, a number of best practice components of the donation conversation itself were often omitted: a designated requester led the FDC in 63% (*n* = 263) of cases but in only (*n* = 137) 33% of cases this designated requester was independent of the managing team. For component 3, the news of death and the donation conversation occurred separately in (*n* = 258) only 62% of cases; for component 6, HCPs mentioned the benefits of donation in only (*n* = 198) 47% of cases.

A number of considerations need to be taken into account when evaluating these adherence statistics in relation to lessons and what might be expected for future roll-out of the intervention. In this study, the specialist donation HCPs- medical and nursing - were anticipated to lead practice change in their ICU. It was anticipated that they would be qualified to deliver this by their roles in donation and their selection as designated requesters at their hospital. At baseline, data revealed uptake of the designated requester role at some (n = 3) sites before the site initiation visit, indicating early adoption of the practice change in those hospitals.

However, managing intensivists in some ICUs (n = 2) had limited introduction of the designated requesters and specialist donation nurses to donor-eligible families in accordance with their personal opinion, thereby restricting uptake of this component of the intervention. Pragmatically, the research team acknowledged from the inception of the project that some HCPs would 'do as they had always done', irrespective of the launch of the study at their site. The preference of some experienced HCPs' to rely on their own experience rather than published evidence is commonly reported in behavioural changes such as this, where interventions are complex; where evidence may not derive from the Australian context, or clear that models tested overseas are equally effective here. Any of these factors may have limited intervention uptake, in addition to potential deterrence due to intensivists' workload, or to a generalised resistance to change (Li Bassi, Ranzani & Torres 2013; Macvean et al. 2020). Interviews with intensivists and ED specialists have revealed some reluctance to both initiate the donation conversation and to "shift responsibility" to a third party donation specialist (Macvean et al. 2020). In effect the intensivist may have made the decision for the donor-eligible patient, and families may have missed the opportunity to consider donation and decide themselves if it was 'right' for their family member.

Operational Factors and Implementation Strategies

Practical challenges related to the delivery of a multi-centre trial made a staged implementation and roll-out of the intervention necessary. However, operational factors, including the turn-over of specialist donation nurses and the time required for the requisite numbers of designated requesters to complete all training workshops (up to a year), led to delay in recruitment at some sites. The original plan for a sequential start in equally spaced time periods could not occur. Practical factors affected protocol

adoption; for example, without funding to allocate designated requesters to on-call rosters, availability was dependent on usual rostering procedures. Such factors will equally affect any future delivery as part of routine practice as well as a research intervention.

Multiple implementation strategies were applied with the goal of embedding the COMFORT intervention as routine practice. Firstly, this study positioned donation specialists as designated requesters, who were expected to act as local opinion leaders, role models and change champions to lead practice change in their organisation, a strategy shown to be effective if carefully deployed (Flodgren et al. 2019). Each site had at least one senior clinician on the COMFORT project management team, whose role included being the local project lead.

To support the designated requester in this role, education featured strongly. This included the national education and training on specialised communication using "interactive educational meetings" (Eastwood, O'Connell & Gardner 2008). Recognising the limitations of even interactive meetings as a medium for learning complex behavioural skills, the simulation program was developed and those nominated to the designated requester role prioritised for attendance. No matter how well-received, education is recognised as only able to achieve small changes in practice (Forsetlund et al. 2009).

The candidate (*refer to page 10*) provided monthly audit and feedback on recruitment and adherence to the intervention to the donation specialists and ad hoc reports as requested for them to disseminate to their colleagues/organisation. Implementation science has demonstrated that audit and feedback are capable of effecting change, but, like education, can only make a small contribution (Ivers et al. 2012). However, drawing on theory from implementation science, in the current study passive spread via education and training ("*diffusion*") was employed, together with opinion leadership by donation specialists to actively "*disseminate*" by persuading target groups (intensivist colleagues) to adopt new practices (Greenhalgh et al. 2004). Once again, the evidence shows that such strategies make important but small and not necessarily consistent contributions to change (Flodgren et al. 2019).

In summary, the current study findings highlight the difficulties of implementing a complex behavioural intervention that disrupts habitual ways of working and highlight the importance of allowing time, resources and expertise to plan, lead and deliver context-specific tailored implementation plans for successful behavioural change.

Research Question 3: Predicting the Senior Next of Kins' Donation Decision

For donor-eligible patients who had not registered their donation preferences and where the intervention was in use, what, if any, characteristics of the decision-making process occurring in hospital predicted the family donation decision?

This research question examined predictors of consent revealed in the pre-post study using data related to the adoption of the intervention for the unregistered subsample. Data from this sub-sample were employed to eliminate the potential confounding (and unmodifiable) effect of a donor-registered decision. Despite the suboptimal uptake of parts of the intervention, some components were independently associated with an increased probability of consent. These included: use of a designated requester independent to the managing team and conducting more conversations per case. Unexpectedly, separation of the end-of-life and donation conversation reduced the probability of consent.

Despite the low adherence rates, these data confirm observational findings from Australian ICUs that independent designated requesters increased the probability of consent (Lewis et al. 2015). A designated requester independent of managing team responsibilities and time commitments is probably better able to allow families greater opportunity to explore complex concepts through multiple conversations. A designated requester may be able to provide more time and continuity of support despite not managing patient treatment.

Only one randomised controlled trial has evaluated changes in the practice approach to donation conversations. In the ACRE study from the UK investigators found consent rates did not increase when the managing intensivist was accompanied by a specialist donation nurse during the conversation offering donation, but this requirement was not adhered to in almost one in four cases (ACRE Trial Collaborators 2009). This current study was similarly challenged: that is, incomplete uptake within each participating ICU was evident in the suboptimal adherence rates for many intervention components, particularly for transfer of leadership of the donation conversation to a designated requester colleague. Even though the NSW simulation-based training was well-received (Potter, Gatward, et al. 2017), it appeared to have had a limited effect on facilitating practice change.

The results support findings from previous studies describing significant positive associations between the amount of time spent with families by independent

OPO personnel and trained ICU nurses on consent rates (Jansen et al. 2011; Shafer et al. 2004; Siminoff et al. 2001; Siminoff et al. 2009). Families prefer continuity of care through end-of-life processes (Truog et al. 2008), and simulation-based training may have increased requesters' knowledge and confidence to continue donation conversations (Potter, Gatward, et al. 2017; Siminoff et al. 2009).

These results confirm previous findings from Australia (Lewis et al. 2015) and the Netherlands that consent may be less likely when a gap in time separated the donation conversation and the end-of-life meeting, particularly when patients were not on a donor register (Witjes, Kruijff, et al. 2019). However, the findings oppose reviews of the evidence describing consent as more likely when the donation conversation is separated from the notification of death (Simpkin et al. 2009; Vincent & Logan 2012). Guidelines recommend waiting to offer donation after the declaration of NDD (Consent/Authorisation Best Practice Development Group 2015; Organ and Tissue Authority 2017; Shemie et al. 2017), yet other experts do not agree (Siminoff, Agyemang & Traino 2013). These disparities may reflect important contextual or cultural influences affecting the capacity of families to accept end-of-life situations. For example, there may be different responses to death determined by neurological versus circulatory criteria as demonstrated in the current study and differing cultural preferences about how such conversations are introduced and managed. Given, for example, the very different approaches of cultures to many end-of-life and post-mortem practices (Lobar, Youngblut & Brooten 2006; Wong 2010).

In summary, these findings demonstrate some components of practice which have significant capacity to influence families' donation decisions and which are open to modification by HCPs and service providers.

Research Question 4: Families' Reasons for Their Donation Decision

For all donor-eligible patients where an evidence-based intervention (as above) was in use, what do SANOK report in relation to the rationale for their final decision in hospital, either to consent or decline organ donation?

The experiences of families' donation decision-making for NDD cases have been evaluated from the perspective of physician requesters and from families themselves (Kentish-Barnes et al. 2019). Less well known are the experiences of families of DCD cases, recently included with NDD cases in studies from Australia

(Marck et al. 2016; Neate et al. 2015), internationally (de Groot et al. 2016; Sarti, Sutherland, Healey, Dhanani, Landriault, et al. 2018; Siminoff et al. 2017; Sque et al. 2018) and this current study. This study found that when asked for a decision (at the hospital), reasons SANOK had agreed were grouped under an overarching theme of finding benefit from disaster /pain / darkness, whether this be as for themselves or for others, or through satisfaction in carrying out actions believed to be what the donor would have wanted. This reflects similar findings from another longitudinal study examining experiences of donor-eligible families in Australia (Neate et al. 2015).

Some families agreed because the donated organ continued to 'live on' in the transplant recipient. Although this is reported as a positive memory by families of NDD donors (Kerstis & Widarsson 2020), families may experience a "second death" if the donated organ was unable to be used for transplantation or if the transplanted recipient dies (Corr et al. 2011). This was also reported as a specific and separate source of regret by SANOK in this study (see case example 1, pp. 128).

Previous personal experience with donation or transplantation was described by Australian families as supporting their decision to consent (Neate et al. 2015), which was reflected both in the current study and in findings from a UK study (Sque et al. 2018). In contrast, there was no evidence of the Australian 'pragmatic' attitude of benefit to the community from organ donation noted by Neate et al (2015). A possible reason for this may be the timing of data collection in this study. While many reasons stated at the hospital matched those reported subsequently, other reasons were not recalled three months later, possibly because their importance changed over time, or there was a simple lack of recall.

Reasons Organ Donation was Declined

Common themes for declining donation were 'cultural, religious, or social' reasons, and the donation process itself, particularly the prolonged time. One cultural reason suggested was families' desire to be protective of the body, for example by declining donation to avoid organ procurement surgery. There are supporting reports from Spain (Lopez et al. 2018) and the UK (Sque et al. 2018) for this finding. Although paradoxically the UK participants had agreed to donation, the beliefs of those families led to selective consent for some organs and not others, for example the heart (Sque et al. 2018). In NSW, an analysis of referrals found family members from culturally and

linguistically diverse populations, who were both non-English speaking and born overseas, were less likely to have had donation offered and when offered, were more likely to have declined (Waller et al. 2020). Of those cases who had declined (n = 524) their reasons, as perceived by the specialist donation nurses, for Australian-born versus overseas-born SANOK varied by (n = 6) 3% versus (n = 22) 19% for cultural reasons, and (n = 5) 3% versus (n = 8) 7% for religious reasons, respectively (Waller et al. 2020). In the UK, a review of retrospective data described family and donor-eligible patient ethnicity of 'Black, Asian or a minority ethnicity' were independently associated with increasing the likelihood of the family to override the registered agreement (Morgan et al. 2017). It is important that 'sociocultural' considerations be included in education initiatives targeting culturally and linguistically diverse communities (Wong 2010).

Religious reasons have been addressed in community education initiatives with varying success. For example, in Iran extensive community education on the organ donation process and brain death significantly decreased family decline decisions due to not understanding brain death. However, decline decisions as a result of religious beliefs in Sunni Muslims had increased over the same decade (Mojtabaee et al. 2018). In NSW, projects to increase engagement and understanding of organ donation within culturally and linguistically diverse communities are ongoing (Moloney et al. 2020; Waller et al. 2020).

Social considerations included a lack of consensus in the family group, resulting in the SANOK being unable to agree to donation. This response to divergent opinions in the family group by declining donation was reported in a review of factors influencing families' donation decisions (Walker, Broderick & Sque 2013), particularly when wishes of the decedent were unknown (de Groot et al. 2016).

Opposing Donor-Eligible Patient and Next-of-Kin Donation Decisions

Previous research examining family experiences of donation decision-making in critical care generally excluded cases in which the donor-eligible patient had registered a decline (Wind et al. 2012; Witjes, Kruijff, et al. 2019). Due to the legislation change in NSW, donation has been offered to those families, a situation where differences in donation beliefs within families could be uncovered. Some families expressed surprise at the discovery of a registered decline for the donor-eligible patient, supporting

donation themselves. Thus, in the absence of recent discussions with their relative indicating a subsequent change of mind to support donation, they had upheld that decision, albeit reluctantly.

Other SANOK expressed '*surprise'* at discovery of a registered 'yes' to donation and had overruled the patient's decision registered while they were alive. This is permitted in Australia and other countries using 'opt-in' systems (Kentish-Barnes et al. 2019). This practice allows the senior next of kin to disregard the patient's expressed wishes. Ethicists argue that it promotes a double-standard in decision making and violates "patient autonomy" (Bramstedt 2013). In the UK, a retrospective review of potential organ donor records (n = 2,244) over a period of three years revealed (n = 263) 11.7% of families had overridden their family members' registered agreement to donate (Morgan et al. 2017). In NSW, there were approximately seven to 10 cases were recorded annually of SANOK declining donation when the donor-eligible patient had registered consent (NSW Ministry of Health 2012). In the UK audit, factors independently associated with increasing likelihood of the family to override a potential organ donor's registered agreement included not involving the specialist donation nurse in the donation conversation, and eligibility for a DCD versus NDD pathway (Morgan et al. 2017). The lengthy donation process was perceived by specialist donation nurses as the main reasons families overrode donor donor-eligible patients' registered decisions, revealed that occurring more often in potential DCD (34%) versus NDD (11%) cases (Morgan et al. 2017).

Donation Process

Features of the donation process also affected SANOK decision-making. Different processes for donation conversation decision-making have been modelled using Australian data, recommending a "Democratic Consensus" in preference to "Veto" method, where the views of a minority of individual(s) to decline donation prevails (Cook & Pilcher 2011). In this as all FDCs, the communication skills of the requester are key to facilitating families' decision-making processes, especially when their relatives' donation wishes are unknown.

These findings highlight the importance of patient-centred communication, ensuring the values of the family members are respected but those of the patient in preference to their family, are upheld. Given the contribution and potential effect of

HCP communication in relation to many of these factors, they reinforce the importance of HCPs' specialised communication skills.

Research Question 5: Do Families' Decisions Endure?

What proportion of SANOK reported that they regretted their final donation decision, either to consent or to decline donation, at around 90 days after enrolment?

When reflecting on their donation decision at some point from 90-days after the death of their relative, almost all interviewees expressed that they would still have made the same donation decision, even had they been able to change. Those few (four) interviewees who were uncertain they would have made the same decision were all SANOK of donor-eligible patients whose death was certified by circulatory criteria, and all indicated difficulty making decisions in this situation. Their difficulties derived from accommodating opposing family opinions, from perceptions that time was limited, causing pressure for donation decision-making, and a sense of confusion and inadequate information about organ donation processes.

Interviewees who would not have made the same decision provided a range of reasons for this. One interviewee who had declined donation, was unaware of her partner's donation wishes and had deferred the donation decision to his extended family; her decision to decline was based on their beliefs. This is not unusual; it has been widely reported that when the wishes of the donor-eligible patient are unknown, decision-making is more difficult for families and many have declined donation to avoid conflict or the fear of adverse family reactions (Walker, Broderick & Sque 2013).

One interviewee who consented to donation had raised the topic of donation in the ICU while her relative was receiving active treatment and the HCP had deferred the donation conversation to an appropriate future time. On reflection, she had felt frustrated at the time by that denial of her request for information when she asked for it. This was particularly concerning because when the time came to make the decision, she described feeling pressured with limited time to make the "right" decision. In general, family members of critically ill patients preferred that their expressed desires for information on organ donation and readiness to discuss this were respected, irrespective of when they raised the topic (Michetti et al. 2018). Some felt that organ donation information should be available in ICU waiting rooms (Michetti et al. 2018), a view expressed by one interviewee in this study but not shared by all families.

Another interviewee, who had declined donation and 'overridden' the donor-eligible patient's registered agreement, recalled being shocked when organ donation was raised, and felt her family had needed more time to adjust to news of the inevitability of death. In this case the donation specialist nurse had not been included in the donation conversation and the patient was only eligible for a DCD pathway, having not progressed to brain death within 24 hours of ICU admission. Their reasons to decline were similar to findings from the UK, that the main reasons families overrode decisions were not wanting surgery to the body (15%), and feeling the patient had suffered enough (8%) (Morgan et al. 2017).

Reviews of family perspectives on deceased donation identified "pressured decision making" when families felt they were given insufficient time to process the information about death and that they lacked emotional and cognitive capacity to make a donation decision (Ralph et al. 2014; Walker, Broderick & Sque 2013). As in this current study, families who declined donation felt surprised when donation was raised, feeling emotionally unprepared to hear that news (de Groot et al. 2016; Walker, Broderick & Sque 2013). These findings underpin the importance of ensuring families understand the inevitability of death before offering donation.

Donation after Circulatory Death Processes

Two of the interviewees had provided written consent but were unsure they would do so again. In one case their relative had proceeded to procurement surgery, but the organ transplant recipient had subsequently died, causing additional distress. She recalled the stress of surrogate decision-making, concerned that medical procedures to facilitate the donation had caused additional pain to the donor. The family had found the DCD process distressing. She remembered the emotional intensity while waiting and watching for her relative to die in the operating theatre, and then feeling unprepared and rushed because of the two-minute time frame after cardiac standstill. The period of waiting for death has been experienced positively by some families (Sarti, Sutherland, Healey, Dhanani, Landriault, et al. 2018; Walker & Sque 2019) while others have found the wait distressing (Walker & Sque 2019). Families who viewed the DCD process positively felt sufficiently forewarned about events anticipated at each time frame, including the rapid transfer to the operating theatre following certification of death (Sque et al. 2018).

Families who provided consent for donation in DCD cases have described a lengthy wait for withdrawal of life-sustaining treatments, without understanding the necessity for this or feeling HCPs had provided sufficient rationale (Walker & Sque 2019); similar experiences were reported by one interviewee in the current study. In the UK, a retrospective analysis of ICU records revealed most (80%) families of DCD cases waited in the ICU until treatment withdrawal/transfer to surgery, staying an estimated 12 hours or longer than families (36%) of NDD cases (Prescott et al. 2019). This has implications for providing ongoing support for families of DCD cases, particularly when their family member did not die in the anticipated time frame for organ procurement and they were returned to the ICU to continue end-of-life care. Australian audit data collected over four years from an ICU in Victoria revealed 24% of DCD cases had not died in the time frame for organ procurement (Cignarella, Redley & Bucknall 2020). Some families have expressed disappointment when death occurred outside the time frame for donation and perceived that organs had been wasted (Sarti, Sutherland, Healey, Dhanani, Landriault, et al. 2018); others found meaning in the attempt to realise organ donation (Taylor et al. 2018).

Strengths and Limitations of the Study

This was a pragmatic study based on the implementation of a real-world program which aimed to modify standard practice for organ donation conversations. Prospective recording of clearly described components of the intervention with minimal loss of data enabled confidence in study findings. The detail collected allowed the tracking on an individual basis of the uptake of the individual elements of the intervention in relation to the progress of the donation event. As a trial conducted within standard practice, all patients considered donor-eligible when the first donation conversation occurred were enrolled, irrespective of whether they proceeded to actual donation, thereby minimising potential selection bias. This recruitment method was similar to the strategy used in an observational study conducted in Victoria, Australia (Marck et al. 2014), with the exception that in the current study cases who had registered a decision to decline donation were enrolled.

Another strength was the contemporaneous capture of the reasons for the families' donation decisions; the first time this has been reported for Australian families and with complete data on all donation conversations. Of note, this enabled accurate

comparisons to evaluate reasons for change or maintenance of the original donation decision at some point around 90-days after bereavement.

There are some limitations of this study. Firstly, there were constraints on design. A pre-post intervention design was chosen in order to maximise recruitment and obtain an adequate sample size within a reasonable time period. Alternative designs were not feasible. For example, a randomised controlled trial design would have incurred a high likelihood of contamination of 'control' sites by features of 'best practice' once national education began to be delivered in NSW. Cluster randomised control designs were discounted as there were insufficient hospitals providing organ donation services in NSW for this design (Grimshaw et al. 2000). A stepped wedge design was not possible as the crossover point for each site was primarily dependent upon staff release for the designated requester training, which in turn was dependent on local staffing; consequently, this could not be randomly allocated. The pre-post design enabled all units to participate in the intervention and made economical use of 'control' data from every site.

Secondly, comparisons were limited by the small size of the pre-intervention control group and potentially incomplete documentation of donation events in the pre-intervention period. Further, resources were limited (especially clinician time but also locally available implementation skills) to develop and deliver implementation strategies that would provide confidence that the new practice was embedded before it was evaluated. We were unable to gauge the impact of ongoing community education activities directed to increase the proportion of families that discussed individuals' organ and tissue donation wishes and people who registered their donation decision (Organ and Tissue Authority 2019a). In Iran, for example, extensive community education on the organ donation process and brain death significantly decreased family decline decisions because of increased community understanding of brain death (Mojtabaee et al. 2018).

Strengths and Limitations of the Follow-up Phase

Regarding follow up interviews with the SANOK, strengths include the response rate of 48%, notable for bereavement research and high compared with other work in this area. Over a similar time frame to this study, the national survey of donor families reported overall response rates of 24% (following deaths in 2012 and 2013),

19% (following deaths in 2014 and 2015) and 23% (following deaths in 2016 and 2017) (Organ and Tissue Authority 2019b). A UK study with a similar recruitment strategy to the current study described a response rate of 32% (Sque et al. 2018).

Another strength was using an interviewer independent of the hospital managing team, thereby facilitating open and complete disclosure of SANOKs' experiences of donation events. The interviewer was an experienced bereavement support expert, knowledgeable about donation processes, and possessing unique skills to support this vulnerable population.

Limitations of the follow up component include selection bias, in that those families who did not wish to be contacted for bereavement aftercare (n = 53, 13%) were excluded from that portion of the study. Additionally, many families who had declined donation were not offered bereavement aftercare (n = 91, 22%) by the managing intensivist and had not met or were not aware of the donation specialist nurse at the hospital so were unaware of the option for bereavement aftercare. By making recruitment into the follow-up component of the study dependent on SANOKs' contact with the Family Support Coordinator via the donation specialist nurse, according to standard practice, some cases were missed and were not invited to participate. This problem could have been avoided if all SANOK had been invited to participate via a difference recruitment route, irrespective of whether they met with the donation specialist nurse. Similar difficulties with compliance in prospective recruitment of SANOK who had declined donation were reported in a UK study (Sque et al. 2018). In this study, conducted across 10 National Health Service Trusts, of families (n = 108) who had declined donation only a small proportion (n = 14, 13%) had been approached by specialist donation nurses to invite contact with the research team within three months after bereavement (Sque et al. 2018). Similarly, in a study where n = 42 "non-consent" cases were recruited from four Melbourne hospitals, only n = 16 (38% of cases) completed interviews after bereavement (Neate et al. 2015). Clearly local practices affected accrual, perhaps because of HCP discomfort with families' perceptions of their role in donation. HCPs' inexperience leading conversations with SANOK who had declined donation and previously had not been routinely offered bereavement support may also have affected accrual.

Chapter 8: Conclusion

Chapter Introduction

This chapter concludes the thesis and considers the implications of the study findings for HCP education, practice, and policy. Content includes some material previously published (Potter et al. 2018). Recommendations arising from the findings are made, with suggested areas for future research.

Implications for Education, Clinical Practice and Policy

Education

The intervention tested in this study combined the merits and value of theoretical content with simulation-based training situated in realist contexts that nonetheless provided safe learning spaces This type of training focusing on specialist communication skills for critical care HCPs responsible for breaking news of death and approaching families after NDD has been recommended in guidelines, and flagged as capable of improving patient/family-centred outcomes (L'Her et al. 2020): in this case, enabling SANOK make decisions that continue to support and can live with.

The training program of this study was feasible but not always easy for the organisations to deliver; despite almost all designated requesters completing the mandatory training, the numbers of designated requesters available were not always adequate at all sites to meet the needs of local donation events. However, the program was well-received by participants (Potter, Gatward, et al. 2017), and it appeared to be broadly effective at preparing clinicians to support SANOK to make donation decisions based on the patient's values and wishes, which they were able to live with, and for which SANOK appeared broadly appreciative. This supports the continuance of a program of education and training comprised of a variety of educational modalities including simulation-based role-play. However, the influence of the work environment has been suggested as commonly a key factor in limiting transfer of learning into clinical practice (Jackson et al. 2019).

Clinical Practice

The aim of implementing the COMFORT intervention was to change clinician behaviours and practices more clearly aligned with specified 'best evidence' organ donation consent procedures. In this current study each site had at least one senior clinician on the COMFORT project management team, and sites were responsible for planning and delivering strategies to introduce this intervention, to promote its uptake and sustainability. No study resources were allocated beyond the training for the COMFORT intervention itself and for study evaluation methods. No training or resources were allocated for developing or delivering an implementation strategy, and sites were expected to use whatever implementation science or change management expertise they had available. Consequently, the introduction of the COMFORT intervention was attended by varied adoption and uptake, and achieved with variable success.

There is a clear need for sites to have access to implementation science expertise and arguably all HCPs should have at least a basic understanding of frameworks that may be used to guide planning for practice and service development. In particular, an assessment should be made of local system/organisational readiness for change, which should then inform development of a locally tailored implementation strategy. Researchers implementing complex interventions, for example multidisciplinary HCP behavioural change interventions in stroke, identified barriers to implementation at baseline and used the findings a priori to inform an implementation strategy (Craig et al. 2017). Such approaches can be effective; for example training on a specific implementation model for ICU nurses leading implementation of an ICU end-of-life care guideline, demonstrated increased self-reported guideline adherence with correspondingly higher scores of family satisfaction compared to those without that support (Noome et al. 2017). However, no specific implementation components were built into the COMFORT study, and there was no evidence or report that any site took a structured or implementation science-informed approach to this.

Future initiatives should take these factors into consideration. Different methods have been used to investigate local ICU cultures regarding organ donation. In Canada, perspectives of the multidisciplinary ICU team regarding NDD and DCD donation were explored using a self-developed questionnaire (Oczkowski, Durepos, et al. 2019), adding interviews to triangulate findings and identify practices to improve organ

donation processes (Oczkowski, Arnold, et al. 2019). Another group used the Theoretical Domains Framework of Planned Behaviour (Cane, O'Connor & Michie 2012) to explore intensivists', ICU nurses' and donation specialists' beliefs of the barriers and enablers to DCD donation (Squires et al. 2018). Multi-faceted behavioural change strategies were planned, which, like this study, included specialist education for HCPs and targeted communication skills training (Squires et al. 2018). Unlike this current study, behaviour change was supported by a range of activities, not just education. This flags the importance of involving an implementation science methodologist from the planning stages to incorporate development of locally-tailored, multi-component approaches to maximise intervention uptake and adoption in the Australian context.

Findings raise questions about the appropriateness for the Australian context of the intervention component that entailed deferring family offers of donation to the planned donation conversation. It is not clear in which contexts this should apply. Family members interviewed in this current study expressed the preference that requests for information on organ donation be met, at whatever time they are made. Such requests arise from families' need for information, and this can occur at various points in the process, not just when clinicians perceive the time is appropriate.

Study findings also highlight the importance of offering follow-up bereavement support not just to donor families but to all families experiencing bereavement in the highly technical, high-stress, complex and potentially traumatising setting of ICU. In the US, families offered bereavement support after death in the ICU experienced reduction in symptoms of prolonged grief (Jones et al. 2018). Findings also reveal the importance of a feedback loop to clinicians, so they may learn from families' experiences. Feedback may lead to improvements in job satisfaction as HCPs are better able to understand the direct impact of their care. Intensive care HCPs have been reported to value feedback on donation outcomes, debriefing and support post-donation (Oczkowski, Arnold, et al. 2019).

Policy

In Australia a recent guideline for conducting donation conversations has recommended that specially trained requesters offer organ donation; ideally this is an individual separate to the managing team (Organ and Tissue Authority 2017). As

indicated in this study, organisations may struggle to achieve all donation conversations led by a trained requester, especially if this needs to be a specially trained individual separate from the treating team.

Family-initiated offers of donation are generally perceived with relief by the treating intensivist (Macvean et al. 2020), and not necessarily seen as a trigger to contact a donation specialist nurse. However, families of donor-eligible patients have appreciated managing HCPs offering donation, who have been reported to disregard opportunities to do this because of the emotional distress connected with their loved one's critical illness (Sque et al. 2018). Policy clearly has an important role in providing a framework for delivery of evidence-based best practice, and an impetus for its enactment. However, to enact and achieve adherence to such a policy will require development and delivery of policy implementation strategies, additional to the provision of training for donation specialists.

Recommendations:

For education

- Critical care HCPs responsible for breaking news of death and approaching families in relation to offering organ donation need specialist training to develop and practice the specialist communication skills required to achieve the best FDC experience and outcomes for families and services.
- Such specialist training programs should include a combination of educational approaches, combining both theory and practical learning, situated in clinical or simulated clinical-like contexts.
- Release time and funding are required to support training and availability of adequate numbers of independent designated requesters to lead donation conversations for every donation event at every site.

For clinical practice

- When planning implementation of changes in clinical practice and clinician behaviours, someone with implementation science expertise should be available to support planning and delivery of implementation strategies. This could be a local clinician or someone in a centralised department (such as a Quality

Improvement unit) or accessed through links to local academic centres. This in turn has educational and funding implications to ensure the availability and sustainability of such a resource, especially if vested in local clinicians.

- As part of the preparation for any practice change in ICUs it is important to conduct a structured exploration of the local culture and readiness for change, recognising that every setting is unique in this respect.
- When a family member mentions the topic of donation that should be treated as a trigger to make available an appropriately skilled individual to provide information and explore whether the family are open to a donation conversation. This could entail, for example, contacting a donation specialist, preferably the donation specialist nurse, who has time and expertise to accurately answer their questions with awareness of the patient's medical condition and prognosis, at a time appropriate to the families' needs for information.
- Study findings should be used to inform service quality improvement initiatives, particularly in relation to those elements of the intervention shown to significantly predict families' donation decisions.
- Formal processes should be established to review processes and procedures to enable opportunities for quality improvement to be recognised, addressed, so that things may be done different subsequently.
- Follow-up bereavement support should be made available not just to donor families but to all families experiencing bereavement in the highly technical, high-stress, complex and potentially traumatising setting of ICU.
- Feedback should be available to clinicians, both so they are able to learn from their families' reports of their experiences, and better understand the impact of their care and for their sense of job satisfaction.

For policy

- Policy in this area needs regular review to ensure recommendations remain reflective of evidence appropriate to the local context as well as drawing on and critically considering international research.

Future Research

Further research is required at multiple points in the organ donation care trajectory. First, there are questions about the different routes by which patients may become organ donors, and the patients that traverse these pathways. Patient-related factors could be investigated such as the differences between donor-eligible patients with death certified by neurological versus circulatory criteria, including in cases where procurement surgery did not occur.

Next, while each of the components of the COMFORT intervention were supported by evidence, further work is required to confirm whether each of these components is essential, whether and how this may change with different cultures and populations. In particular, it will be important to elucidate the role of separating donation offers from discussions about end-of-life. Further, cohorts could be analysed to identify the best "dose" of the intervention, that is how many and which elements of the intervention predict an organ donation decision that is sustained at around 90 days. Additional research could investigate features of the donation conversation which have not to date been studied: these include whether there is an optimal number of family members in attendance and the corresponding effect on the ability to achieve consensus and consent. The impact of the ratio of HCP to family members could be examined, particularly where HCPs outnumber the family members present for the conversation. Further considerations include whether the time of day of the donation conversation affected families' experiences of decision making, particularly when the donation conversation started after 18:00 hours - currently permitted in Australia but discouraged in other countries such as Spain.

Finally, it will be important to apply implementation science approaches to examine the processes whereby the evidence supporting 'best practice' in donation conversations can be not just implemented but also adopted and sustained, including examination of the different cultures of various ICUs and how cultural enablers and barriers affect local adoption of evidence-based interventions. Extending the work to include international sites would enrich the data by enhancing the cultural dimensions of the investigation.

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Appendices

Appendix 1: Published Manuscript – Study Protocol

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COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT): protocol for an intervention study

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Abstract

Background: Discussing deceased organ donation can be difficult not only for families but for health professionals who initiate and manage the conversations. It is well recognised that the methods of communication and communication skills of health professionals are key influences on decisions made by families regarding organ donation.

Methods: This multicentre study is being performed in nine intensive care units with follow-up conducted by the Organ and Tissue Donation Service in New South Wales (NSW) Australia. The control condition is pre-intervention usual practice for at least six months before each site implements the intervention. The COMFORT intervention consists of six elements: family conversations regarding offers for organ donation to be led by a "designated requester"; family offers for donation are deferred to the designated requester; the offer of donation is separated from the end-of-life discussion that death is inevitable; it takes place within a structured family donation conversation using a "balanced" approach. Designated requesters may be intensivists, critical care nurses or social workers prepared by attending the three-day national "Family Donation Conversation" workshops, and the half-day NSW Simulation Program. The design is pre-post intervention to compare rates of family consent for organ donation six months before and under the intervention. Each ICU crosses from using the control to intervention condition after the site initiation visit. The primary endpoint is the consent rate for deceased organ donation calculated from 140 eligible next of kin families. Secondary endpoints are health professionals' adherence rates to core elements of the intervention; identification of predictors of family donation decision; and the proportion of families who regret their final donation decision at 90 days.

Discussion: The pragmatic design of this study may identify 'what works' in usual clinical settings when requesting organ donation in critical care areas, both in terms of changes in practice healthcare professionals are willing and able to adopt, and the effect this may have on desired outcomes. The findings of this study will be indicative of the potential benefits of the intervention and be relevant and transferrable to clinical settings in other states and countries.

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Keywords: Communication, Decision making, Family decision, Intensive care unit, Organ donation, Requester, Third party consent, Tissue and organ procurement

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Background

Organ and tissue transplantation is the definitive treatment for people with a wide range of end-stage organ failures. Escalating worldwide demand continues to drive efforts in many countries to increase the rate of deceased organ donation [1]. In Australia in 2011 the annual rate of deceased organ donation (15.1 donors per million population, dpmp) was below similar countries in the developed world such as the United Kingdom (UK) (17 dpmp), and international leaders such as the United States of America (USA, 25.9 dpmp), and Spain (35.9 dpmp) [2].

In New South Wales (NSW), Australia, consent for organ donation must be provided either from the patient while living or, when incapacitated, from the senior available next-of-kin (SaNOK): that is, a relative identified in line with an agreed family hierarchy [3]. In NSW the annual consent rate increased from 51% in 2011 [4] to 62% in 2013 [*unpublished 2014 NSW Organ and Tissue Donation Service (OTDS) data*], contributing to an annual national increase from 57% [5] to 61% [6] respectively. Other countries with similar health systems such as the UK, also reported a national consent rate of around 60% for 2013/14 [7]. Yet this consent rate is comparatively low in contrast to overwhelming positive public opinion in surveys of the UK and Australian populations with 90% and 69% respectively supporting donation and willing to become organ donors, describing predominantly altruistic beliefs on the topic [7–9]. Furthermore the consent rate decreased to 29% *[unpublished 2011 NSW OTDS data]* when families have been offered organ donation at the hospital and the patient had not previously registered their donation decision.

Physicians need effective communication skills when approaching families regarding end-of-life decisions, and skill enhancement has been advocated to maximise the consent rate for deceased donation [10, 11]. The difficulty of raising the subject of organ donation has long been recognised. North American research revealed Intensive Care Unit (ICU) physicians were poorly prepared to understand grief reactions, missed opportunities to provide emotional support, and failed to listen to families and support informed decision-making [12–14]. In Australia, a one-day donor awareness program designed to increase health professional's understanding of organ donation and to provide skills to sensitively conduct family donation conversations has been available since 1994 [15], with intensivists reporting this training as adequate preparation [16]. Despite that training, ICU nurses, intensivists and specialist donation nurses may avoid raising the topic due to their own perceptions of a family's grief, fear or guilt, or of adding to a family's distress [17, 18]. However, a longitudinal study of 49 relatives in the UK reported that discussing organ donation did not increase families' distress [19].

The approach and skill of the health professional making the donation request has been shown to be a key influence on families' donation decisions [20]. In countries that lead in this field such as Spain and the USA, health professionals working as transplant coordinators or organ procurement coordinators receive specialised communication training and make the initial approach to families [10, 21, 22]. In Australia, the managing intensivist traditionally leads donation discussions with introduction to the donation specialist nurse (DSN) subsequent to verbal agreement to organ donation. DSNs are trained in organ donation activities, but not necessarily in leading the conversation [23]. Many intensivists only participate in organ donation discussions a few times per year, providing limited opportunities to practice the necessary specialised communication skills [16].

'Best practice' family approach

Intensive care medicine professional organisations and health authorities in Australia and the UK provide practice guidelines for communication between families and health professionals during end-of-life care, including organ donation decisions [23, 24]. In Spain and the UK a 'family approach' has been recommended with the requesting conversation planned between the managing team and a Specialist Nurse-Organ Donation [10, 25]. Ensuring families understand that the patient has died or that death is inevitable before donation is raised is a key feature. The initial approach to the topic of donation has been identified as a pivotal point in the process because families often make their donation decision at that time [26].

Effective communication within a structured multidisciplinary family meeting, also termed 'family conference', has been recommended for ICU physicians to facilitate informed decision making based on the anticipated wishes of the patient rather than those of the patient's relatives [27–31]. Meetings ideally require multidisciplinary team planning, a private location and effective communication techniques such as the use of everyday language, listening and acknowledging relatives' emotions or opinions and demonstrating compassion verbally and through non-verbal techniques [23, 32]. In the USA communication approaches have moved from a "neutral" position towards organ donation towards one of "dual advocacy". This entails use of positive language, equally presenting the needs of the donor family and people on transplant waiting lists, assuming that most people would want to help others by donation [33, 34]. Training organ procurement coordinators ($n = 22$) in effective communication techniques for requesting organ donation increased the consent rate in participating

hospitals by 9.2%, over 2 years [22, 35]. Families who were certain of their organ donation decision reported that health professionals providing them with clear information and emotional support were key factors in helping them make decisions with which they remained comfortable over time [36].

Studies conducted in North America have shown some donation decisions were later regretted, and that this occurred more frequently when the decision was to decline donation. For example, of 285 relatives interviewed an average of 13 ± 9 days after death, only 4% (6/147) who had agreed to donation would later have preferred they had declined. By contrast, of those who declined donation, 27% (37/138) later wished they had agreed [37]. Decisional regret, where relatives either regretted their decision or were unsure they would make the same decision again, persisted up to 10 months after bereavement. A study of 199 relatives interviewed eight to ten months after death revealed decisional regret was more evident in those who declined (42%; 19/45) than agreed to donation (9%; 15/154) [36]. Decisional regret was more likely when organ donation was raised before relatives were informed of the patient's death, and when the first approach was by a health professional who managed the patient's care, before a formal request from a separate organ procurement team [37].

Specialised communication training

In Australia, training in specialised communication for health professionals who offer donation has been a key component of a national reform agenda [38]. A national program of specialised training in family-centred communication regarding organ donation, developed in collaboration with the Gift of Life Institute (Philadelphia, USA), was introduced in October 2011 [39]. The revised program delivered in two modules over three days, incorporated face-to-face presentations of theory followed by practical training with role-play exercises [40]. This approach — the Organ and Tissue Authority (OTA) Family Donation Conversation (FDC) core and practical modules – (see Additional file 1) has been adopted as 'best practice'; intensive care specialists and organ donation health professionals elect to attend, and the College of Intensive Care Medicine made completion of the core module a mandatory training requirement for intensive care trainees from 2014 [41]. However, role-play alone may not adequately replicate the emotional nature of donation conversations.

In NSW, training for health professionals selected as "designated requesters" to lead donation conversations has been supplemented by a simulation program [4]. Piloted in 2012 the program uses real donation scenarios with standardised relatives played by professional actors [42]. Health professionals are able to rehearse, review and reflect on their developing effective communication skills when offering donation in a protected learning environment, and thereby become more comfortable discussing these topics. These 'best practice' methods involving use of specialised requesters to lead deceased organ donation discussions with families are based on work from other countries adapted to but not formally tested in Australian conditions. This study will examine implementation of a 'best practice' family approach intervention and identify its effectiveness in terms of family consent rates, and later decisional satisfaction or regret.

Methods/Design

Aims and hypothesis

The aim of this study is to examine the process of organ donation decision-making, and to test whether changes in requesting practices change rates of family consent for organ donation and other family-based outcomes. A secondary aim is to examine whether changes in requesting practices result in increased satisfaction by families with their donation decision. The hypothesis for the trial component is that, compared to current usual practice, a 'best practice' family approach intervention will increase the family consent rate for deceased organ donation.

Design

This is a pre-post intervention design where rates of consent for organ donation for at least six months before implementation of the program in each ICU will be compared to the rates of consent for organ donation under the intervention.

Settings

The study will be conducted in the ICUs or locations such as Emergency Departments when the patient is managed by ICU health professionals, of nine metropolitan and rural hospitals in NSW, with follow-up conducted by the NSW OTDS.

The COMmunication with families regarding ORgan and tissue donation after death in intensive care (COMFORT) intervention

The intervention is a modification of current standard practice procedures for offering donation to families of potential organ donors. There are six essential 'best practice' elements of the intervention:

1. A designated requester has primary responsibility for discussions regarding organ donation with the family of a potential donor. Primary communication with families regarding end of life management and death remains the responsibility of the managing team.

2. Designated requesters are volunteer intensivists, experienced critical care nurses, or social workers who have been deemed appropriate by the site principal investigator/ICU department head to undertake the role, and complete mandatory training (see Additional file 1). Up to six designated requesters are estimated to be required at each study hospital.
3. The offer of donation is separated from the conversation where families are informed of the patient's death. It is important the family have accepted the inevitability of death before donation is raised [25].
4. If families raise the topic of organ or tissue donation, the managing health professional sensitively defers the first donation conversation to the designated requester.
5. Donation conversations are conducted within the structure of a family meeting, based on evidence-based guidelines for high quality communication regarding end-of-life care [23, 28–30].
6. The requester uses a 'balanced approach': information is provided in a proactive manner, using open-ended questions to encourage active participation of family members in discussion. Information is provided about the benefits of organ and tissue donation for both families and recipients [39].

Key features to which the multidisciplinary team and designated requesters are expected to adhere are set out in Table 1.

The training provides designated requesters preparation and opportunities to practice elements three to six of the COMFORT intervention. Designated requester training requirements are completed subsequent to attending the Organ and Tissue Authority FDC core and practical modules and the NSW simulation workshop (see Additional file 1) [40, 42]. Subsequent attendance at the simulation workshop is required for annual refresher training for DSNs and social workers, and 18 monthly for intensivists, for the duration of the COMFORT study.

As the study intervention is a modification to health service delivery, it is led in each hospital by local specialist donation nurses and doctors. Education sessions are delivered as required to colleagues in the departments of emergency medicine, intensive care, neurosurgery and social work to support and provide information and feedback on the implementation process of the new intervention. Information is collected from and on the health professionals involved in each organ donation event to track intervention fidelity.

Participants

Participants in this study are the families of patients who are potential deceased organ and tissue donors and the health professionals involved in each organ donation event. Members of the managing team identify a possible deceased organ donor who is apparently medically suitable for organ donation, and notify the donation specialist at the hospital or the OTDS. To be eligible for the study a donation event must meet all inclusion and no exclusion criteria as detailed below:

Inclusion criteria

Donation events identified by patients of all ages managed in the ICU or under the care of ICU health professionals, who are potential deceased organ and tissue donors. For the primary endpoint only, patients must not have registered their donation wishes.

Exclusion criteria

Donation events or patients who fulfil one or more of the following criteria:

a) A patient who is not medically suitable for deceased organ and tissue donation;
b) A patient who does not have a SaNOK to participate in donation conversations;
c) An adult patient in the ICU who is able to provide first person consent for deceased donation, for example a patient with cervical spine injury;
d) A patient who is suitable to donate only tissue after death.

Endpoints

The primary endpoint for the study is the family consent rate for deceased organ donation where the potential donor had not previously registered their donation wishes.

Secondary endpoints are: health professionals' adherence rates to core elements of the COMFORT intervention; identification of predictors of family donation decision; and the proportion of SaNOK who report they regretted their final donation decision at around 90 days after enrolment.

Study outline

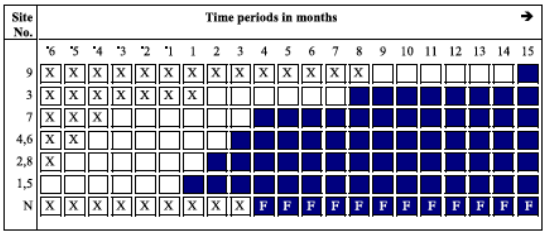
In line with usual practice, potential donors are identified, a registry check is performed to find any recorded preference regarding organ donation by the patient, and the process of assessing medical suitability is commenced (not necessarily in that order). In the COMFORT intervention condition the managing team is responsible for delivering the news of death, and contacts the donation specialist/designated requester to plan the approach to the family and initiate the donation offer (as above and Table 1). In the pre-intervention control condition, the donation conversation is managed by the healthcare professional(s) and processes are the usual practice in that setting. A chart of the study design and

Table 1 Key adherence criteria for delivery of the 'COMFORT' intervention

- **Plan:** a pre-conversation action plan
  The multidisciplinary team and the designated requester share information including: the patient's medical and social history; family dynamics and acceptance of the patient's death or inevitability of death. Health professional participants' roles in the meeting are agreed [25, 28].
- **Site:** conversation occurs in a private room or special area for meetings.
- **Tools:** use of effective communication techniques and language within the meeting such as everyday language, listening and acknowledging relatives' emotions, using a 'balanced' approach [12, 22, 23, 27, 28, 32, 39].
- **Transition:** the managing intensivist introduces the designated requester to the family, sensitively transfers leadership of the meeting to the designated requester, and may then leave to assume usual clinical responsibilities, at their discretion.
- **Evaluation of family donation conversation**: at the closure of the meeting health professional participants meet to verbally reflect on the process, plan subsequent follow-up and document the process.

data collection periods is shown in Fig. 1. The site initiation visit is the point where hospitals crossover from the control to the intervention condition. In both groups families may take up to 72 h for a final donation decision.

Bereavement support provided by the OTDS Family Support Coordinator is offered to families who participated in the donation requesting conversation regardless of their final organ donation decision. Senior next of kin, or the delegated decision maker, who agrees to



Notes: F=follow-up interview; X=periods of no data collection.

Fig. 1 Chart of the study design and data collection periods. Shaded cells represent intervention periods; Blank cells represent control periods. Each cell represents a data collection point, except those with 'X' *N* = NSW Organ and Tissue Donation Service, f = follow-up interviews

bereavement aftercare is invited to participate in the subsequent follow-up interview at day 90 after enrolment.

Evaluation: data collection and management

Setting

To characterise and describe the setting, data recorded at the beginning and at completion of the study at each site include: number of hospital and ICU beds; categories (medical/surgical/paediatric) of patients admitted to the ICU; areas of specialty; medical, nursing and allied health staffing establishments and ratios; availability of private meeting rooms; frequency of multidisciplinary communication (ward rounds; and family meetings).

Current control

To describe practice for the 'control condition' i.e. pre-intervention details of donation events for the period of six months before each site implements the intervention and joins the program will be extracted retrospectively. Data will include: eligibility for deceased organ donation; patients' date of birth, donation intent registered on their motor vehicle licence and the Australian Organ Donor Register; initiator of the donation conversation; family final donation decision, and outcome of the donation event.

Intervention period screening

A screening log is maintained at the OTDS of notification of patients who are apparently medically suitable for deceased organ donation during the study intervention period. DSNs routinely coordinate data collection at each hospital and forward completed forms to the OTDS for validation and consistency checks.

Donation events

A unique number is allocated to each potential organ donor at enrolment. Data from eligible potential donation events include donation pathway (i.e. brain or circulatory death), designation of initiator of the family donation conversation, donation intent on a register, and family donation decision. Also characteristics of potential donors such as: date of birth, gender, ethnicity, religion, primary event/cause of death, dates and times of ICU admission and death, commencement of retrieval surgery, and family contact details.

Family donation conversation

Adherence to elements of the family donation conversation is consecutively recorded on a case report form for each donation event by self-report from the observations of health professionals who participated in the meeting. Details include general features of a structured family meeting and specific topics discussed in the first meeting. The role of the ICU health professional who led the initial family donation conversation (termed the 'requester') is central to this process; their demographic, training and number of donation requesting conversations experiences in the preceding calendar year are collected by self report. Reporting is undertaken at the closure of the conversation to minimise potential recall bias. A consensus approach is used with equal weight given to each health professional's observations. Completion of the case report form may extend to one week. The final donation decision by the family is recorded at conclusion of the process. Reasons stated by the family and/or perceived by the health professional for that decision at that time point will be noted. See Additional file 2 for the case report form.

Follow-up with the SaNOK

Follow-up bereavement aftercare will be offered to SaNOK as part of the donation conversation process. An invitation to participate in the follow-up interview and the participant information sheet and consent form are posted to SaNOK who agreed to follow-up approximately two weeks before the 90-day post bereavement time point. Written or verbal consent are subsequently sought from the SaNOK for the follow-up interview and to audio-record it, although the interviewer will take notes rather than audio-recording if participants prefer. This contact procedure is similar to that used in previous research with families of potential organ donors [43]. Hence the three-stage process for consent to follow-up entails:

1. Initial verbal consent to the offer of bereavement aftercare, followed by
2. Provision of written information and written or verbal consent, and
3. Confirmation of consent before conducting the interview, and for audio-recording.

The OTDS Family Support Coordinator conducts the telephone interviews with senior next of kin who agree to bereavement aftercare. Data sought include: demographic details; bereavement support received; information received regarding organ and tissue donation, and family members' perception as to whether this was adequate for them to make a decision; previous discussions with their relative regarding organ and tissue donation; if they would now make the same donation decision, and their decision rationale.

Consent rates over time

To describe trends in family donation decisions over the same time period as the COMFORT study and identify any trends/changes over time notification data from all

NSW hospitals ICUs and Emergency Departments are collected. Data variables collected have been listed at *Donation events*, above (with the addition of ethnicity, religion, ICU stay and retrieval data as appropriate).

Statistical methods

The sample size calculation was performed using the Simon's two-stage design [44]. 140 eligible next of kin families are required to be approached to provide consent for organ donation. This will yield 80% power with 95% confidence to exclude a consent rate of 29% in favour of a clinically worthwhile rate of 40% for the intervention. An eligible next of kin family are those of patients who had not registered their donation decision.

Additionally, in the first 46 eligible next of kin families who are approached, if less than 15 have consented to organ donation, consideration will be given to modifying the study.

Statistical analysis

A patient flow-chart shows the number of patients eligible and the numbers enrolled at each site. No imputation is envisaged to be performed for next of kin where the primary outcome is unknown. Summary statistics will be presented for continuous variables, and counts and percentages presented for categorical variables.

All analyses will apply the intention to treat principle. For example in a case where the intervention was not properly followed, such as the SaNOK had organ donation raised by an inappropriate requester instead of a designated requester, the patient will still be included in the study and considered to have received the intervention.

Paediatric cases defined as those aged less than or equal to 16 years, will be analysed as a separate cohort.

To address the primary endpoint

- Consent rates provided by the next of kin for organ and tissue donation where the potential donor had not registered their decision will be calculated.

To address the secondary endpoints

1. Adherence to core elements of the intervention will be obtained via the case report form and rates calculated.
2. The proportion of all next of kin who report they regretted their final decision either to consent or to decline donation at 90 days will be calculated with 95% Confidence Interval.
3. Characteristics of the donation process including staff adherence to core elements of the intervention and demographic characteristics of the potential donor, senior next of kin and of the requester will be explored. Exploratory analysis using both univariate and multivariate regression methods will be used as needed. A p-value of < 0.05 will be considered statistically significant for retention in the multivariate model and only univariate variables with a p-value <0.20 will be considered for inclusion to the multivariate model.

Categorical data (e.g. details of gender, religion, ethnicity of patient and health care professional and reasons to consent or decline donation) will be summarised by frequencies and percentages. Continuous data (e.g. age, time in family meetings) will be summarised using the mean and standard deviation.

Additional analysis: consent rates over time

Consent rates for hospitals that have participated in the "best practice" family approach intervention training will be compared up to six months before the site initiation visit with the consent rates under the intervention.

To establish the baseline (pre COMFORT) and concurrent data trends NSW state-wide, consent rates in hospitals not participating in "best practice" family approach intervention training at any point during the study will be presented over time.

The consent rates between NSW hospitals that had ICU health professionals trained in the intervention and NSW hospitals that never received the training will be presented. This analysis will only include families that were approached about organ donation before the hospital introducing the intervention training.

Additional analysis: follow-up data

Summary statistics will be provided showing the next of kin's knowledge of their loved one's organ donation wishes.

Summary statistics of the next of kin's demographic data and their circumstances of the organ donation request will be presented by donation decision and by the next of kin's enduring (90 days) regret or support of their donation decision.

Monitoring

The project manager will conduct a site initiation visit and subsequent visits to each study site during the intervention phase to support protocol compliance and adherence to good clinical practice in research. Hospital records, source documents and other study files will be accessible at all study sites for monitoring and auditing purposes. The OTDS will regularly monitor recruitment by screening notifications of possible organ donors to the organisation.

Ethical considerations

The study is a pragmatic evaluation "in practice" of adoption of key elements of the FDC training representing adherence to evidence-based guidelines for end-of-life communication with families. As part of routine care, health professionals delivering this intervention are able to access existing psychological supervision for support should they wish.

It is possible that contacting families may cause them anxiety or distress. This possibility is addressed by offering bereavement aftercare provided by the OTDS Family Support Coordinator to families who declined organ donation, currently not available to them under standard care conditions, but routinely offered to families who agreed to donation. In light of their existing relationship with the family, their counselling expertise and independence from the managing clinicians, the OTDS Family Support Coordinator will conduct the Day-90 interview subsequent to family verbal or written consent. Participants are able to change their mind at any time without affecting eligibility for ongoing bereavement support.

Discussion

This study has been designed to evaluate the uptake and outcomes of a 'best practice' intervention entailing a framework of evidence-based family conversations led by a skilled 'designated requester' convened after the news of a loved one's death has been delivered, to make decisions regarding end-of-life care and organ donation. This is an important initiative to identify 'what works' in usual clinical settings when requesting organ donation in critical care environments, both in terms of what changes in practice healthcare professionals are willing and able to adopt, and what effect this may have on desired outcomes.

A strength of this study is its pragmatic, 'real world' nature; findings will be immediately relevant and potentially generalisable to other clinical settings as the study is conducted as part of routine care. Standard care procedures of the 'control' condition will be detailed, enabling other sites to make comparisons between their practice and the practice employed in both 'conditions' of this study. Introduction of the designated requester role to lead the initial family donation conversation will be examined in both metropolitan and rural ICUs. Reasons for health professionals' decisions to deviate from the intervention pathway will be collected prospectively, to maximise understanding of the results of this study and identify procedures to review or to incorporate in future innovative implementation models.

Further strengths include characterisation of the donation requesting process in such a way as to enable identification of features of 'best practice' that are important both from Australian healthcare professionals' and families' perspectives, particularly in cases when they were unaware of the donation preference of the potential organ donor. Reasons for the families' donation decisions are recorded contemporaneously, thereby minimising the effect of recall bias. Use of an interviewer independent of the hospital managing team for family follow-up interviews is intended to facilitate open disclosure of their experiences of events.

There are some limitations of this study. Firstly, there were constraints on design. A pre-post intervention design was chosen in order to maximise recruitment and obtain an adequate sample size within a reasonable time period. Alternative designs were not feasible. For example, a randomised controlled trial design would have incurred high likelihood of contamination of 'control' sites by features of 'best practice' once national education began to be delivered in NSW. Cluster randomised control designs were discounted due to insufficient numbers of hospitals in NSW. A stepped wedge design was not possible as the crossover point for each site was primarily dependent upon staff release for the designated requester training, which in turn was dependent on local staffing; consequently this could not be randomly allocated. The pre-post design enabled all units to participate in the intervention and made economical use of 'control' data from every site.

Secondly, there are some potential threats to the validity of study findings. The delivery of the national FDC training may result in increased family consent rates independent of the study intervention. However, this training is only one part of the support planned for core elements of this intervention, so, if effective, consent rates would still be expected to increase more rapidly under the 'intervention' compared to the 'control' condition. We are unable to gauge the impact of ongoing community education activities directed to increase the proportion of people who register their donation decision. Selection bias is acknowledged for the follow-up interviews, in that those families who either were not offered or do not wish to have bereavement aftercare are excluded from this portion of the study.

Practical issues related to the delivery of a multicentre trial made a staged roll-out of implementation necessary. However, operational issues, including the turn-over of DSNs and the time required for the requisite numbers of designated requesters to complete all training workshops (up to a year), caused delay in recruitment at some sites. The original plan for sequential start in equally spaced time periods could not occur. Practical issues may also affect protocol adherence; for example, without funding to allocate designated requesters to on-call rosters, availability is dependent on usual rostering procedures. Implementation of the intervention is therefore pragmatic being

dependent on factors that will equally affect any future delivery as part of routine practice as well as a research intervention.

Additional files

Additional file 1: Summary of training program. (DOCX 115 kb)
Additional file 2: COMFORT study case report forms 2–6. (PDF 264 kb)

Abbreviations

DSN: Donation specialist nurse; FDC: Family donation conversation; HREC: Human research ethics committee; ICU: Intensive care unit; NSW: New South Wales; OTA: Organ and Tissue Authority; OTDS: Organ and Tissue Donation Service; SaNOK: Senior available next of kin; UTS: University of Technology Sydney

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Availability of data and materials

Not applicable.

Authors' contributions

RGH developed the original concept of a designated requester for the COMFORT intervention and is the NSW Coordinating Investigator. *The COMFORT writing committee*: JEP wrote and revised all drafts, and together with LP, RME, AA, JLB, EC, ATHC, MJOL and IMS, revised drafts critically for important intellectual content. All authors made substantive contributions to the study conception and design as members of the COMFORT study management committee and as principal investigators. VG conceptualised the research design and developed the statistical analysis plan. All authors read and approved the final manuscript.

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Competing interests

The authors declare that they have no competing interests. Investigators are conducting the study as part of their usual employment.

Consent for publication

Not applicable.

Ethics approval and consent to participate

This study was approved by the St Vincent's Hospital Sydney HREC (HREC/12/SVH/271) on 22 January 2013. This HREC has been accredited by the NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and certified by the NHMRC under the national model for Harmonisation of Multicentre Ethical Review (HoMER). Ratification of ethics approval was provided by the University of Technology Sydney (UTS) UTS HREC REF No. 2013000133 on 3 April 2013. The study commenced at each participating centre following HREC approval and completion of local governance procedures.

The procedure for requesting consent for organ and tissue donation is a routine, although relatively infrequent component of end-of-life care for ICU health professionals. The study intervention was determined a quality improvement initiative by the relevant Human Research Ethics Committee (HREC), anticipated to improve usual care to emotionally distressed families where organ donation is being offered. This enabled use of patient, staff and family data to examine adherence to key elements of the intervention as these procedures occur as part of usual care. Patient, family and requester data are de-identified and allocated a code, separate to the medical record number and donor number.

Trial status

The study commenced in several centres from May 2013 to pilot data collection tools and study processes. At 30 November 2015, there were nine ICUs participating; 819 patients have been screened with 302 patients enrolled. Recruitment and data collection are ongoing and estimated to be complete by the end of 2016, with an additional five-month window to complete SaNOK follow-up interviews.

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Appendix 1: Additional File 1

Summary of training program

The specialised communication training for designated requesters has two components: the national Family Donation Conversation (FDC): core and practical modules and the New South Wales (NSW) Designated Requester Simulation Training Program [1, 2].

Family Donation Conversation: Core Module

This is a two-day workshop on the advanced theory behind family donation conversations, and introduces specialised communication tools for requesters to support potential donor families in acute grief while raising organ and tissue donation. Training is provided on the new Australian model, the "balanced approach" of offering organ donation to families to ensure their donation decision is based on information, is proactive, and would be repeated if asked at a future time. Attendance is capped at 30 health professionals with two facilitators each workshop [3].

From February 2013 workshops are facilitated from a national group of Australian health professionals, known as the LEAD (Learn, Evolve, Achieve, Discover) trainers. These people are intensivists, experienced donation nurses, and grief and family support specialists, who had completed a training program provided by the Gift of Life Institute, Philadelphia [3].

Revised in 2014, aims of the core workshop are to provide participants with an understanding of:

- Specific elements of family care and communication.
- Range of reactions experienced by families who receive catastrophic news.
- Key factors in the process, timing and sequence of the donation conversation.
- Best practices for supporting families in grief and in the donation conversation.
- Strategies to ensure informed and enduring decision-making regarding donation [4].

Family Donation Conversation: Practical Module

This is a one-day practical workshop for health professionals who have completed the FDC: core module, to practice planning and to manage a complex family donation conversation. Three experienced donation specialists, including LEAD trainers, facilitate workshops.

Revised in 2014, aims of the practical module are to enable participants to:

- Reflect on learnings from the core module.
- Identify and discuss the benefits of separating the conversations about death and donation.
- Prepare and plan a family donation conversation using a team approach.
- Practise the first conversation of raising donation with a family.
- Practise responses to family concerns.
- Use tools to support learning and practice [5].

Designated Requester Simulation Training Program

This accredited training was developed in partnership with the NSW Organ and Tissue Donation Service and the University of Technology Sydney, and builds on communication skills from previous workshops. These half-day workshops are conducted in university simulation laboratories in small groups with professional actors, with a maximum of four participants. Real donation scenarios are used with standardised relatives played by professional actors. Donation scenarios include pathways of donation after brain death and donation after circulatory death determination. The role of the designated requester and the family donation conversation are highlighted. Debriefing is led by qualified experts with video assisted reflective debriefing as a key tool in training evaluation, in addition to feedback from the actors both 'in' and 'out-of-character' [2].

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Appendix 1: Additional File 2

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COMFORT Study	Form 2	ÅFĀÄĚEFĚĬČĖĖĘĘFĬÉĈĘ ĪĀĨĨÄĀĀÄĨĨÄ ÆFGÇĢĀĂĖI ÄĨĨÄĀĀÄĨĨÄĀĀÄĨĨÄĀĀÄĨĨÄĀĀÄĨĨÄ

FoĖm 2: Pre-conversation action plan

2.1 **Date:** ĨĨĨĀ ĨĨĨĀ ÍĀĨĨĀ ĨĨĨĀ ÍĀĨĲĨĨĀĨĨĨĨĀĨĨĿĨĨĀĨĨĨ *(dd/mm/yyyy)*

Start timeĦĨĨĨĀ ĨĨĨĦĨĨĨĀ ĨĨĨĀ ĲĴĀĐĖ

2.2 **Participants: health professionals** — Please tick ☑ one per person

- ☐ Ā AĦĀĀĐĚĘEĜEĘFĀĪĬĀÊĈĚĈĐEĚĐĀFĐDĀĒĈFEDĚFĪ
- ☐ ĄĂĦĀAËĚĈĖĚĀÆĒDĈĖĘFĀĞĖĘD
- ☐ ĄĂĦĈĖĖĊĈFDÇĀĈĖDĀĎĀĈFĐĚFĀËÇĈĢ
- ☐ ĄĂĦĀFĐDĖĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨ ĨĨĨ
- ☐ Ā ĦĀĀËĘĒĖĈĀĈĐĈĒĈĚ
- ☐ ÅFĐDĖĄĒĖĖGĈĖĄGĒĒËĖFĦĀĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨ
- ☐ ADĘEĐĚĈFDÇĀĖDĚGDĘFDĖĀÏEĎĀĒĚĖĐĀĞĀÇDĐĚĈFĖĚĀĈČËĜDĪ
- ☐ Ā AĦĀĚFDĚĜĖĘFÏÊ ĈĚĈĐĖĐĀĐDĀĈFĐĚFĪ
- ☐ Ā AĦĀĄDĐEĘFĖĈĖĀÏÄ B
- ☐ Ā AĦĄDĘĆDĚFĀÄ BĪ
- ☐ ÆCĦĀÆËĊECĈĖĀĈDĖ
- ☐ ÅFĐDĖĀ*specify*ĦĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨ
- ☐ ÄĚFDĖĒĖDFĀĈĚĖDGĈĐDĦĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨĨ

2.3 **Who will lead the conversation today** — Please tick ☑ one

- ☐ ĄĂĦĀAËĚĈĖĚĀÆĒDĈĖĘFĀĞĖĘD
- ☐ ÅFĐDĖĀ*specify*Ħ
- ☐ Ā AĦĀĚFDĚĜĖĘFÏÊ ĈĚĈĐĖĐĀĐDĀĈFĐĚFĪ
- ☐ ADĘEĐĚĈFDÇĀĖDĚGDĘFDĖ

2.4 **News of brain death or inevitability of death delivered to the family**

Date: ĨĨĨĀ ĨĨĨĀ ÍĀĨĨĀ ĨĨĨĀ ÍĀĨĲĨĨĀĨĨĨĨĀĨĨĿĨĨĀĨĨĨ *(dd/mm/yyyy)* **Time**ĦĨĨĨĀ ĨĨĨĦĨĨĨĀ ĨĨĨĀ ĲĴĀĐĖ

2.5 **Was organ donation raised with the family before this planning meeting?**

- ☐ ĆDĘĤĀĐĀĎĈ EÉĢĀĖĈÇĀF
- ☐ ĆDĘĤĐDĀ ĈĚĈĐĚĐĀDĈÊĀĈĖDÇĀF
- ☐ ĂË

2.6 **If yes to 2.5, who discussed organ donation with them?**

- ☐ ADĘĐĚĈFĖĚĦĨĨĨĨĨĨĨĨĨĨĨĨĨĨ ĨĨĨĨĨĨĨĨĨ

2.7 **Topics of planning discussion** — Please tick ☑ all that apply

- ☐ ÅĈĚĚDÇĄĈFDĈĚÇĀÊDĀËĎĀDDĄËĚĈFËĚĀĊĚĜDĖĘĈĖĚH
- ☐ ÂËĈĖĘĀĎĀDĘĀĊËĚĜDĖĘĈĖĚH
- ☐ C ĐĖĀĘĐĖGĘĀĈDĀĖDĘDĚĐĀĖÊĀFĐDĀ ĈĚĈĐĖĐ FDĈÊH
- ☐ ĄËĐĘĀĎËĖĀĈĖFĊĒĈĚFĘĀĀFĐDĄËĚĈFËĚĀĊËĚĜDĖĘĈĖĚH
- ☐ ÄĊĚFEFGĀĎĀĐĀÉDĀĊĊĖĘĖĀ ĈÈDĖÍĘDĖĖĖĀĎĠFĀĎĀÈEĚH
- ☐ ÆĐDĀĈFĐĚFÌĘĀ DÇĖĈĀĐĘFËĖĢĀĚÇ DĜDĚFĘĚĀFĐDĀĐËĘĈĖÉH
- ☐ ÆFĈFĘĀĎĀĐĠFĀĎĀÈĀĚĀĈĊĊDĒFĈĚĊDĀËŐĀĄĐĖĀĐĜEFĈĖÉEFĢĎĀĖÇDĈFĐ
- ☐ ÀĜDĖĢĚDĀĐĖDĞĐË ĘĐË GÉĄĎ ĎËĀFĐĀĎĠFĀĎĀÈĖĚ
- ☐ ĚĢĀĊĚĎÉEĊFĀDĠĒDĖEDĚĈĖDĢĚĀFĐDĀĎĈÊÉĢH
- ☐ ĚĢĀĊËĚĎÉEĐFĀĒDĖEDĚĊĎĊDFĞDDĚĀĎĈÊÉĢĀĈĚÇĀFĖDĈFĐĚĈĐH
- ☐ GĖĖDĚFĀĈ ËFËĚĈĀĈĈĒĈĊĖĢĀĎĀDDĀDĠFĀĎĀĖ ĖDĀĐĜDĀĚĎĀËĒĒĚĐH
- ☐ ĂDĠFĀĎĀĖÌĘĀGDĘFËĚĘĀĈČËGFĀ DÇĖĈĀFĖDĈFÊDĚFĀĐĈĖĢĀĈĚĘĞDĖDÇH
- ☐ ĂDĠFĀËĎĀĖĘĀĒĐĢĖĈĀDDÇĘĀĈFDĚÇDÇĀÏĎËĀÇĐĖÇĀDĢĐDĚDĪH
- ☐ ÅFĐDĖĈĜĈĈĈĐĄĢĒĒËĖFĀĖĒDĠFĀĎĀĖĚH
- ☐ ÅFĐDĖĀ*specify*Ħ

2.8 ☐ **Pre-conversation action plan did not occur**

2.9 **Donation Specialist Nurse introduced to the family**

Date: ĨĨĨĀ ĨĨĨĀ ÍĀĨĨĀ ĨĨĨĀ ÍĀĨĲĨĨĀĨĨĨĨĀĨĨĿĨĨĀĨĨĨ *(dd/mm/yyyy)* **Time**ĦĨĨĨĀ ĨĨĨĦĨĨĨĀ ĨĨĨĀ ĲĴĀĐĖ

ĄÁĀĲĀĜDĖĘĀĄĈFDÇĶĀĂËĜĀĲĲ ÅĈĐDĀËĎĀ

COMFORT Study	Form 3	Pt Initials (first_last) Study No.	I__I I__I I__I I__I I__I I__I I__I I__I

Form 3: Meeting for the family donation conversation

Part A: First meeting *(to be completed with health professionals who attended this meeting)*

3.1 **Date:** |__| |__| / |__| |__| / |_2_| |_0_| |_1_| |__| *(dd/mm/yyyy)*

Start time:|__| |__|:|__| |__| 24 hr **Stop time:**|__| |__|:|__| |__| 24 hr

3.2 **Location** Please tick ☑ one

☐ Patient's bedside ☐ Private room set aside for meetings ☐ Other, *specify*:_____

3.3 **Who led the conversation** Please tick ☑ one (& complete Form 5)

☐ RN: Donation Specialist Nurse ☐ MD: Intensivist (managing the patient)
☐ Other, *specify*: ☐ Designated requester

3.4 **Transparent introduction of the requester (by the managing team)** Please tick ☑ one

☐ Yes, stated works in organ donation ☐ NA, designated requester not introduced
☐ No, blinded with role stated in general terms ☐ NA, one of the managing team led the meeting

3. 5 **Time the managing intensivist left before the meeting closed** Complete one of Y, N or NA

3.5.1 **Yes**, left the meeting at time: |__| |__|:|__| |__|24 hr

3.5.2 **No**, did not leave because: Please tick ☑ the main reason for "N"

☐ Also a designated requester (DR)
☐ Led the meeting because a DR was unavailable
☐ Stayed to answer clinical management questions
☐ Stayed to observe the method of communication or to mentor a DR
☐ *Specify other reason for staying*:

3.5.3 ☐ **NA** the managing intensivist did not attend this meeting.

3.5.4 *If applicable*: the DR left before the meeting closed at time: |__| |__|:|__| |__|24 hr

3.6 **Topics discussed** Please tick ☑ all that apply and circle "F" if raised by a member of the family

☐ F Understanding of brain death
☐ F Understanding of plan to withdraw/withhold treatment
☐ F Discussion about loved one, circumstances of death etc
☐ F Rare opportunity for organ donation
☐ F Emphasis on the benefits of donation and the potential to help others
☐ F Description of the organ donation process
☐ F Does not incur additional costs to family
☐ F Knowledge of patient's donation wishes
☐ F Reassurance regarding the fairness of organ allocation
☐ F Other, *specify:*

3.7 **Participants: health professionals** Please tick ☑ one per person (more on page 2)

☐ MD: Intensivist (not managing the patient) ☐ MD: Intensivist (managing the patient)
☐ RN: Donation Specialist Nurse ☐ MD: Registrar (ICU)
☐ RN: allocated care of patient today ☐ MD: Resident (ICU)
☐ RN: other_____ ☐ SW: Social Worker
☐ HC: Hospital chaplain ☐ Other spiritual support:_____

☐ Other, *specify*:_____ ☐ Interpreter, language:_____
☐ Designated requester (if not working in designation above)

3.8 Participants: family Please tick ☑ all that apply and write number of attendees

☐ Spouse/partner/de facto/same sex partner (include ex)	No.: |__| |__|
☐ Adult child (18yrs or older) (include step children)	No.: |__| |__|
☐ Parent (include step or adoptive parents)	No.: |__| |__|
☐ Adult sibling	No.: |__| |__|
☐ Adult sibling's partner	No.: |__| |__|
☐ Grandparent	No.: |__| |__|
☐ Other, *specify*:	No.: |__| |__|

3.9 Designation of the SaNOK, *specify relationship to the potential donor*:

3.10 *If applicable*: The SaNOK **delegated decision making** to *(specify relationship to the potential donor)*:

3.11 Outcome of the initial family donation conversation Please tick ☑ one

☐ Definite in principle consent ☐ Initial decline: "reactive no"
☐ Agreement to consider ☐ Definite in principle decline
☐ Other, *specify*:

Part B: Final outcome *(to be completed with the individual who led the first conversation)*

3.12 Final donation decision Please tick ☑ one (and complete Form 4)

☐ Written consent ☐ Definite in principle decline
☐ Other, *specify*:

3.13 Date: |__| |__| / |__| |__| / |_2_| |_0_| |_1_| |__| *(dd/mm/yyyy)* **Time**:|__| |__|:|__| |__| 24 hr

3.14 Total of family donation conversations to reach the final donation decision: No.: |__| |__|

3.15 Did each family member who attended the initial donation conversation attend all follow up meetings?

☐ Yes ☐ No ☐ NA (only one meeting)

3.16 Please comment if response was "No" in 3.15:

3.17 Procurement surgery commenced incision time *(if applicable)*

Date: |__| |__| / |__| |__| / |_2_| |_0_| |_1_| |__| *(dd/mm/yyyy)* **Time**:|__| |__|:|__| |__| 24 hr

3.18 Revocation of consent at the hospital *(if applicable)* (and complete Q 3.19)

Date: |__| |__| / |__| |__| / |_2_| |_0_| |_1_| |__| *(dd/mm/yyyy)* **Time**:|__| |__|:|__| |__| 24 hr

3.19 Please comment on reason(s) for revocation of consent stated by SaNOK.

Reason(s) for the final donation decision

Categorise reasons as:
S= **stated** verbally by the senior available next of kin to the requester and/or delegate
P= **perceived** by the requester

4.1: Reasons for consent *(selected after completing Q3.12)*

Circle S or P

S	P	What other donor families have shared
S	P	Knew donor's wishes from donor registry / driver's licence
S	P	Knew donor's wishes from previous discussion
S	P	Enabling someone else to live a better life
S	P	Donor would have wanted to help others
S	P	Opportunity for something positive to come out of a tragedy
S	P	Part of a relative living on in someone else
S	P	Previous personal experience with donation
S	P	The donor had never said "no"
S	P	Other, *specify*:

4.2: Reasons for decline *(selected after completing Q 3.12)*

Circle S or P

S	P	Concerns over delay to funeral/burial process
S	P	Concerns regarding integrity of process e.g unfair organ allocation, organ selling
S	P	Disagreements among the family group
S	P	Dissatisfaction with the patient's treatment in the ICU
S	P	Dissatisfaction with the patient's treatment in other areas of the hospital
S	P	Dissatisfaction with duration of the donation process
S	P	Longstanding negative views on organ donation
S	P	Not wishing surgery to the body/concerns regarding disfigurement
S	P	Emotional exhaustion
S	P	Religious/cultural reasons
S	P	Decided on their own that organs would not be suitable
S	P	Thought that the patient had suffered enough
S	P	Unable to accept death, lack of understanding of brain death
S	P	Uncertainty regarding the patient's wishes
S	P	Knew donor's wishes from donor registry / driver's licence
S	P	Knew donor's wishes from previous discussion
S	P	Other, *specify*:

COMFORT Study	Form 5	Pt Initials (first_last) Study No.	I__I I__I I__I I__I I__I I__I I__I

Form 5: Requester details *(to be completed by the individual who led the first meeting in Form 3)*

5.1 Requester details

5.1.1 Date of birth: |__| |__| / |__| |__| / |_1_| |_9_| |__| |__| *(dd/mm/yyyy)*

5.1.2 Country of birth: ☐ Australia ☐ Other, *(specify)*:

5.1.3 Gender: ☐ Male ☐ Female

5.2 Ethnicity Please tick ☑ one or more

- ☐ Oceanian: Australian or New Zealander
- ☐ Oceanian: Aboriginal or Torres Strait Islander
- ☐ Oceanian: Pacific Islander (except Maori)
- ☐ Oceanian: Maori
- ☐ North-West European
- ☐ Southern and Eastern European
- ☐ North African and Middle Eastern
- ☐ South-East Asian
- ☐ North-East Asian
- ☐ Southern and Central Asian
- ☐ Peoples of the Americas
- ☐ Sub-Saharan African
- ☐ Prefer not to answer

5.3 Religion Please tick ☑ one

- ☐ Buddhism
- ☐ Christianity
- ☐ Hinduism
- ☐ Islam
- ☐ Judaism
- ☐ No religion
- ☐ Other, *specify*_____
- ☐ Prefer not to answer

5.4 Country completed pre-registration health professional training

Please specify:

5.5 Communication training Please tick ☑ all that apply

- ☐ Australasian Donor Awareness Program (ADAPT)
- ☐ Core workshop ***and*** *attendance* ☐ some or ☐ completed
- ☐ Practical workshop ***and*** *attendance* ☐ some or ☐ completed
- ☐ Simulation workshop ***and*** *attendance* ☐ some or ☐ completed
- ☐ Other, *specify*:
- ☐ Have not attended

5.6 Years worked in intensive care I__I |__I years **or** ☐ ≤ 1 year

5.7 Number of family donation conversations led in the last complete calendar year? I__I I__I

5.8 Designation Please tick ☑ all that apply

- ☐ RN: Donation Specialist Nurse
- ☐ MD: Donation Specialist Medical
- ☐ SW: Social worker
- ☐ Other, *specify:*
- ☐ MD: Intensivist
- ☐ MD: Registrar (ICU)
- ☐ MD: Resident (ICU)

5.9 Responsible for the potential donor's medical management while raising donation with the family?

- ☐ Yes
- ☐ No

COMFORT Study	Form 6	Pt Initials (first_last) Study No.	|__| |__| |__| |__| |__| |__| |__|

Form 6: Potential donor details

6.1 Potential donor details

6.1.1 Date of birth: |__| |__| / |__| |__| / |__| |__| |__| |__| *(dd/mm/yyyy)*

6.1.2 Country of birth: ☐ Australia ☐ Other, *(specify)*:

6.1.3 Gender: ☐ Male ☐ Female

6.2 Was the potential donor's donation decision registered in life? Please tick ☑ all that apply

☐ Yes to donation	*found on*	☐ AODR	and/or	☐ RMS	
☐ No to donation	*found on*	☐ AODR	and/or	☐ RMS	
☐ Not registered/not found	*registers checked*	☐ AODR	and/or	☐ RMS	
☐ Registers not accessed	*because*	☐ infant/child	or	☐ overseas resident	

6.3 Ethnicity Please tick ☑ one or more

☐ Oceanian: Australian or New Zealander	☐ South-East Asian
☐ Oceanian: Aboriginal or Torres Strait Islander	☐ North-East Asian
☐ Oceanian: Pacific Islander (except Maori)	☐ Southern and Central Asian
☐ Oceanian: Maori	☐ Peoples of the Americas
☐ North-West European	☐ Sub-Saharan African
☐ Southern and Eastern European	
☐ North African and Middle Eastern	☐ Missing from medical record

6.4 Religion Please tick ☑ one

☐ Buddhism	☐ Judaism
☐ Christianity	☐ No religion
☐ Hinduism	☐ Other, *specify:*_____
☐ Islam	☐ Missing from medical record

6.5 Primary event/cause of death Please tick ☑ one

☐ Motor vehicle accident	☐ Spontaneous subarachnoid haemorrhage
☐ Motor bike accident	☐ Other spontaneous intracranial haemorrhage
☐ Cyclist	☐ Cerebral infarct
☐ Pedestrian	☐ Hypoxia
☐ Other road accident	☐ Cerebral oedema
☐ Fall	☐ Cerebral tumour, specify benign or malignant
☐ Other accident	☐ Drowning
☐ Gunshot	☐ Hanging
☐ Felony or crime e.g assault	☐ Asthma
☐ Other, *specify:*	

6.6 Certification of death ☐ Brain death criteria ☐ Circulatory death criteria

Date |__| |__| / |__| |__| / |_2_| |_0_| |_1_| |__| *(dd/mm/yyyy)* Time |__| |__|:|__| |__|

6.7 Admission to this intensive care unit

Date |__| |__| / |__| |__| / |_2_| |_0_| |_1_| |__| *(dd/mm/yyyy)* Time |__| |__|:|__| |__|

***Forms 2-6 are complete**:_____ **(DSN sign)** _____**(date)**

Appendix 2: Submitted Manuscript – Review, Supplemental Tables

Table A2.1

Search Terms

Database	Population/ phenomenon: HCP	Intervention: communication skills education & training	Outcome: Communication skills, consent for organ donation	Setting: ICU/critical care
PubMed (MeSH)	Professional family relations'	Communication; simulation training; education medical; education nursing; inservice training	Tissue and organ procurement	Critical care; intensive care
PubMed Key words (title/ abstract)	Professional family relations'	Communication, simulation training; education medical; education nursing; inservice training	Tissue and organ procurement; organ donation	Critical care; intensive care; intensive care unit
CINAHL (EBSCO) (SH and 'exploded')	Professional family relations	Communication; expert clinicians-education; communication skills training; education, medical, continuing; education, medical; education, nursing; education, nursing continuing	Organ donation; organ procurement	
CINAHL (EBSCO) Key words	Professional family relations; professional-family relations	Communication; expert clinicians; simulation training; education medical continuing; education medical; education nursing; education nursing continuing; inservice training	Organ donation	Intensive care unit; critical care
EMBASE: Excerpta Medica (OVID) (SH and 'exploded')	Human relation,	Interpersonal communication; education; simulation train*, medical education; nursing education; in service training;	Organ don* mapped to organ donor or brain death	Intensive care, intensive care unit (critical care mapped to intensive care)

Table A2.1

Search Terms

Database	Population/ phenomenon: HCP	Intervention: communication skills education & training	Outcome: Communication skills, consent for organ donation	Setting: ICU/critical care
EMBASE: Excerpta Medica (OVID) Key words	Human relation,	Interpersonal communication; education; simulation train*, medical education; nursing education; continuing education; in service train*	Organ don* mapped to organ donor or brain death	Intensive care, intensive care unit*
ProQuest Dissertations & Theses Global Key words	Professional family relations	Communication; education; simulation training;	Organ donation, consent	Intensive care

Abbreviations: CINAHL, Cumulative Index to Nursing and Allied Health Literature; HCP, healthcare professional; ICU, intensive care unit.

Table A2.2

Typology of communication principles and behaviours for the donation conversation

Setting/preparation
• Quiet location with seating for everyone, tissues (Downar et al. 2012; Potter et al. 2018) • Adequate time (eliminate distractions; arrange colleagues to cover clinical responsibilities) (DeVita, Arnold & Barnard 2003; Downar et al. 2012) • Timing: separate meetings for the news of neurological death and the donation request) (Blok et al. 2004; DeVita, Arnold & Barnard 2003; Morton et al. 2000; Potter et al. 2018)
Receptive behaviours
• Introduces self and role in patient management (DeVita, Arnold & Barnard 2003; Tobler, Grant & Marczinski 2014) • Addressing the family members (and donor-eligible patient) by name, putting them at ease (DeVita, Arnold & Barnard 2003; Downar et al. 2012; Meyer et al. 2009; Tobler, Grant & Marczinski 2014; Vaidya et al. 1999) • Appropriate body language (e.g. sitting instead of standing) (Meyer et al. 2009; Vaidya et al. 1999) • Asking family member's opinion/understanding of events, principle of "ask tell ask" (Meyer et al. 2009; Tobler, Grant & Marczinski 2014; Vaidya et al. 1999) • Active listening (Downar et al. 2012; Meyer et al. 2009; Tobler, Grant & Marczinski 2014) • Cultural, religious values/differences (respectful communication, appropriate language, use of interpreter) (Downar et al. 2012; Fico & Feeley 2019; Hales & Hawryluck 2008; Johnson et al. 2017; Siminoff et al. 2009) • Expressing sympathy and compassion (Meyer et al. 2009; Vaidya et al. 1999) • Maintaining an open dialogue/discussion (DeVita, Arnold & Barnard 2003; Hales & Hawryluck 2008) • Anticipating/strategies to manage common family responses (DeVita, Arnold & Barnard 2003; Hales & Hawryluck 2008) • Apologise (verbal) for errors or inappropriate expression (Fico & Feeley 2019) • Noticing and comparing verbal with non-verbal cues (Fico & Feeley 2019; Tobler, Grant & Marczinski 2014) • Verbal encouragement, principle of "tell me more" (Tobler, Grant & Marczinski 2014) • Responds to family showing personal confidence and warmth, relaxed style (Downar et al. 2012; Vaidya et al. 1999) • Open-ended questions (Downar et al. 2012; Potter et al. 2018)

Table A2.2

Typology of communication principles and behaviours for the donation conversation

- Respectful silence (Fico & Feeley 2019; Meyer et al. 2009; Potter et al. 2018; Tobler, Grant & Marczinski 2014; Vaidya et al. 1999)
- No interruption (allowing the family time to talk) (Downar et al. 2012; Vaidya et al. 1999)
- Show respect and kindness (Downar et al. 2012; Morton et al. 2000)
- Professional integrity, open-mindedness (Downar et al. 2012; Fico & Feeley 2019; Meyer et al. 2009)

Information behaviours

- Breaking/reiteration of bad news ("therapy is not working", inevitability of death, plan to test for neurological death) (DeVita, Arnold & Barnard 2003; Downar et al. 2012; Johnson et al. 2017; Morton et al. 2000)
- Differences in discussing organ donation after neurological versus circulatory determination of death (Siminoff et al. 2009)
- Responding to requests for information, answering clearly and honestly e.g. when the (HCP) did not know the answer to a family member's question (Downar et al. 2012; Vaidya et al. 1999)
- Simple, clear, understandable language by using nontechnical terms and avoiding medical jargon (DeVita, Arnold & Barnard 2003; Downar et al. 2012; Meyer et al. 2009; Tobler, Grant & Marczinski 2014; Vaidya et al. 1999)
- Constructive and appropriate when refusing requests (Downar et al. 2012)
- Initiating the donation request with specific wording (positive framing of donation) (DeVita, Arnold & Barnard 2003; Potter et al. 2018; Siminoff et al. 2009)
- Providing information about organ and tissue donation (positive framing of the benefits; explaining the benefits of donation using statistics) (Hales & Hawryluck 2008; Potter et al. 2018; Siminoff et al. 2009)
- Eliciting information about the patient's values, beliefs and wishes, such as Advanced Directives, donor registration (Downar et al. 2012)
- Eliciting and discussing the values of family members (Siminoff et al. 2009)
- Prompting family members for their donation beliefs, probing misinformation or fears about donation (Siminoff et al. 2009)
- Support services: counselling, religious support, chaplaincy services (Downar et al. 2012; Hales & Hawryluck 2008; Vaidya et al. 1999)
- Closing the donation conversation, preparation/planning for future events over the next 24 hrs e.g negotiating time and timing of withdrawal of life-sustaining treatments (Downar et al. 2012; Morton et al. 2000; Siminoff et al. 2009; Vaidya et al. 1999)

Table A2.2

Typology of communication principles and behaviours for the donation conversation

Interpersonal and affective (emotion) behaviours
• Demonstrated empathy (DeVita, Arnold & Barnard 2003; Downar et al. 2012; Hales & Hawryluck 2008; Johnson et al. 2017; Meyer et al. 2009; Potter et al. 2018) • Elicit family member concerns, psychosocial problems and emotions (Downar et al. 2012; Meyer et al. 2009; Vaidya et al. 1999) • Reflection on emotion, explore and encourage families to discuss strong emotions (Downar et al. 2012) • Identifies, allows, acknowledges family's individual reactions /strong emotions e.g. anger and grief reactions such as crying, threatening behaviour, shouting (DeVita, Arnold & Barnard 2003; Downar et al. 2012; Meyer et al. 2009; Morton et al. 2000; Siminoff et al. 2009; Tobler, Grant & Marczinski 2014) • Effective leadership of the interview, e.g. setting ground rules when conflict between family members (Downar et al. 2012) • Self-reflection e.g. awareness of the effects of HCPs' personal and professional responses to loss and bereavement, donation; their beliefs, personal bias, and attitudes particularly during conflict situations (Blok et al. 2004; Downar et al. 2012; Fico & Feeley 2019; Hales & Hawryluck 2008; Morton et al. 2000) • Conflict resolution skills (Downar et al. 2012; Hales & Hawryluck 2008; Siminoff et al. 2009)

Note. HCP = healthcare professional

Appendix 3: Published Manuscript - Simulation-based Communication Skills Training

Research

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Simulation-Based Communication Skills Training for Experienced Clinicians to Improve Family Conversations About Organ and Tissue Donation

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Abstract

Introduction: The approach, communication skills, and confidence of clinicians responsible for raising deceased organ donation may influence families' donation decisions. The aim of this study was to increase the preparedness and confidence of intensive care clinicians allocated to work in a "designated requester" role. **Design:** We conducted a posttest evaluation of an innovative simulation-based training program. Simulation-based training enabled clinicians to rehearse the "balanced approach" to family donation conversations (FDCs) in the designated requester role. Professional actors played family members in simulated clinical settings using authentic scenarios, with video-assisted reflective debriefing. Participants completed an evaluation after the workshop. Simple descriptive statistical analysis and content analysis were performed. **Results:** Between January 2013 and July 2015, 25 workshops were undertaken with 86 participants; 82 (95.3%) returned evaluations. Respondents were registered practicing clinicians; over half (44/82; 53.7%) were intensivists. Most attended a single workshop. Evaluations were overwhelmingly positive with the majority rating workshops as outstanding (64/80; 80%). Scenario fidelity, competence of the actors, opportunity to practice and receive feedback on performance, and feedback from actors, both in and out of character, were particularly valued. Most (76/78; 97.4%) reported feeling more confident about their designated requester role. **Discussion:** Simulation-based communication training for the designated requester role in FDCs increased the knowledge and confidence of clinicians to raise the topic of donation.

Keywords

communication, decision-making, education, multidisciplinary team, simulation training, tissue and organ procurement

Background

Conversations with potential organ donor families can be one of the most difficult clinical activities, irrespective of practitioner expertise or prior experience. Interactions playing out during these discussions can trigger raw emotions for loved ones and may influence opinions about organ donation. Recently, in Australia, approximately half of families approached to authorize organ donation on behalf of their relative have declined, a finding that contrasted with the high levels of support shown in population surveys. Evidence indicates that dedicated communication training focused on organ donation conversations increases health professionals' confidence and results in improved consent rates.[1-3] Countries with high rates of organ donation, such as Spain and the United States, have used specialist requesters who completed specific donation conversation training.[1,4,5] National reform strategies to increase organ donation rates included education for health professionals discussing organ donation with families.[6] In 2011, the Professional Education Package (PEP) introduced an Australian balanced approach to help families in acute grief

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make organ donation decisions that were informed, proactive, and enduring.[7,8] The PEP modules provided opportunities to rehearse these conversations through role-play with peers and to practice answers to potential questions.[7]

Raising the topic of organ donation has historically been the responsibility of the intensivist managing care of the potential donor, with the donation specialist nurse (DSN) introduced to the family after they agreed to consider organ donation.[9] In Australia, education for this comprised attendance at a 1-day donor awareness program that included communication training.[10] Intensivists reported training was adequate preparation.[11] Clinicians develop their approach and repertoire from observing colleagues' interactions with families, but opportunities to rehearse organ donation conversations occur only a few times per year for many intensivists.[11] Health professionals have reported a tendency to avoid raising organ donation due to concerns about adding to a family's distress arising from their own perceptions of the emotional burden.[12,13] It is unknown whether attending the PEP to train in the balanced approach is sufficient to enable experienced health professionals to confidently adopt the new process.

The designated requester (DR) role was introduced in New South Wales (NSW) in 2012. The DR was an experienced health professional who underwent specialized communication training to develop expertise to offer donation sensitively and improve decision making.[14] This study aimed to evaluate the NSW Simulation Program of the family donation conversation (FDC) in relation to health-care professionals' perceptions of its contribution to their preparedness and confidence to undertake the DR role.

Methods

Design

We conducted a posttest evaluation of an innovative simulation program with the specific aim of increasing the preparedness and confidence of clinicians undertaking the DR role.

Setting

The study was conducted in NSW, Australia. The provision of intensive care services is almost all exclusively the responsibility of accredited intensivists who manage all patients. Intensivists perform regular reviews where treatment goals/plans are adjusted according to patient needs. The registered nurse (RN) to patient ratio is 1:1 for mechanically ventilated patients and RNs perform the majority of patient care.

The simulation program was conducted in simulation clinical laboratories equipped with full audiovisual capabilities in a university health faculty in Sydney, Australia. The simulated intensive care unit (ICU) family meeting room was similar to a room available in most ICUs.

Population

Participants were eligible for this study if they were an experienced, practicing ICU clinician or donation specialist and had completed the PEP, and selection as a DR was confirmed by their ICU department head (or delegate). Invitations to participate in the simulation program were e-mailed from the Organ and Tissue Donation Service.

Intervention

The simulation program was developed by a team of organ donation, intensive care medicine, and simulation training experts. For practice-based professions, meaningful learning is best if situated within authentic environments, is contextually based, and incorporates interactions with peers and experts, concepts that lent themselves to simulation activities.[15] The design incorporated educational strategies to increase learning: active participation and formative feedback,[16] aligned with concepts from *sociomaterial* educational frameworks.[17,18] Additional meaning was constructed through interactions between and with others, and with environmental materials (artifacts). The specific environment (for the FDC) was authentically represented in a simulation laboratory with arrangements of furniture, and the contextual materials critical for participant engagement were patient scenarios based on de-identified real cases (see Supplemental Material). Interactions were planned with experts and peers (facilitators) with family members portrayed by professional actors. Appropriately briefed, actors were able to realistically portray family member conversations and elicit meaningful engagement of participants, resulting in socially constructed learning.[17] Subsequent video-assisted and facilitated debriefing helped focus on specific areas and assisted with reflection and active co-construction or refinement of clinical practice.[19]

Before the workshop, actors were provided a debriefing guide, scenario synopsis, and character outline including family background, personality, and current state-of-mind, and that the level of emotional intensity expected could be varied in response to the participant. Actor briefing included the participant's experience level so they could tailor their questions and reactions. The actors prepared in a separate area to participants. Two weeks before the workshop, participants received the program outline, workshop expectations, an assessment guide, and a confidentiality agreement. At the beginning of the workshop, the facilitator reviewed this material with all participants. Those who took on the DR role in the simulation were advised to assume their usual work role (intensivist, DSN, or social worker), although few DSNs had initiated the topic of organ donation before. Participants were encouraged to take their time, to use the skills learned in the PEP, and not offer organ donation until they believed the family was ready.

Procedures

The 3-part simulation workshop ran for 4 hours or a half-day. Each workshop catered for 2 participants; 1 enacted the role of requester while the other observed. These people swapped roles to experience or observe a different patient case scenario. Two

simulation laboratories ran concurrently so that 2 half-day workshops accommodated 8 participants per day.

Minimum personnel requirements for each workshop included 2 professional actors, 1 health-care simulation expert (facilitator), and another subject expert. The subject expert often played the role of the bedside nurse. A minimum facility requirement was a simulated ICU family meeting room equipped with audiovisual recording equipment and visual access for 2 observers: the facilitator, who made notes or annotated the recording while observing, and a participant observer (Figure 1).

The facilitator provided an overview of the patient scenario to the DR and managing team. Each scenario commenced when the family had been informed either of the inevitable death or the death determined by neurological criteria (brain death) of their loved one.

Part 1: planning meeting. The DR participant met the managing intensivist and "bedside nurse" to gather information and plan the FDC. They specified the manner of their introduction to the family; for example, either by stating they work in organ donation or by using general terms such as an end-of-life specialist. A short debrief of this part followed (see Figure 2 part 1).

Part 2: the FDC. The scenario and audiovisual recording began when the bedside nurse showed the family into the simulated meeting room and joined the conversation. The intensivist facilitator showed the DR participant into the room and introduced the family in the manner determined in part 1, then left the room to observe and make notes. The participant led the FDC using the balanced approach, raising organ donation when appropriate. At the conclusion of the conversation the audiovisual recording was stopped and a 3-stage debriefing process was facilitated.[19] The actors and nurse debriefed immediately, in and out of character (Figure 2 part 2).

Part 3: facilitated debriefing of the conversation. The video recorded conversation was viewed and discussed between the facilitator, subject expert, observer, and participant, guided by annotations or notes (Figure 2 part 3).

Potential facilitator intervention and exit points were integrated into the simulations to ensure the workshops ran smoothly for DR participants and family members. For example, if a participant felt the family needed a break and would normally divide the conversation, the participant drew the conversation to a temporary halt and left the room. The actors were briefed that time had elapsed, another meeting was scheduled, and a second donation conversation was initiated from where the first was left. The simulated conversations were expected to take around an hour; the facilitator could intervene to bring it to a close if the conversation was not progressing.

Data Collection

Participants were invited to complete evaluation forms at the conclusion of each workshop. A simulation training evaluation form was created for the program (E.M. and M.A.K.), because there were no existing evaluation methods that aligned with this type of initiative. The form comprised 8 items with 5 forced choice responses and 3 open-ended questions. Three items with "yes or no" response options and space for free text comments sought participants' views whether the workshop complemented or built on the PEP; its value as additional or essential training for the DR role; and if participants felt more confident undertaking the role after the workshop. Two items with Likert-scaled response options, from poor to outstanding, recorded participants' expectations and overall opinions of the workshop. Respondents were asked what they liked best and least and suggestions for future developments.

Personnel	Facilities and equipment
• One workshop coordinator: to brief the actors, facilitate the timetable, welcome and organize participants.	• Separate area with a table for the facilitator to brief participants as a group at the beginning and debrief after the workshop.
• Professional actors experienced in playing patient roles and debriefing: roles of two family members. • Managing team: roles of an intensivist (played by the facilitator), and a bedside nurse.	• Separate area for actors to create backstories, rehearse and get into character in preparation for their roles.
• Two participants (learner 'designated requesters'). • Two experts: a health professional facilitator and a subject expert in the FDC module content.	• Simulation laboratory with a viewing room for the participant observer to watch the scenario in real time.
• Staff for scene setup and take down; sourcing appropriate props.	• Scenario props: a three-seat sofa, two armchairs, a coffee table, tissues, water and glasses.
• One simulation technician to run the AV system including playback; subsequent minor editing.	• AV system with essential features of real time viewing, replay, digital file copying facilities; optionally, editing with annotation.

Figure 1. Workshop minimum personnel and resource requirements. AV indicates audiovisual; FDC, family donation conversation.

Data Analysis

Quantitative and qualitative methods of analysis were used. Simple descriptive statistics (percentages and frequencies) reported quantitative data. Free text responses were transcribed verbatim and content analyzed for systematic interpretation.[20] Two authors (experienced intensive care nurses: J.E.P. and

Debriefing	Activity
Part 1 Planning meeting debrief.	After the planning meeting, an informal discussion led by the facilitator, reflects on the team plan and conduct of the meeting. Any information missed by the participant is raised at this point. If the participant has not specified how they would like to be introduced to the family, this is established.
Part 2 End of the FDC debrief.	When the FDC is ended, the facilitator enters the room. Feedback is sought from the family in character, to garner initial reactions and emotions, and the participant is encouraged to question the family. Then, at the discretion of the facilitator, the family and nurse are directed to come out-of-character, and offer further feedback. Once the initial debrief is complete the actors leave the room.
Part 3 Facilitated video-reflexive feedback.	The observer and the subject matter expert enter the debriefing area. A final facilitated debrief uses a video-reflexive technique to trigger participants' insight and reflection on practice. Annotations/notes on the A-V recording are used as discussion points between the facilitator, subject matter expert, observer and participant. Standardized criteria are used to guide achievement of key learnings from the national FDC workshops. A digital file of the video recording is provided for the participant's personal ongoing reflection.

Figure 2. The debriefing process. A-V indicates audiovisual; FDC, family donation conversation.

R.M.E.) who were not involved in the development or delivery of the program performed the primary analysis. The items and responses were read repeatedly. Initially, common content within the responses was identified and coded using key words. Similar or related words were confirmed in a thesaurus and grouped into categories manually by one researcher (R.M.E) and using NVivo 10 for Windows Software (©QSR International Pty Ltd. Version 10, 2012) by another (J.E.P.). Responses were reread and the frequency that each category occurred was counted. Responses and key words were reread some days after the initial content analysis to check for inconsistencies; none were found.

To reduce potential bias, the analysts were blinded to respondents' designation and gender. To support credibility of the analysis, the selection of categories was identified independently and then discussed and agreed, with any disagreements settled in consultation with a third author (L.P.).

Table 1. Characteristics of Workshop Evaluation Respondents.

Characteristic	Total (n = 82)
Female, No. (%)	41 (50.0)
Intensivist, No. (%)	44 (53.7)
Intensive care nurses and social worker,[a] No. (%)	38 (46.3)
Attended workshop on 1 occasion, No. (%)	66 (80.5)
Attended workshop twice, No. (%)	13 (15.9)
Attended workshops 3 or more times, No. (%)	3 (3.6)

[a]Only 1 social worker attended.

Results

Twenty-five simulation workshops were conducted between January 2013 and July 2015. Eighty-six health professionals were invited and participated; 82 (95.3%) returned an evaluation form with few incomplete responses. Respondents were practicing health professionals; more than half (n = 44; 53.7%) were intensivists (denoted as "M"; nurses as "N"; social workers as "SW"; Table 1). The majority attended a single workshop.

All workshops were delivered without any participant withdrawing from any component. The simulated donation conversations lasted on average 40 minutes; most were effectively managed by the DRs with a few requiring facilitator input to bring the conversation to a timely close.

Quantitative evaluation was overwhelmingly positive. The respondents rated the simulation workshop highly (78/81; 96.3%) and agreed that it complemented and built on the PEP. Nearly all (78/79; 98.7%) agreed that it was valuable or necessary training for the DR role. Most (76/78; 97.4%) subsequently felt more confident to be a DR. Expectations of the training were well-met, and rated as outstanding (63/80; 78.8%) or good (17/80; 21.3%).

Qualitative evaluation was predominantly positive. Three respondents disagreed that the simulation workshop built on national training but commented that it "... stands alone in its own right" (M), and "may be helpful for someone starting out but not for experienced clinicians" (M). Personal insights from the simulation workshop included that:

> ... It is possible that the CORE and Practical sessions affected my practice in some ways. I think I will be more self-conscious of my performance after the simulation session. (M)

Three respondents who did not respond to the value of simulation training commented positively (2 respondents) and the other stated a preference for mentorship by experienced clinicians: "A single session in isolation is interesting, but a larger group forum with senior colleagues would be more useful" (M). One respondent, whose confidence did not improve, felt they had learnt a lot about communication.

All respondents gave examples of what they liked most. The main categories identified were feedback, use of professional actors, and realism (Table 2).

For the "feedback" category the value of the actors' feedback was specifically highlighted: "The FB [sic] from the

Table 2. Categories of Elements Liked Most in the Simulation Workshop.

Category and Subcategory	Count[a]
Feedback: person providing it, quality, topic, debriefing, video playback	55
Use of professional actors	47
Realism/high-fidelity scenarios	44
Opportunity to practice/usefulness	20
Setting: organization, safe learning environment	10

[a]Count equals the number of times referred to.

Table 3. Categories of Elements Liked Least in the Simulation Workshop.

Category and Subcategory	Count[a]
Nothing	22
Performance anxiety	13
Being watched by self and others	12
Setting: practical considerations	12
Feedback	3
Actors	2
Processes	2

[a]Count equals the number of times referred to.

actors both in character and out of character was exceptional" (M & N). The quality of feedback overall was rated as good to excellent: "Good feedback, very helpful debriefing sessions, and ability to relate to peers" (M). Respondents valued this feedback because of their respect for the experts providing it: "Excellent feedback from experienced educators" (M). The topics covered included key elements of the national education, for example: "... the use of certain language or expansions" (M, SW). Participants appreciated the constructive manner in which it was delivered: "Peer debriefing was safe and constructive" (N). Personal insights were gained from feedback with video playback: "Debrief with video. Really unnerving seeing myself in action. Will make me think" (M).

For the use of professional actors category, their ability to portray an actual family's reactions, thereby immersing respondents in the unfolding scenario was flagged: "The realistic scenario and how you forgot that they were in fact actors but a family going through this conversation" (N); "The actors are exceptionally realistic. I had absolutely no problem engaging with them as if they were a real family. I enjoyed watching the scenarios of others" (M).

For the category of realism, the similarities of the scenarios to real situations was reiterated: "The scenarios were very realistic and the actors were very professional" (M); with tolerance for some loss of fidelity: "... not perfect but as close as you can get!" (M).

Other categories were opportunities to practice and the setting. Opportunities to practice mainly related to skill development: "Excellent realistic practice with good skill consolidation" (M). This allowed practice in responding to displays of emotion: "Realistic, with emotions and tears. Good to practice comments" (M). The workshop setting was a suitable place for learning, "Away from hospital, well set out and well managed as a collegial nonthreatening exercise" (M). Seven respondents made similar comments.

Most respondents (66/82; 80.5%) detailed what they liked least (Table 3). For many this was nothing, reflecting the overall positive evaluation. Performance anxiety, being watched, and the setting were raised.

Performance anxiety occurred before and during the workshop: "Anxiety and apprehension on my part before participation" (M); "... people around you and observing you is nerve racking" (N). Many disliked watching themselves on video. The inconvenience of locating the workshop in the city and the room design was raised. Personal reactions to criticism were highlighted: "I don't take criticism well, but I understand and value it" (M). Finally, the unpredictability of actor reactions was raised and a few participants had difficulty engaging in the observer role.

Fifty-nine participants (72%) made suggestions for future developments. Half related to providing more sessions such as annual refreshers or repeat attendance. More difficult scenarios that included family disagreement, pediatric cases, and donation after circulatory determination of death were also suggested. Feedback suggestions included providing real-time feedback from a facilitator while watching the alternate scenario and creating a montage of the best aspects discussed at some of the simulations.

Discussion

We developed this simulation program to prepare intensivists, DSNs, and social workers involved with donation conversations to undertake the DR role. Participants' evaluations were overwhelmingly positive with most agreeing the program was valuable, complemented the PEP, and increased their confidence as a DR. Debriefing with actors in and out of character was viewed as powerful and a rare opportunity for appraisal of one's performance during an emotional conversation with a family member in acute grief. The video-reflexive feedback was especially useful in identifying areas for improvement in requesters' body language, phraseology, and pace of conversation. Aspects least liked related to performance anxiety, the observer role, and being observed. These results support the use of simulation training to increase the preparedness of experienced clinicians as DRs.

This study examined participants' opinions of rehearsing the donation conversation using the balanced approach in actual, deidentified potential organ donor scenarios with a comprehensive debriefing process. Other programs have also used feedback from peers and facilitators on performances in role-play of hypothetical scenarios with professional actors for communication training for multidisciplinary groups of clinicians exposed to difficult organ donation and end-of-life conversations in adult and pediatric populations previously.[1,21-24] As in this study, participants reported simulation resulted in better preparation and greater confidence immediately posttraining and 5 months later.[23] The ICU consultants showed improved sensitivity to relatives' needs when conveying news of death and raising organ donation at 6 months posttraining.[24]

Feedback from actors has been obtained using questionnaires or rating scales and sought directly during workshops and included in evaluations.[21,22] In England, videotaped recordings of 64 ICU consultant–nurse pair encounters during hypothetical scenarios were independently rated.[24] Videotaped recordings have also been used to highlight improvements in communication techniques in a group feedback session.[21] A similar program, a 1-day educational intervention on communicating about organ donation used real-time critique of videotaped performances of organ procurement coordinator participants and additional expert debriefing of the simulation, has recently been reported.[1] Key to the effectiveness of these feedback methods for learning was the creation of a safe environment.

Outcome measures have included consent rates for organ donation; an increase of 9.2% over 2 years after the intervention has been achieved.[1] In Australia, organ donation consent rates have increased by 3% over 2 years following introduction of the PEP.[8] Participation in the simulation program, focusing on enhancing communication approaches combined with video-reflexive debriefing may increase the skills and preparedness of specialist requesters and further contribute to increased organ donation consent rates.

Participant evaluations of learning experiences of role modeling and the observer role have varied across jurisdictions. For example, in the European Donor Hospital Education Program workshops (United Kingdom), significantly higher learning was reported by those who actively role-played a doctor or a nurse compared to those who observed. This result contrasted with the findings from the Netherlands where there was no difference in learning between those who role-played and those who observed.[25] These differences may have been a result of experiences from previous training or requesting, or an effect of the level of participation (dose) in scenarios. Preparation of the observer participants and how they contributed to the debriefing was discussed with a view to enhancing observer engagement during the simulation and debriefing. This is a growth area in simulation as the benefits of vicarious learning are clear and worth enhancing in the simulation program.[26,27]

The program had a number of strengths. The authenticity of the experience was universally appreciated; actors' expertise immersed participants in the scenarios. Real-life (deidentified) scenarios based on local case mix, policies, and procedures were fundamental to the authenticity. The simulation program was designed to enhance realism and maximize the time available to rehearse the FDC. The multidisciplinary training approximated the clinical environment and fostered collaboration between disciplines in support of bereaved families.

The program has some limitations. The workshops took place in a university simulation laboratory rather than in a clinical setting, and while the actors' performances were excellent, the realism of the surroundings was not perfect. Inevitably, the actors knew that organ donation would eventually be raised, and it was a challenge for some to "reset" and remember specific dialogue in each scenario. Evaluation of simulation workshops using self-report questionnaires is open to subjectivity and bias. However, grasping a sense of the impact of the simulation on individuals' sense of professional practice is important for program evaluation, and this is an established, low-cost approach.

Evaluation of such programs is essential, both in the clinical environment and from the perspective of relatives who ultimately are the most affected by the quality of communication by health professionals. Furthermore, factors affecting participation of experienced health professionals in communication skills training and adoption of alternative requesting approaches require investigation. The addition of a validated rating form such as the multirater communication skills instrument with gap analysis may increase the robustness of self-appraisal and enable monitoring of learning over time.[28] The program is ongoing with a specific focus on exploring how the outcomes of the simulation program influence clinicians' practice and, ultimately, family experiences and rates of family decline to organ donation. Evaluation of the program in clinical practice is being undertaken in a multicenter study in NSW, Australia.[29]

Conclusions

We developed and delivered a highly effective and well-received simulation program that provided an opportunity to refine communication skills and techniques to increase the confidence of health professionals leading the donation conversation. Participants identified that skills learned in this program and the opportunity to rehearse conversations in realistic scenarios greatly enhanced their confidence. Overall, it is anticipated that this specialized and targeted training for DRs will contribute to enhanced donation conversations conducted by clinicians with greater skills and confidence, achieving improved family experiences of this difficult situation and subsequently increased consent rates for organ and tissue donation in NSW.

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Statement of Informed Consent

Evaluation material provided data for ongoing review of teaching and content of the simulation program (SP). The human research ethics committee approval was not required for this educational activity; however, advised notifying participants of the use of their completed evaluation forms for publication and provide them an opportunity to decline the use of their deidentified data. All participants had previously volunteered their names on the evaluation forms and investigators provided individuals with e-mailed information for informed consent. No participant declined the use of his or her evaluation material included in the study. All participants signed a confidentiality agreement and consent for audiovisual recording before each workshop. Actors signed a confidentiality and media agreement annually.

Declaration of Conflicting Interests

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Supplemental Material

Supplementary material for this article is available online.

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Appendix 3: Supplemental Material

A case example: Donation after circulatory determination of death.

"Sam" is a 24-year-old male with a large subdural hemorrhage and base of skull fracture following an unprovoked assault that has received national media attention. Family members present in the hospital are his parents and twin brother. The family is in shock by this unexpected and public event. The managing intensivist considers progression to brain death unlikely; therefore, donation after circulatory determination of death is to be discussed with the family. The family members have several concerns that need to be addressed before they will consent to donation.

Appendix 4: Published Manuscript – Findings for the Unregistered Subsample

ORIGINAL ARTICLES

Communication with Families Regarding Organ and Tissue Donation after Death in Intensive Care (COMFORT): a multicentre before-and-after study

Julie E Potter, Lin Perry, Rosalind M Elliott, Anders Aneman, Jorge L Brieva, Elena Cavazzoni, Andrew TH Cheng, Michael J O'Leary, Ian M Seppelt, Robert G Herkes and the COMFORT study investigators

Consent rates for deceased organ donation in Australia have varied from 54% to 61% over the past decade,[1] remaining below the espoused community support for donation.[2] Evidence from observational studies, predominantly from the United States, suggests that higher consent rates are achieved when specific organ procurement organisation personnel, rather than the treating health care teams, request donation.[3-6] In Australia, education in communication skills for raising donation had been included in a one-day donor awareness program, but that training alone may be insufficient preparation for family donation conversations (FDCs). Specialised communication education for health care professional requesters (ie, intensive care specialists, such as intensivists, consultants, advanced trainees and Fellows; critical care nurses; and social workers) was a national initiative from October 2011.[7,8] In New South Wales, from January 2013, this initiative was enhanced with simulation-based FDC training.[9]

In Australia, organ donation requests have traditionally been initiated by the treating intensivist,[10,11] but this practice has limitations. Even in busy intensive care units (ICUs), organ donation opportunities are uncommon; many intensivists (42%) conduct less than four FDCs each year.[10] FDCs can be lengthy, which may be problematic for intensivists responsible for other critically ill patients. Moreover, families might perceive that the intensivist may have a conflict of interest when they are responsible for patient treatment alongside identifying and managing potential organ donors.[12]

In this study, we evaluated the implementation of a best-practice approach to FDCs in the hospital setting to test the hypothesis that the Communication with Families Regarding Organ and Tissue Donation after Death in Intensive Care (COMFORT) intervention[13] increased family consent rates. Only donor-eligible patients who had not recorded their organ donation preference or who were aged ≤ 16 years were included because evidence suggests that registration is associated with consent.[14,15]

Methods

We conducted a multicentre before-and-after intervention study in nine ICUs in NSW, Australia, between 1 November 2012 and 8 July 2016. Sites included seven metropolitan

ABSTRACT

Objective: To implement a best-practice intervention offering deceased organ donation, testing whether it increased family consent rates.
Design: A multicentre before-and-after study of a prospective cohort compared with pre-intervention controls.
Setting: Nine Australian intensive care units.
Participants: Families and health care professionals caring for donor-eligible patients without registered donation preferences or aged ≤ 16 years.
Intervention: A multicomponent intervention including offers of deceased organ donation from specially trained designated requesters using a structured conversation separate to end-of-life discussions.
Main outcome measure: Proportion of families consenting to organ donation.
Results: Consent was obtained in 87/164 cases (53%) during the intervention period compared with 14/25 cases (56%) pre-intervention ($P = 0.83$). The odds ratio (OR) of obtaining consent during the intervention period relative to pre-intervention was 1.13 (95% CI, 0.48–2.63; $P = 0.78$). During the intervention period, designated requesters obtained consent in 55/98 cases (56%), compared with 32/66 cases (48%) in which the medical team managing patient care raised donation ($P = 0.34$). Factors independently associated with increased consent were: family-raised organ donation (OR, 4.34; 95% CI, 1.79–10.52; $P = 0.001$), presence of an independent designated requester (OR, 3.84; 95% CI, 1.35–10.98; $P = 0.012$), and multiple donation conversations per case (OR, 3.35; 95% CI, 1.93–5.81; $P < 0.001$). Consent decreased when patients were of non-Christian religion (OR, 0.18; 95% CI, 0.04–0.91; $P = 0.038$) and end-of-life and donation meetings were separate (OR, 0.38; 95% CI, 0.16–0.89; $P = 0.026$).
Conclusion: Implementation of a multicomponent intervention did not increase consent rates for organ donation, although some components of the intervention exerted significant effect.
Trial registration: Australian New Zealand Clinical Trials Registry: ACTRN12613000815763. ClinicalTrials.gov: NCT01922310.

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Box. Components of the Communication with Families Regarding Organ and Tissue Donation after Death in Intensive Care (COMFORT) intervention

No.	Description of each component of the intervention
1	Organ donation conversations were the responsibility of a designated requester[13]
2	Designated requesters were experienced ICU health care professionals who had completed the educational core (2 days) and practical (one day) programs,[18,19] followed by the NSW simulation-based workshop (half day)[9]
3	The offer of organ donation was separated from end-of-life family meetings[6]
4	If families mentioned the topic of organ donation prior to it being introduced in an FDC, the conversation was sensitively deferred to the designated requester[20]
5	Donation conversations were conducted within a structured family meeting.[21-23] Key features included: a pre-conversation multidisciplinary action plan; FDC held in a private location; FDC led by the designated requester (as above) with the managing intensivist leaving the conversation (at their discretion)[13]
6	The requester used a balanced approach during the FDC, including providing families with information on the benefits of donation for themselves and recipients.[8] Requesters encouraged active participation of family members in the conversation by using communication techniques such as open-ended questions, silence and showing empathy[24,25]

ICU = intensive care unit. FDC = family donation conversation. NSW = New South Wales.

teaching hospitals, a tertiary paediatric hospital and a major regional hospital. The metropolitan hospitals included the specialties of neuroscience and trauma, and three offered transplantation services. At each site, the intervention period (1 May 2013 – 8 July 2016) began after the initiation visit. The control period (1 November 2012 – 29 July 2014) included aggregated donation events from the 6 months pre-intervention at each site. The study protocol is published elsewhere;[13] this article reports the outcomes for the primary cohort — that is, donor-eligible patients who had not recorded their donation preference on the Australian Organ Donor Register or their NSW driver's licence or who were aged ≤ 16 years.

Participants were the families of critically ill patients who were treated in the ICU and were considered potential deceased organ donors (patients) and the health care professionals involved in each organ donation event (per patient). Excluded patients were those not medically suitable for deceased organ donation,[16] had no senior next-of-kin able to participate in FDCs[17] who could have provided first person consent, or were only eligible for tissue donation.

St Vincent's Hospital Sydney Human Research Ethics Committee approved this study (HREC/12/SVH/271), with the approval ratified by the University of Technology Sydney Human Research Ethics Committee (reference no. 2013000133). The intervention was determined a quality improvement initiative.

Intervention

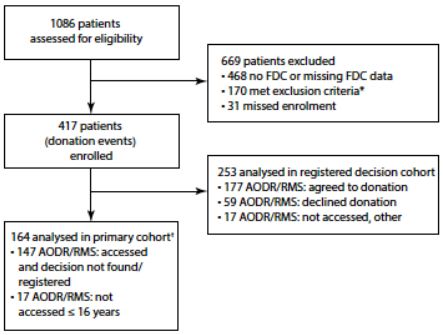
The COMFORT intervention incorporated six best-practice components for offering organ donation in the hospital setting[13] (Box).

Procedures

Staff undertaking the designated requester role at each site, mostly intensivists and donation specialists, implemented the intervention locally. Communication training for designated requesters continued throughout the pre-intervention and intervention study periods.

During the intervention period, the ICU managing team was responsible for the primary communication with families regarding death and end-of-life care and for the identification of potential organ donors. The approach to each family was planned with the donation specialist or designated requester as described above. Before the intervention, health care professionals raised organ donation according to usual practice at each site: generally, the managing intensivist or ICU registrar requested the organ donation.[10,26]

Figure 1. Screening and enrolment of patients in the period of intervention



AODR = Australian Organ Donor Register. FDC = family donation conversation. RMS = Roads and Maritime Services Registry. * Exclusion criteria (number of patients): not medically suitable (140), only eligible for tissue donation (20), unavailable next of kin or first person consent (ten). † Includes patients who were subsequently ineligible for organ donation after the FDC (ten).

Data collection

The data collection timeline for the pre-intervention and intervention periods at each site appears in Appendix 1 (online at cicm.org.au/journal.php).

During the intervention period, donation specialist nurses collected patient and requester demographic data, FDC characteristics, and staff adherence to intervention components. For the pre-intervention period, donation event referral data were extracted from the NSW Organ and Tissue Donation Service databases. Variables were limited to the data collected using standardised methods, patient demographic data, donor registry preferences and FDC outcomes.

The NSW Organ and Tissue Donation Service performed source data verification of registered donation preferences for the primary cohort in 100% of cases for both study periods. In the intervention period, depiction of events was verified contemporaneously in discussions with the donation specialist nurses and requester so deviations were captured accurately.[27] The study management committee adjudicated cases found to be not medically suitable (ineligible) for organ donation subsequent to the FDC.

The primary end point for the study was the next of kin (family) consent rate for organ donation. Secondary end points included identification of predictors of the donation decision.

Statistical analysis

The sample size calculation was performed using Simon's two-stage design,[28] requiring 140 eligible FDCs. This sample size had 80% power (95% confidence interval [CI]) to detect a relative increment of 11% in the consent rate of the intervention group.[13] All analyses were performed on an intention-to-treat principle. Inferential analysis tests were two-sided with α set at 0.05. Patient, requester and FDC characteristics were reported by case.

The primary end point of consent for donation (agreed or declined) was analysed using the χ^2 or Fisher's exact test. Continuous variables were compared using unpaired Student *t* tests or the Mann–Whitney U test. Data were assessed for normality and log-transformed where appropriate. Binary logistic regression was used to explain the impact of relevant context, patient data, and intervention adherence on the probability of consent.

Results

Over the intervention period, there were 417 eligible patients (entire study cohort), with 164 patients in the primary cohort (Figure 1). In the pre-intervention period, 135 patients were screened; of these, 25 patients met the criteria for the primary cohort.

Demographic characteristics of the patients and requesters (per case) in the intervention period are set out in Table 1 and Table 2, respectively. In the pre-intervention period, the average patient age was 43 years (range, 0.8–

Table 1. Clinical and demographic characteristics of patients (intervention period)

Characteristic	Value
Number of patients	164
Male sex	100 (61%)
Age in years, mean (SD), (range)	45 ± 22 (0.3–88)
Age (years), categories	
≤ 16	17 (10%)
17–70	127 (77%)
≥ 71	20 (12%)
Country of birth: Australia	114 (70%)
Ethnicity	
Australian or New Zealander	96 (59%)
Aboriginal or Torres Strait Islander peoples	10 (6%)
Māori or Pacific Islander peoples	6 (4%)
East Asian	21 (13%)
Other and mixed ethnicities*	31 (19%)
Religious affiliation†	
Christianity	88 (54%)
No religion or non-religious beliefs	57 (35%)
Other religions‡	17 (10%)
Death determined by neurological criteria (brain death)	86 (52%)
Cause of death	
Intracranial haemorrhage	57 (35%)
Cerebral hypoxia/anoxia	51 (31%)
Traumatic brain injury	36 (22%)
Cerebral infarction/other neurological	14 (8%)
Non-neurological	6 (4%)
Donation outcome	
Actual donor after brain death§	53 (32%)
Actual donor after determination of circulatory death¶	28 (17%)
Non-donor	83 (51%)
Patient duration of stay in ICU to FDC (hours), median (IQR)**	43 (20–106)
Patient length of stay in ICU to death (days), median (IQR)	2.2 (0.9–5.0)

FDC = family donation conversation. ICU = intensive care unit. IQR = interquartile range. SD = standard deviation. * Mixed ethnicities are Australian or New Zealander and another for four patients. † Missing for two patients. ‡ Includes Buddhism, Islam, Hinduism, Judaism, Baha'i, Druze, Māori faith and Sikh. § Includes five patients who did not proceed to procurement surgery. ¶ Includes ten patients who did not proceed to procurement surgery. ** Missing for two patients.

Table 2. Characteristics of requesters for the first family donation conversation (FDC) (intervention period)

Demographic characteristics of requesters	Number (proportion)
Number of requesters by donation event	164
Male sex	116 (71%)
Age (years)*	
≤ 34	5 (3%)
35–54	125 (78%)
≥ 55	30 (19%)
Country of pre-registration training,† Australia	67 (41%)
Length of time working in ICU, years	
5–10	57 (35%)
11–15	39 (24%)
≥ 16	68 (41%)
Designation of health care professional leading the first FDC	
Intensivist (DR)‡	75 (46%)
Intensivist (managing the patient)	60 (37%)
Donation specialist nurse (DR), social worker (DR)	23 (14%)
Other health care professional (managing the patient)§	6 (4%)
Total of actual FDCs led by health care professionals	
1	18 (11%)
2–4	59 (36%)
≥ 5	87 (53%)

DR = designated requester. FDC = family donation conversation. ICU = intensive care unit. * Missing for four cases. † Missing for one case. ‡ Includes 52 cases of intensivists who were also a donation specialist. § Includes four cases of ICU registrars, two cases of social workers, one case of an ICU nurse.

77 years). Twelve patients (48%) were male, 16 (64%) had death certified by neurological criteria (brain death), and for nine (36%) death was caused by traumatic brain injury.

The intervention

For intervention components 1 and 2, designated requesters led the first FDC in 98/164 patients (60%), and for 46/164 patients (28%) these were independent of the managing team. Most designated requesters (97/98) had completed the educational core, practical and simulation training, while many managing teams had received some form of organ donation communication training (Table 3).

Adherence to component 3 — separation of the FDC from the end-of-life meeting — occurred in 99/164 cases (60%). Health care professionals raised organ donation before the first FDC in nine cases (5%).

Uptake of component 4 — deferral of family offers of donation — was high. Families offered donation before health care professionals introduced the topic in 50/164 patients (30%), half before the first FDC. Offers made before the FDC were sensitively deferred to a designated requester in 23/25 patients (92%).

The delivery of key features of component 5 varied. Of the 164 patients, 127 (77%) featured a multidisciplinary pre-FDC planning meeting, and 158/164 FDCs (96%) were held in a private location. The first FDC was attended by, on average, three (range, 1–8) health care professionals and four (range, 1–26) family members. A donation specialist nurse met the family in 111/164 cases (68%).

For component 6 — balanced approach — requesters mentioned the benefits of donation for 79/164 patients (48%) and the rare opportunity of organ donation for 107/164 (65%) (Table 3). Requesters enquired if families knew the patients' donation wishes in 90/164 cases (55%).

Intervention components associated with the organ donation decision in bivariate analyses are depicted in Table 3. Consent rates were higher but not significantly different when a designated requester, rather than a managing intensivist, led the FDC ($P = 0.34$). When the designated requester was independent of the managing team, consent was obtained in 28/46 cases (60%) ($P = 0.19$). Some components were associated with significant differences in consent rates: decreased consent with separation of the FDC from the end-of-life death meeting ($P = 0.04$), and increased consent with families mentioning donation before health care professionals ($P < 0.01$).

Patient demographic and clinical characteristics associated with donation decisions are set out in Table 4 and Table 5. Significantly lower consent rates were associated with patients' religious affiliation ($P = 0.003$) and circulatory death ($P = 0.009$). There were no associations with staff characteristics.

Primary end point

Consent was provided in 87/164 cases (53%) (95% CI, 0.45–0.61) in the intervention period, and in 14/25 eligible cases (56%) (95% CI, 0.37–0.74) pre-intervention ($P = 0.83$). The OR of consent in the intervention period relative to the pre-intervention period was 1.13 (95% CI, 0.48–2.63; $P = 0.78$). In patients aged ≤ 16 years, consent was obtained for 8/17 cases (47%) (95% CI, 0.23–0.72).

Secondary end point

Logistic regression analysis revealed six characteristics independently associated with family consent to organ donation. When the family raised organ donation before a health care professional offer, when the FDC was led by a designated requester independent of the managing team, and when more than one FDC occurred were each associated

Table 3. Association of intervention components 1–6 with the donation decision

Component	Final decision		Bivariate test	
	OD agreed	OD declined	χ^2 statistic	*P*
1. HP leading the FDC			0.92	0.34
Designated requester (DR)	55/98 (56%)	43/98 (44%)		
Managing team	32/66 (48%)	34/66 (52%)		
2. Communication training			1.07	0.58
Completed all training (DR)*	54/97 (56%)	43/97 (44%)		
Some workshops (core, practical)†	12/27 (44%)	15/27 (56%)		
ADAPT, other communication training‡	21/40 (52%)	19/40 (48%)		
3. Separation of end-of-life and FDC			4.34	0.04
Yes, separated	46/99 (46%)	53/99 (54%)		
No, OD mentioned in the same meeting	41/65 (63%)	24/65 (34%)		
4. Family raised OD before a HP			12.68	< 0.01
Yes	37/50 (74%)	13/50 (26%)		
No	50/114 (44%)	64/114 (56%)		
5. Structured family meeting				
Pre-FDC action plan occurred	66/127 (52%)	61/127 (48%)	0.26	0.61
FDC held in a private location	83/158 (53%)	75/158 (48%)	—	0.68§
6. Balanced communication				
HP mentioned the benefits of OD	42/79 (53%)	37/79 (47%)	—	0.02§
Family mentioned the benefits of OD	10/11 (91%)	1/11 (9%)		
HP mentioned the rare opportunity of OD	53/107 (50%)	54/107 (50%)	—	0.18§
Family mentioned the rare opportunity of OD	4/5 (80%)	1/5 (20%)		
HP mentioned knowledge of the patient's OD wishes	47/90 (52%)	43/90 (48%)	0.64	0.42
Family mentioned the patients' OD wishes	13/21 (62%)	8/21 (38%)		

ADAPT = Australasian Donor Awareness Program. DR = designated requester. FDC = family donation conversation. HP = health care professional. OD = organ donation. * Educational core and practical program, New South Wales simulation workshop. † Includes one DR who completed the national core workshop only. ‡ Nil communication training for six cases: two in agreed group and four in declined group. § Fisher's exact test.

with increased family consent; whereas the patient being of a non-Christian religion, there being a separation in time between the end-of-life conversation and the FDC, and the patient spending a longer time in the ICU before the FDC were associated with reduced consent (Table 6). The Hosmer–Lemeshow goodness of fit test showed that the model was well calibrated ($P = 0.47$).

Discussion

In this study examining implementation of a best-practice multicomponent intervention, we found no difference in family consent rates during the intervention compared with pre-intervention periods. In the intervention period, although most health care professionals adopted key components of the intervention required before the FDC, best-practice components of the FDC itself were often omitted. The study highlights the difficulty of implementing a complex behavioural intervention that disrupts habitual ways of working.

Despite the low uptake of parts of the intervention, we identified two components independently associated with an increased probability of consent: the use of a designated requester independent of the managing team and holding more conversations per patient. We found that separation of the communication of end-of-life from the FDC reduced the probability of consent.

Our results support findings from previous studies describing positive associations between the amount of time spent with families by independent personnel from organ procurement organisations and trained ICU nurses on consent rates.[20,25,29,30] Unexpectedly, we found that separation of end-of-life and donation conversations was associated with reduced probability of consent. This may suggest that families prefer continuity of care through end-of-life processes,[31] but it is also possible that in our study, simulation-based training may have increased requesters' knowledge and confidence to continue FDCs.[9,25]

Table 4. Association of patient characteristics with donation decision

	Final decision		Bivariate test	
	OD agreed	OD declined	χ^2 statistic	*P*
Number of patients	87	77		
Male sex	53 (53%)	47 (47%)	0.00	0.99
Age in years, mean (SD), (range)	44 ± 21 (0.8–87)	47 ± 23 (0.3–88)	—	0.44
Born in Australia	60 (53%)	54 (47%)	0.03	0.87
Ethnicity: Australian or New Zealander*	58 (60%)	38 (40%)	5.04	0.02
Religious affiliation†			11.86	0.003
Christianity	45 (51%)	43 (49%)		
No religion or non-religious beliefs	37 (65%)	20 (35%)		
Other religions	3 (18%)	14 (82%)		
Certification of death			6.89	0.009
Neurological criteria (brain death)	54 (63%)	32 (37%)		
Circulatory criteria	33 (42%)	45 (58%)		
Causes of death‡			1.91	0.12
Traumatic brain injury	23 (64%)	13 (36%)		
Other neurological	62 (51%)	60 (49%)		

FDC = family donation conversation. ICU = intensive care unit. OD = organ donation. SD = standard deviation. * Other includes mixed ethnicity of Australian or New Zealander and another for four patients: three in agreed group, one in declined group. † Missing for two patients in agreed group. ‡ Excludes six patients with a non-neurological cause of death.

Table 5. Comparisons of clinical and family donation conversation

	Final decision		Bivariate tests*
	OD agreed	OD declined	*P*
Number of patients	87	77	
Patient duration of stay in ICU to FDC in hours, median (IQR)†	30 (17–107)	56 (24–106)	0.05
Individual FDC duration in minutes, mean (SD), (range)‡	30 ± 13 (5–75)	28 ± 19 (1–120)	0.41
Number of FDCs to final decision, mean (SD), (range)	2.2 ± 0.9 (1–5)	1.5 ± 0.8 (1–5)	< 0.01
Total time, FDC start to final decision in hours, median (IQR)§	4.0 (1.9–14.5)	0.6 (0.4–1.3)	< 0.01
Patient length of stay in ICU to death in days, median (IQR)	1.9 (0.9–5.1)	2.5 (1.1–4.9)	0.31

ICU = intensive care unit. IQR = interquartile range. OD = organ donation. SD = standard deviation. * Independent samples Student *t* test and Mann–Whitney U test. † Missing for two patients: one patient in agreed group, one in declined group. ‡ Missing for one patient in agreed group. § Missing for one patient in agreed group.

Previous studies have been conflicting on the benefits of separation, with one study also finding that consent may be less likely when a gap in time separates conversations.[14] Others, however, have described consent as being more likely when donation conversations are separated from meetings to break news of brain death,[6,32] and recent guidelines recommend waiting to offer donation after the declaration of brain death.[33-35] Other experts do not think this necessary.[36] These disparities may reflect important contextual or cultural influences affecting the capacity of families to accept end-of-life situations, including differential responses to death determined by neurological versus circulatory criteria.

Despite the low adherence, our data confirm observational findings from Australian ICUs that independent designated requesters increase the probability of consent.[14] An independent

Table 6. Association of patient, context and intervention characteristics with family consent for organ donation (multivariate logistic regression analysis)

Characteristics	Odds ratio (95% CI)	*P*
Patient religion		
No religion, non-religious beliefs	1	
Christianity	0.59 (0.26–1.33)	0.201
Non-Christian	0.18 (0.04–0.91)	0.038
Duration of stay in ICU, admission to FDC (hours)	0.70 (0.50–0.98)	0.037
Number of FDCs to final donation decision	3.35 (1.93–5.81)	< 0.001
FDC: intervention components		
1. Managing team leading the FDC	1	
Designated requester leading the FDC (independent of team)	3.84 (1.35–10.98)	0.012
Designated requester leading the FDC (managing team)	1.19 (0.47–3.00)	0.714
3. Separation of news of death and FDC	0.38 (0.16–0.89)	0.026
4. Family offered donation before HP	4.34 (1.79–10.52)	0.001

CI = confidence intervals. FDC = family donation conversation. HP = health care professional. ICU = intensive care unit.

designated requester is probably better able to allow families greater opportunity to explore complex concepts through multiple conversations, providing continuity despite not managing patient treatment.

Only one randomised controlled trial evaluating a change in practice approach to donation conversations has been reported. The British ACRE (Assessment of Collaborative REquesting) study found that consent rates did not increase when the managing intensivist was accompanied by a donor transplant coordinator for the donation conversation; however, this requirement was not adhered to in almost one in four cases.[37] Our study was similarly challenged: incomplete uptake within each participating ICU was evident in the low adherence rates for many intervention components, particularly for transfer of leadership of the FDC to a designated requester colleague. Non-adherence may reflect the effect of the intensivists' workload or their resistance to change.[38] Despite the NSW simulation-based training being well received,[9] it appeared to have a limited effect to facilitate practice change.

This was a pragmatic study based on the implementation of a real-world strategic program to modify standard practice for FDCs. The prospective recording of clearly described components of the intervention with minimal loss of data affords confidence in study findings. We enrolled all patients considered donor-eligible when the first FDC occurred, irrespective of whether they proceeded to actual donation, thereby minimising potential selection bias.

Limitations of this study include the small size of the pre-intervention control sample, and the potential impact on the consent rate of the nationally delivered educational program. Inadequate documentation of donation events pre-intervention meant some may have been missed, and may have limited the determination of FDC timing and donor eligibility status. The consent rate (56%) was higher than had been anticipated in this cohort, much greater than the estimate of 29%[13] that had determined sample size. Consequently, our study design may have been underpowered. Nationally, a consent rate of 56% for unregistered donor-eligible patients was also reported over a similar time period.[39] Usual practice may have already been shifting towards the intervention, potentially diluting any possible effect. Furthermore, limited time was available to confidently embed the new practice before it was evaluated.

In Australia, a recent guideline for conducting FDCs recommends that specially trained requesters offer organ donation; ideally, an individual separate to the managing team.[33] As indicated in this study, it is probable that hospitals may struggle to ensure all FDCs are led by a trained requester, especially as a separate individual. Implementation strategies additional to just the provision of training for donation specialists are required.

Standardising implementation, training and evaluation of end-of-life communication in real time may improve clinician skills but will require broader culture change in many ICUs to have an effect on donation consent.[40] Future research in optimising family consent should include examination of ICU cultural barriers to local adoption of evidence-based interventions, and elucidate the role of separating end-of-life and donation conversations.

In conclusion, we were unable to demonstrate an overall effect of the implementation of a multicomponent intervention for health care professionals to increase rates of family consent to organ donation in nine ICUs. Adherence to many components of the intervention was low. Nonetheless, some components of the intervention were associated with consent rates, providing important information to support future practice improvement.

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Competing interests

None declared.

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Authorship

RGH instigated the project and with JEP developed the original concept of an independent designated requester for the COMFORT intervention, and was the NSW Coordinating Investigator.
The COMFORT writing committee: MJ O'Leary (Chair) (MJOL), A Aneman (AA), JL Brieva (JB), E Cavazzoni (EC), ATH Cheng (ATHC), RM Elliott (RE), RG Herkes (RGH), L Perry (LP), JE Potter (JEP) IM Seppelt (IMS).
JEP wrote and revised all drafts, and together with LP, RME, AA, JLB, EC, ATHC, RGH, MJOL and IMS interpreted data analysis and revised drafts critically for important intellectual content.
All authors made substantive contributions to the study conception and design as members of the COMFORT study management committee and as principal investigators.
All authors read and approved the final manuscript.

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Appendix 5: Case Report Form 1 Site Details

COMFORT Study	Form 1	Centre No:	|__| |__|

Form 1: Setting: site details		
Structure		
1.1	Number of hospital beds	|__| |__| |__|
1.2	Number of funded ICU beds	|__| |__|
1.3	Number of open ICU beds	|__| |__|
1.4	Number of single patient rooms in the ICU	|__| |__|
1.5	Number of waiting rooms	|__| |__|
1.6	Number of private rooms specifically for family meetings	|__| |__|
Patients		
1.7	Categories of patients admitted to the ICU	Please ☑ all that apply ☐ General medical ☐ General surgical ☐ Both medical and surgical
1.8	Areas of specialty of the ICU	Please ☑ all that apply ☐ Neurological conditions ☐ Cardiac surgical ☐ Burns ☐ Spinal injuries ☐ Trauma ☐ Other, *specify:*
Staffing		
1.9	Donation Specialist Medical	|__| |__| FTE
1.10	Donation Specialist Nursing	|__| |__| FTE
1.11	Intensivists (staff specialists and senior staff specialists)	|__| |__| FTE
1.12	Number of intensivists working less than 75% of FTE	|__| |__|
1.13	Intensive care trainees (registrar)	|__| |__| FTE
a	Duration of rotation (registrar)	|__| |__| Months/weeks
1.14	Resident medical officers	|__| |__| FTE
a	Duration of rotation (residents)	|__| |__| Months/weeks
1.15a	Numbers of medical staff rostered per day (weekday)	|__| |__| intensivists
b		|__| |__| registrar
c		|__| |__| resident
1.16a	Numbers of medical staff rostered per day (weekend)	|__| |__| intensivists
b		|__| |__| registrar
c		|__| |__| resident

Form 1: Setting: site details		
1.17	Number of registered nurses	|__| |__| FTE
1.18	Number of registered nurses with post-registration critical care nursing qualifications (any)	|__| |__|
1.19	Number of registered nurses working less than 75% of FTE	|__| |__|
1.20	The average vacancy rate of registered nurses	|__| |__|
1.21	Shifts available for nurses ☐ 8 hr ☐ 10 hr ☐ 12 hr	Please ☑ all that apply
1.22	Number and availability of Clinical Nurse Educators (CNE) during hours (DH) and after hours (AH)	DH No. |__| |__| AH No. |__| |__|
1.23	Number and availability of Nurse Unit Manager (NUM) during hours (DH) and after hours (AH)	DH No. |__| |__| AH No. |__| |__|
1.24	Number and availability of Clinical Nurse Consultant (CNC) during hours (DH) and after hours (AH)	DH No. |__| |__| AH No. |__| |__|
1.25	Number and availability of social worker (SW); during hours (DH) and after hours (AH)	DH No. |__| |__| AH No. |__| |__|
1.26	Number and availability of hospital chaplain (HC) during hours (DH) and after hours (AH)	DH No. |__| |__| AH No. |__| |__|

Communication

1.27	Responsibility for introducing donation and leading the family donation conversation Please *specify*:	
1.28	Determinants of nurse allocation to potential organ donors ☐ Discretion of the team leader ☐ Experienced nurses (CNS) ☐ Special group (self-selected) ☐ Model of care (team approach) ☐ Other, *specify*:	Please ☑ all that apply
1.29	Number of multidisciplinary ward rounds per day	|__| |__| per day
1.30	Formal multidisciplinary intensivist handover meeting	|__| |__| per week
1.31	Other meetings that should be included ☐ Yes, *specify:* ☐ No	
1.32	Policy for formal family meetings/update following the patient's admission to ICU? ☐ Yes, *please supply a copy* ☐ No	
1.33	**Date:** |__| |__| / |__| |__| / |_2_| |_0_| |_1_| |__| *(dd/mm/yyyy)*	

Appendix 6: Interview Schedule (CRF 7)

COMFORT Study	Form 7	Pt Initials (first_last) Study No.	I__I I__I __ __ __ __ __

To be completed within one month of day 90 after enrolment.

Form 7: Interview with the senior next of kin

Date: |__| |__| / |__| |__| / |_2_| |_0_| |_1_| |__|

Start time:|__| |__|:|__| |__| 24 hr **Stop time:**|__| |__|:|__| |__| 24 hr

Speaking with (*specify relationship to the potential donor*):_____

If an interpreter is used, please specify language:_____

Introduce yourself, offer condolences

We are contacting families of patients who died in the intensive care unit, and who participated in discussions about organ donation while at the hospital. We would like to have a better understanding of the families' experiences of the process of making a decision regarding organ and tissue donation on behalf of ther relative, at that time.

Forewarn about how long the interview will take and the possibility that some of the questions may stir up painful memories. Discuss how the participant will 'take care of themselves' following the interview. Obtain verbal consent to proceed, or to arrange an alternative time that is more convenient.

First I have some factual questions I would like to ask you; after that I would like to ask you about your experience more generally, and finish by asking a few details about yourself. Your responses will be coded, so you will not be able to be identified personally.

7.1 What types of bereavement support have you received?

a Written material Please tick ☑ all that apply

☐ Pamphlet ☐ Booklet ☐ Did not receive

Comments:

b Phone call(s) Please tick ☑ all that apply

☐ DSN ☐ Social Worker ☐ Hospital chaplain

☐ Other, *specify* ☐ Did not receive

Comments:

c Home visit(s) from Please tick ☑ all that apply

☐ DSN ☐ Social Worker ☐ Hospital chaplain

☐ Other, *specify* ☐ Did not receive

Comments:

I would like to ask you some questions about the information provided to you about organ donation at the hospital

7.2 **Do you feel the information provided to you about organ and tissue donation was understandable?**

☐ not at all understandable ☐ somewhat understandable ☐ yes, very understandable

7.3 **Were you provided with adequate information about organ and tissue donation to make an informed decision?**

☐ not at all adequate ☐ somewhat adequate ☐ yes, very adequate

7.4 **Thinking back to the decision you made regarding organ and tissue donation 3 months ago, would your decision today remain the same?**

☐ Yes ☐ No ☐ Don't know

7.5 **Can you tell me a little bit more about the reasons for your original decision (and if appropriate) why your decision has changed)?**

7.6 **Did you previously have discussions with *your relative*** *[insert name if appropriate]* **regarding organ donation, at any time?**

☐ Yes ☐ No

☐ NA discussion not appropriate because the relative was an infant or child

7.7 **Is there anything you would like to tell me about your experience regarding the death of your relative and the subsequent discussions of organ and tissue donation?**

(Prompts – for example, was there anything that you felt was done particularly well, or that you felt could have been done better?)

7.8 **Is there anything else regarding organ and tissue donation or the processes for this, that you would like to raise?**

7.9 **Do you have any unanswered questions regarding *your relative's*** *[insert name if appropriate]* **care at the hospital?**

7.10 **Did you live with *your relative*** *[insert name if appropriate]***?**

☐ Yes If yes, specify years_____

☐ No

I would like to finish by asking you a few details about yourself

7.11 **Demographic data**

7.11.1 Age: |__| |__| *(years)*

7.11.2 Gender: ☐ Male ☐ Female

7.11.3 Country of birth ☐ Australia ☐ Other, (specify):

7.12 **Ethnicity** Please tick ☑ one or more

☐ Oceanian: Australian or New Zealander
☐ Oceanian: Aboriginal or Torres Strait Islander
☐ Oceanian: Pacific Islander (except Maori)
☐ Oceanian: Maori
☐ North-West European
☐ Southern and Eastern European
☐ North African and Middle Eastern
☐ South-East Asian
☐ North-East Asian
☐ Southern and Central Asian
☐ Peoples of the Americas
☐ Sub-Saharan African
☐ Prefer not to answer

7.13 **Religion** Please tick ☑ one

☐ Buddhism
☐ Christianity
☐ Hinduism
☐ Islam
☐ Judaism
☐ No religion
☐ Other, *specify*_____
☐ Prefer not to answer

7.14 **Highest education level** Please tick ☑ one

☐ Some primary school
☐ Completed primary school
☐ Some high school
☐ Completed high school
☐ Other, *specify:*
☐ Some college/university
☐ Completed college/university
☐ Some technical school (e.g TAFE)
☐ Completed technical qualification

Thank you for your time today. Arrange further bereavement support if required. Ensure they have the toll free number: 1 800 355 042.

Appendix 7: Cover Letter and Participant Information Sheet and Consent Form

Insert date

Insert next of kin's address

Dear *insert name of the senior next of kin,*

On behalf of Donate Life NSW Organ and Tissue Donation Service and my colleague(s) *insert name of Principal Investigator at hospital* we wish to extend our condolences to you on the sudden death of your *(insert relationship(s) e.g husband and father John)*.

We are conducting research into next of kins' experiences of the processes of making a decision regarding organ and tissue donation on behalf of their relative, while in the intensive care unit. I am writing to invite you to participate in the research.

The research will involve participating in a telephone survey with the Family Support Coordinator. Completion of the interview should take no more than 20 minutes of your time.

Enclosed with this letter are a Participant Information Sheet and Consent Form, with a section for declining contact. I am mindful that this will be a very sensitive area for you, but if you feel able to help us, please complete the consent or decline form enclosed and return it in the stamped addressed envelope at your earliest convenience.

The Family Support Coordinator, will telephone you in approximately two weeks to complete the survey with you. You may consent or decline participation then if you wish, if you have been unable to return the consent or decline form.

This is voluntary, you are under no obligation to participate in this research but I thank you for considering this request and hope you will take part in the telephone survey.

Yours Sincerely

Dr Robert Herkes
State Medical Director
NSW Organ and Tissue Donation Service

NSW Organ and Tissue Donation Service
Level 6, 4 Belgrave Street, KOGARAH NSW 2217
PO Box 486, KOGARAH NSW 1485
Tel (02) 8566 1700 Fax (02) 8566 1755
South Eastern Sydney Local Health District
ABN 70 442 041 439
A State-wide clinical service hosted by South Eastern Sydney Local Health District

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Title: Communication with Families regarding Organ and Tissue Donation after Death in Intensive Care (COMFORT) Study

Invitation

You are invited to participate in a research study into next of kins' experiences of the process of making a decision regarding organ and tissue donation on behalf of their relative, while in the intensive care unit.

The study is being conducted by:

Dr Robert Herkes, NSW Organ and Tissue Donation Service
Dr Elena Cavazzoni, The Children's Hospital at Westmead
Dr Jorge Brieva, John Hunter Hospital
A/Prof Anders Aneman, Liverpool Hospital
Dr Gordon Flynn, The Prince of Wales Hospital
Dr Ray Raper, Royal North Shore Hospital
A/Prof Michael O'Leary, Royal Prince Alfred Hospital
Dr Andrew Cheng, St George Hospital
Dr Suhel Al-Soufi, St Vincent's Hospital
Dr Michael Lindley-Jones, The Tweed Hospital
Prof. Lin Perry, University of Technology Sydney
Ms Julie Potter, NSW Organ and Tissue Donation Service.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. 'What is the purpose of this study?'

The main purpose is to have a better understanding of next of kins' experiences of the process of making a decision regarding organ and tissue donation on behalf of their relative, while in the intensive care unit.

2. 'Why have I been invited to participate in this study?'

You have received this invitation because the possibility of organ donation for your relative was discussed with you at the hospital.

3. ''What does this study involve?'

If you agree to participate in this study by returning the enclosed consent form and indicating dates and times convenient to you in the attached stamped addressed envelope, the Family Support Coordinator will telephone you in approximately two weeks. You will be invited to talk about your experiences and opinions, including the quality of information provided to you in the intensive care unit regarding organ and tissue donation, and of the support provided by health professionals when your relative died, and some personal details. The call may take up to 20 minutes, and you can take more time if you wish. If you agree, we would like to audio-record this call to make sure we include all your comments for analysis.

4. What if I don't want to take part in this study, or if I want to withdraw later?'

Participation in this study is voluntary. It is completely up to you whether or not you participate and if you agree to an audio-recording of the interview. If you decide not to participate, it will

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South Eastern Sydney Local Health District
ABN 70 442 041 439

not affect your entitlement for continued bereavement support, either now or in the future. You can let us know you do not wish to participate by returning the "decline consent form" (at the back of this letter). If this form has gone astray in the post and we do not hear from you, the Family Support Coordinator will telephone you in approximately two weeks to ask you whether you would like to participate. You may decline the interview then if you wish.

5. 'Are there risks to me in taking part in this study?'
You may feel that talking about your experiences might be stressful or upsetting because we are asking you to revisit that difficult time. If you do not wish to answer a question you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the study, the Family Support Coordinator will be able to help you.

6. 'Will I benefit from the study?'
The results of this study will help us to understand how we can best support families when they are making a decision regarding organ donation on behalf of their loved one. You may benefit from receiving additional bereavement support from the Family Support Coordinator if you wish.

7. 'Will taking part in this study cost me anything, and will I be paid?
Participation in this study will not cost you anything. You will not be paid for participating.

8. 'How will my confidentiality be protected?'
Only those named above or necessary others eg health professionals involved in your bereavement care, will know if you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above, the Family Support Coordinator and the Human Research Ethics Committee (HREC) for monitoring purposes, will have access to your identifiable details and results which will be held securely at the NSW Organ and Tissue Donation Service.

9. 'What happens with the results?'
If you give us your permission by signing the consent document, we plan to discuss or provide reports for the NSW Ministry of Health, The Organ and Tissue Authority, the Human Research Ethics Committee, publish the results in peer-reviewed journals, and deliver presentations at conferences or other professional forums. In any publication or presentation, information will be provided in such a way that you cannot be identified.

10. 'What should I do if I want to discuss this study further before I decide?'
The Family Support Coordinator will ring you in approximately two weeks to discuss the interviews with you and answer any questions you may have. If you would like to know more at any stage, please do not hesitate to contact her on telephone (02) 8566 1705, toll free 1 800 355 042, or email alison.barnwell@sesiahs.health.nsw.gov.au, and she will be happy to answer your questions.

11. 'Who should I contact if I have concerns about the conduct of this study?'
This study has been approved by St Vincent's Hospital Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research Officer who is nominated to receive complaints from research participants. You should contact them on 02 8382 2075 and quote SVH 12/201.

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

CONSENT FORM

Title: Communication with Families regarding Organ and Tissue Donation after Death in Intensive Care (COMFORT) Study

1. I,.....

of.....
agree to participate in the study described in the Participant Information Sheet set out above.

2. I acknowledge that I have read the attached Participant Information Sheet, outlining the nature and purpose of the research study and I understand what I am being asked to do.

3. I am aware of the possible risks relating to any possible emotional distress I might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the NSW Organ and Tissue Donation Service.

5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

6. I understand that if I have any questions relating to my participation in this research, I may contact the Family Support Coordinator on telephone (02) 8566 1705 or toll free 1 800 355 042, who will be happy to answer them.

Complaints may be directed to the, Research Office, Phone: 02 8382 2075

Signature of participant **Please PRINT name** **Date**

Best day of the week to be telephoned *(please circle):* Mon Tues Wed Thurs Fri

Best time of day *(please circle):* morning | afternoon | evening

This Consent Form should be forwarded to Dr Robert Herkes, State Medical Director, NSW Organ and Tissue Donation Service, P.O Box 486, Kogarah, NSW 1485.

NSW Organ and Tissue Donation Service
Level 6, 4 Belgrave Street, KOGARAH NSW 2217
PO Box 486, KOGARAH NSW 1485
Tel (02) 8566 1700 Fax (02) 8566 1755
South Eastern Sydney Local Health District
ABN 70 442 041 439
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Title: Communication with Families regarding Organ and Tissue Donation after Death in Intensive Care (COMFORT) Study

DECLINE CONSENT

I hereby wish to **DECLINE** my consent to participate in the study described above and understand that decision **WILL NOT** jeopardise any ongoing or future bereavement support from the NSW Organ and Tissue Donation Service.

Signature Date

Please PRINT Name

This Decline Consent form should be forwarded to Dr Robert Herkes, State Medical Director, NSW Organ and Tissue Donation Service, P.O Box 486, Kogarah, NSW 1485.

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Appendix 8: Lead HREC Approval Letters and UTS HREC Ratification

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25 January 2013

Dr Robert Herkes
State medical Director
NSW Organ and Tissue Donation Service
South Eastern Sydney Local Health District
PO Box 486
Kogarah NSW 1485

Dear Dr Herkes

SVH File Number: 12/201
Project Title: The Communication with families regarding organ and tissue donation after death in Intensive Care study (HREC Reference Number: HREC/12/SVH/271)

Thank you for submitting the above project for ethical and scientific review. The project was first considered by the St Vincent's Hospital HREC at its meeting held on **11 October 2012.** This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the Committee at an Executive meeting on **22 January 2013** has granted ethical and scientific approval of the above **multi centre** project.

You are reminded that this letter constitutes *ETHICAL* and *SCIENTIFIC* approval only. You must not commence this research project at a site until a completed Site Specific Assessment Form/Access Request and associated documentation have been submitted to the site Research Governance Officer and Authorised. A copy of this letter must be forwarded to all site investigators for submission to the relevant Research Governance Officer.

The project is approved to be conducted at:

- Liverpool Hospital
- Prince of Wales Hospital
- St George Hospital
- St Vincent's Hospital
- NSW Organ and Tissue Donation Service
- Royal Price Alfred Hospital
- John Hunter Hospital
- Tweed Heads Hospital
- Royal North Shore Hospital

If a new site(s) is to be added please inform the HREC in writing and submit a Site Specific Assessment Form (SSA) to the Research Governance Officer at the new site.

The following documentation has been reviewed and approved by the HREC:

- Curriculum vitae for: Dr Anders Aneman, Dr Gordon Flynn, Dr Suhel Al-Soufi, Dr Andrew Cheng and Prof Lin Perry,
- Designated Requestor: Role and Responsibilities dated 10 December 2012
- Case Report Form (CRF) Completion Guidelines, Version 1 dated 21 December 2012
- Communication with Families regarding Organ and Tissue Donation after Death in Intensive Care (COMFORT) Study Protocol FINAL, Version 2 dated 21 December 2012

- Case Report Forms (CRF),Version 2 dated 21 December 2012
- Cover letter to Senior available Next of Kin (SaNOK), Version 2 dated 21 December 2012
- Participant Information Sheet and Consent Form, Version 2 dated 21 December 2012
- COMFORT study Fact Sheet, NSW Master Version 2 dated 21 December 2012
- COMFORT study poster NSW Master Version 2 dated 21 December 2012

The National Ethics Application Form (NEAF) document reviewed by the HREC was NEAF **AU/1/444F011.** Please note the following conditions of approval:

- HREC approval is valid for **5 years** from the date of the HREC Executive Committee meeting and expires on **22 January 2018**. The Co-ordinating Investigator is required to notify the HREC 6 months prior to this date if the project is expected to extend beyond the original approval date at which time the HREC will advise of the requirements for ongoing approval of the study.

- The Co-ordinating Investigator will provide an annual progress report beginning in **January 2014**, to the HREC as well as a final study report at the completion of the project in the specified format.

- The Co-ordinating Investigator will immediately report anything which might warrant review of ethical approval of the project in the specified format, including unforeseen events that might affect continued ethical acceptability of the project and any complaints made by study participants regarding the conduct of the study.

- Proposed changes to the research protocol, conduct of the research, or length of HREC approval will be provided to the HREC for review, in the specified format.

- The HREC will be notified, giving reasons, if the project is discontinued before the expected date of completion.

- Projects that are undertaken by Investigators holding an academic appointment (including conjoint appointments) or by students as part of a University course are also required to notify the relevant University HREC.to seek advice from the university regarding their requirements.

Please note it is the responsibility of the sponsor or the co-ordinating investigator of the project to register this study on a publicly available online registry (eg Australian Clinical Trial Registry www.actr.org.au).

Should you have any queries about your project please contact the Research Office, Tel: 8382-2075, email research@stvincents.com.au. The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and standard forms are available on the Research Office website: www.stvincents.com.au/researchoffice or internal at http://exwwwsvh.stvincents.com.au/researchoffice

Please quote **12/201** in all correspondence.

The HREC wishes you every success in your research.

Yours sincerely

Production Note:
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prior to publication.

Maria Mury
Acting HREC Executive Officer
Research Office
L6 deLacy Building

CC: Julie Potter
Trim File Number: D/2013/4678

St Vincent's Hospital

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30 April 2013

Dr Robert Herkes
State medical Director
NSW Organ and Tissue Donation Service
South Eastern Sydney Local Health District
PO Box 486
Kogarah NSW 1485

Dear Dr Herkes

SVH File Number: 12/201
Project Title: The Communication with families regarding organ and tissue donation after death in Intensive Care study (HREC Reference Number: HREC/12/SVH/271)

Thank you for submitting a request for an amendment dated **22 April 2013** to the above project. This was considered by the St Vincent's Hospital HREC at its Executive meeting held on **29 April 2013.** This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the documents reviewed and approved at the meeting were:

- Protocol FINAL Version 3 dated 10 April 2013
- Case Report Forms (1-7) Version 3 dated 10 April 2013
- Case Report Form Guidelines Version 2 dated 10 April 2013
- Comfort Study Fact Sheet, NSW Master Version 3 dated 10 April 2013

The HREC Executive also noted the following:

- External Ethics ratified by UTS letter dated 3 April 2013

This amendment has also been reviewed by the Research Governance Officer at St Vincent's Hospital. Further authorisation of the above approved documents is not required for any site that has the Research Governance conducted by St Vincent's Hospital Research Office. Implementation of this amendment can now proceed.

For multi-site projects reviewed by the HREC after 1 July 2007 a copy of this letter must be forwarded to all Principal Investigators at every site approved by SVH HREC for submission to the relevant Research Governance Officer along with a copy of the approved documents.

Should you have any queries about your project please contact the Research Office, Tel: 8382-2075, email research@stvincents.com.au. The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and standard forms are available on the Research Office website: www.stvincents.com.au/researchoffice or internal at http://exwwwsvh.stvincents.com.au/researchoffice

Yours sincerely

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Maria Mury
Acting HREC Executive Officer
Research Office

CC: Julie Potter
TRIM Ref: D/2013/22457

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27 November 2013

Dr Robert Herkes
NSW Organ and Tissue Donation Service
South Eastern Sydney Local Health District
PO Box 486
Kogarah NSW 1485

Dear Dr Herkes

SVH File Number: 12/201
Project Title: The Communication with families regarding organ and tissue donation after death in Intensive Care study (HREC Reference Number: HREC/12/SVH/271)

Thank you for submitting a request for an amendment dated **18 November 2013** to the above project. This was considered by the St Vincent's Hospital HREC at its Executive meeting held on **26 November 2013.** This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the documents reviewed and approved at the meeting were:

- Protocol, Version 4 dated 15 November 2013
- Participant Information Sheet and Consent Form, Version 3 dated 15 November 2013
- Case Report Forms 2, 3, 4, 5, 6 & 7, Version 4 dated 15 November 2013
- Case Report Form Completion Guidelines, Version 3 dated 15 November 2013

In addition, HREC approval has been extended to the following site:

- The Children's Hospital, Westmead – Principal Investigator: Dr Elena Cavazzoni

This amendment has also been reviewed by the Research Governance Officer at St Vincent's Hospital. Further authorisation of the above approved documents is not required for any site that has the Research Governance conducted by St Vincent's Hospital Research Office. Implementation of this amendment can now proceed.

For multi-site projects reviewed by the HREC after 1 July 2007 a copy of this letter must be forwarded to all Principal Investigators at every site approved by SVH HREC for submission to the relevant Research Governance Officer along with a copy of the approved documents.

Should you have any queries about your project please contact the Research Office, Tel: 8382-2075, email research@stvincents.com.au. The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and standard forms are available on the Research Office website: www.stvincents.com.au/researchoffice or internal at http://exwwwsvh.stvincents.com.au/researchoffice

Yours sincerely
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prior to publication.
Sarah Charlton
HREC Executive Officer
St Vincent's Research Office
Level 6 deLacy Building
cc: Julie Potter
D/2013/65617

Continuing the Mission of the Sisters of Charity

St Vincent's Hospital

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8 October 2015

Dr Robert Herkes
NSW Organ and Tissue Donation Service
South Eastern Sydney Local Health District
PO Box 486
Kogarah NSW 1485

Dear Dr Herkes

SVH File Number: 12/201
Project Title: The Communication with families regarding organ and tissue donation after death in Intensive Care study
Short Title: COMFORT Study
HREC Reference Number: HREC/12/SVH/271

Thank you for submitting a request for an amendment dated **16 September 2015** to the above project. This was considered by the St Vincent's Hospital HREC at its Executive meeting held on **6 October 2015.** This HREC has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National model for Harmonisation of Multicentre Ethical Review (HoMER). This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the documents reviewed and approved at the meeting were:

- Protocol, Version 5, dated 21 August 2015
- COMFORT Study: Criteria for Protocol Violations, Version 3 dated 18 June 2015
- Hospital Referrals Case Report Form, Version 1.1, dated 21 August 2015
- NSW Hospitals Referrals Data Dictionary, Version 1.1, dated 21 August 2015

This amendment has also been reviewed by the Research Governance Officer at St Vincent's Hospital. Further authorisation of the above approved documents is not required for any site that has the Research Governance conducted by St Vincent's Hospital Research Office. Implementation of this amendment can now proceed.

You are reminded that this letter constitutes ongoing ETHICAL and SCIENTIFIC review only. For multi-site projects reviewed by the HREC after 1 July 2007 a copy of this letter must be forwarded to all Principal Investigators at every site approved by SVH HREC for submission to the relevant Research Governance Officer along with a copy of the approved documents prior to implementation of the amendment.

Please note that only an electronic copy of this letter will be provided, if you require the original signed letter please contact the Research Office and we will be happy to provide this.

Should you have any queries about your project please contact the Research Office, Tel: (02) 8382-2075, email SVHS.Research@svha.org.au. The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and

standard forms are available on the Research Office website found at: https://svhs.org.au/home/research-education/research-office

Yours sincerely,

Production Note:
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Sarah Charlton
HREC Executive Officer
St Vincent's Hospital Research Office
Level 6, de Lacy Building

cc: Julie Potter
TRIM REF: D/2015/56537

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11 October 2016

Dr Robert Herkes
NSW Organ and Tissue Donation Service
South Eastern Sydney Local Health District
PO Box 486
Kogarah NSW 1485

Dear Dr Herkes

SVH File Number: 12/201
Project Title: The Communication with families regarding organ and tissue donation after death in Intensive Care study
Short Title: COMFORT Study
HREC Reference Number: HREC/12/SVH/271

Thank you for submitting a request for an amendment dated **27 September 2016** to the above project.

This was considered by the St Vincent's Hospital HREC at its Executive meeting held on **11 October 2016.** St Vincent's Hospital HREC (EC00140) has been accredited by NSW Ministry of Health as a Lead HREC under the model for single ethical and scientific review and Certified by the NHMRC under the National Certification Scheme. This lead HREC is constituted and operates in accordance with the National Health and Medical Research Council's *National Statement on Ethical Conduct in Human Research* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. No HREC members with a conflict of interest were present for review of this project.

I am pleased to advise that the documents reviewed and approved at the meeting were:

- NSW Hospital Referrals Case Report Form, Version 2, dated 27 September 2016
- NSW Hospital Referrals Data Dictionary, Version 2, dated 27 September 2016

As indicated by the amendment application form, the Coordinating/Principal Investigator has declared that there are no governance implications for this amendment at any site/s under St Vincent's Hospital Research Office Governance jurisdiction. Therefore, this amendment does not require further review by the Research Governance Officer at St Vincent's Hospital.

You are reminded that this letter constitutes ongoing ETHICAL and SCIENTIFIC review only. For multi-site projects reviewed by the HREC after 1 July 2007 a copy of this letter must be forwarded to all Principal Investigators at every site approved by SVH HREC for submission to the relevant Research Governance Officer along with a copy of the approved documents prior to implementation of the amendment.

Please note that only an electronic copy of this letter will be provided, if you require the original signed letter please contact the Research Office and we will be happy to provide this.

Should you have any queries regarding this project please contact the Research Office, Tel: (02) 8382-4960, email SVHS.Research@svha.org.au. The HREC Terms of Reference, Standard Operating Procedures, *National Statement on Ethical Conduct in Human Research* (2007) and the *CPMP/ICH Note for Guidance on Good Clinical Practice* and standard forms are available on the Research Office website found at: https://svhs.org.au/home/research-education/research-office

Yours sincerely,

Production Note:
Signature removed
prior to publication.

Sarah Charlton
HREC Executive Officer
St Vincent's Hospital Research Office
Translational Research Centre, 97-105 Boundary Street

cc: Julie Potter
TRIM REF: D/2016/92044

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3 April 2013

Professor Lin Perry
Health
CB10.07.207
UNIVERSITY OF TECHNOLOGY, SYDNEY

Dear Lin,

UTS HREC 2013000133 – Professor Lin PERRY, Dr Robert Herkes (for Ms Julie Potter, PhD student) – "COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT) study"
[External Ratification: St Vincent's Hospital (SVH) Human Research Ethics Committee HREC approval - HREC/12/SVH/271 - 22/01/13 to 22/01/18]

The UTS Human Research Ethics Expedited Review Committee reviewed your application titled, "COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT) study", and agreed that the application meets the requirements of the NHMRC National Statement on Ethical Conduct In Human Research (2007). I am pleased to inform you that your external ethics approval has been ratified.

Your approval number is UTS HREC REF NO. 2013000133

Please note that the ethical conduct of research is an on-going process. The National Statement on Ethical Conduct in Research Involving Humans requires us to obtain a report about the progress of the research, and in particular about any changes to the research which may have ethical implications. This report form must be completed at least annually, and at the end of the project (if it takes more than a year). The Ethics Secretariat will contact you when it is time to complete your first report.

I also refer you to the AVCC guidelines relating to the storage of data, which require that data be kept for a minimum of 5 years after publication of research. However, in NSW, longer retention requirements are required for research on human subjects with potential long-term effects, research with long-term environmental effects, or research considered of national or international significance, importance, or controversy. If the data from this research project falls into one of these categories, contact University Records for advice on long-term retention.

If you have any queries about your ethics clearance, or require any amendments to your research in the future, please do not hesitate to contact the Ethics Secretariat at the Research and Innovation Office, on 02 9514 9772.

Yours sincerely,

Production Note:
Signature removed
prior to publication.

Professor Marion Haas
Chairperson
UTS Human Research Ethics Committee

Appendix 9: Study Protocol

Communication with Families regarding Organ and Tissue Donation after Death in Intensive Care Study

Short title: The COMFORT Study

Protocol FINAL version number: 5, dated 21 August 2015

Australian New Zealand Clinical Trials Registry (ANZCTR) ACTRN: ACTRN12613000815763
DOI: http://www.ANZCTR.org.au/ACTRN12613000815763.aspx
ClinicalTrials.gov Identifier: NCT01922310
Universal Trial Number: U1111-1145-3724

The Organ and Tissue Authority
NSW Organ and Tissue Donation Service

MANAGEMENT COMMITTEE

Responsibilities:

- Advise on the development and conduct of the study
  - Oversight of study, continuing input and feedback
  - Approval of full protocol, data collection tools and methods;
  - General study management issues;
  - Review and agree data analyses.
- Advise on the development of education and training
- Collaboration and approval of study publications, promulgation of study results

Membership:

Name	Designation	Organisation	Role
Michael O'Leary	NSW State Medical Director, Senior Staff Specialist	NSW OTDS/Royal Prince Alfred Hospital	Chair
Elena Cavazzoni	NSW State Medical Director, Staff Specialist, Donation Specialist Medical	NSW OTDS/Children's Hospital Westmead	Member
Ray Raper	Department Head ITU, Donation Specialist Medical	Royal North Shore Hospital	Member
Ian Seppelt	Senior Specialist in Intensive Care Medicine	Nepean Hospital	Member
Jorge Brieva	Staff Specialist, Donation Specialist Medical	John Hunter Hospital	Member
Anders Aneman	Staff Specialist, Donation Specialist Medical	Liverpool Hospital	Member
Lin Perry	Professor of Nursing Research and Practice Development	University of Technology Sydney	Member
Julie Potter	Research Coordinator	NSW OTDS	Member, Secretariat
Myra Sgorbini	Donation Specialist Nurse	Royal Prince Alfred Hospital	Member
Alison Barnwell	Donor Family Support Coordinator	NSW OTDS	Member
Eva Mehakovic	Director Clinical Programs	The Organ and Tissue Authority	Member
Leigh McKay	Education Coordinator	NSW OTDS	Member
Robert Herkes	Clinical Director	Australian Commission on Safety and Quality in Healthcare	Ex-officio
Danielle Fisher	General Manager	NSW OTDS	Ex-officio
Juliana Celcer	Clinical Manager	NSW OTDS	Ex-officio

Meetings:

As required.

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SUMMARY

Study title: Communication with families regarding organ and tissue donation after death in intensive care.

Primary endpoint:
Consent rates for deceased organ and/or tissue donation.

Secondary endpoints:
a) Health professionals' adherence rates to core elements of the intervention.
b) Identification of predictors of senior available next of kin consent or decline to donation.
c) Proportion of senior next of kin who report they regretted their final decision either to consent or to decline donation at 90 days.

Study design: The study design is a single arm Phase II study with current 'controls' (i.e. current practice), conducted in the intensive care units of approximately 10 NSW hospitals where donation specialist nurses audit hospital deaths. Donation events will be recorded in each ICU; each unit will crossover from control to intervention status as training is received and 'designated requesters' become available.

Planned sample size: 140 patients who are eligible for organ donation and had not registered their preference for deceased donation in life, will provide 80% power with 95% confidence to exclude a 29% increase in consent rate in favour of a clinically worthwhile rate of 40% for the intervention. Secondary endpoints will be calculated from the cohort of all patients eligible for donation.

Inclusion criteria:
a) A patient who is a potential deceased organ and/or tissue donor.
Additionally, for the primary endpoint, patients must not have registered their donation wishes.

Exclusion criteria:
a) A patient who is not medically suitable for deceased organ or tissue donation.
b) A patient who does not have next of kin available to participate in donation conversations.
c) An adult patient in the ICU who is able to provide first person consent for deceased donation, for example a patient with cervical spine injuries.
d) A patient who is suitable to donate only tissue after death.

Study procedures:
Discussion of the opportunity of organ donation with families is part of usual care for patients who are potential organ donors in the ICU. The study intervention is a staff education and training module intended to provide a framework and preparation for select critical care staff to conduct organ donation discussions in line with best practice. Donation decision-making processes will be compared before ('control') and after ('intervention') staff have received this training.
Critical care staff will be asked to complete a form to record details of request conversations and procedures. Clinical and administrative data will be collected from databases and paper records.
In addition to standard bereavement follow-up provided by the hospital, senior next of kin who declined donation will be offered bereavement aftercare provided by the NSW Organ and Tissue Donation Service.
Senior next of kin will be invited to participate in a structured telephone interview 90 days after bereavement, to explore their donation decision experiences.

Duration of the study: Three years.

STUDY TIMELINE

This section provides details of the projected timeline for development of the training packages, consultation and development of the study protocol, implementation, analysis, and reporting of the study findings.

Table 1 Description of the development and implementation of the study

Date	Activity
July 2011 to July 2012	Initial discussions with stakeholders, draft of study design and communication training materials.
Oct 2011 to Feb 2013	Family Donation Conversation Core Workshops supported by the Gift of Life Institute, Philadelphia.
Oct 2011 to Oct 2012	Development of the National Professional Education package. This includes the Family Donation Conversations: core and practical modules.
July 2012 to Sep 2012	Development of the Simulation Training Program for NSW
Apr 2012 to Dec 2012	Finalise protocol, centre selection, nominate designated requesters.
Sep 2012	Convene Management Committee.
Sep 2012	Submit application to lead Human Research Ethics Committee (HREC) and Site Specific Assessments for review by local governance.
May 2013	Initiation of study at participating centres, commence recruitment, ongoing family donation conversation training, data collection and follow-up.
May 2013 to Sep 2016	Ongoing recruitment, data collection and follow-up. Completion of family donation conversation training.
Dec 2016	Complete data cleaning, database lock.
Apr 2016 to Mar 2017	Data analysis, publications.

DEFINITION OF TERMS

This section provides definition for terms and phrases used in this protocol.

Table 2 Definition of terms

Term	Definition
Designated requester	A health professional who is responsible for requesting organ donation, who has completed the core and practical Family Donation Conversation Workshops (1), and the Simulation Training Program (see Appendix A), regarding a balanced approach to discussing organ donation within the FDC.
Balanced approach to the FDC	**Balanced**: informed, proactive, open-ended questions; introduce information in an open and respectful manner that provides information of the benefits of organ and tissue donation to families and recipients (2)
Health professional	A term including: specialist intensive care doctors such as intensivists (staff specialist); trainee doctors such as registrars or residents; registered nurses, specialist critical care nurses, donation specialist nurses; and social workers.
Medically suitable[a]	A potential donor is medically suitable to donate one or more organs for transplantation if they do not meet medical exclusion criteria including donor/organ issues of: transmissible diseases such as HIV, recent or metastatic cancer other than primary cerebral cancer, and untreated systemic infection.
Potential organ donor	A patient with a devastating brain injury or lesion, or a patient with circulatory failure, and apparently medically suitable for organ donation, and: • whose clinical condition is suspected to fulfil brain death criteria, or • the cessation of circulatory and respiratory functions is anticipated to occur within a timeframe that will enable organ recovery (3).
Not medically suitable	For this study not medically suitable includes reasons a potential donor did not proceed to donation in categories of "system" and "donor/organ". Examples of system reasons are a potential organ donor who was not anticipated to become brain dead and was not eligible for the circulatory death pathway due to age; a patient who was anticipated to die outside a timeframe that would enable organ recovery; lack of recovery teams or of a suitable recipient (3).

FDC=Family Donation Conversation

[a] definitions used in the DonateLife Audit, the tool used in reporting hospital deaths to The Organ and Tissue Authority (OTA).

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1. BACKGROUND

Introduction

Organ and tissue transplantation is the definitive treatment for people with a wide range of end-stage diseases. Patients who are potential organ donors are critically ill, requiring treatment in an intensive care unit (ICU). In order for organ donation to proceed, a potential donors' senior available next of kin must provide consent. However, in New South Wales (NSW) only half (51%; in 2011) of potential donors' next of kin approached to provide consent for organ donation agreed to proceed, which is below the national target of 75% (4). Reasons for this low consent rate in comparison to national and overseas experiences are unknown, and are not supported by results of surveys (5), and focus groups (6) where Australians reported predominantly altruistic beliefs regarding organ donation.

Discussions with families in the ICU undertaken to elicit a patient's values and preferences regarding end of life care and organ donation require ICU health professionals to have specialised communication skills(7). These skills include recognition of grief reactions, caring for families by providing information and emotional support, having sufficient time to spend with families, and confidence to conduct requesting conversations, coming from conducting them on a regular basis (8-10). In countries with higher rates of donation such as Spain and the United States (US) (11), families of potential donors are approached by health professionals such as intensivists (8), and critical care nurses (12), who have received specialised communication training in donation conversations. Improvements in communication between health professionals and next of kin in the ICU may be a contributing factor in increasing consent rates for donation.

Family experiences

The experiences of next of kin of the process of organ donation have been explored in comparative studies of donor and non-donor families, interviewed either face to face or by telephone, conducted from 1 month to three years post bereavement. Predominant findings were that next of kin more often agreed to consent when they perceived they had sufficient time, were satisfied with the quality of communication and information regarding the patient's condition, and when they were aware of the donation wish of the deceased from previous discussions (13-17). Communication strategies to assist families to achieve consensus were important, as opinions of friends and family influenced decision making for donation (14), and family disagreement was a common reason for declining organ donation in cases when the donation wish of the deceased was not expressed in life (17, 18). Next of kins' perceptions of positive experiences such as good communication and family care in the hospital were found to decrease subsequent symptoms of grief and depression in a longitudinal study of 49 donor and non-donor family members (17). A Canadian study of donor families, interviewed an average of 37 months (range three months to five years) post-bereavement, found a higher risk of post-traumatic stress disorder (PTSD) in next of kin who felt the donation experience was negative, for example if they were confused regarding brain death (14).

Decisions made regarding donation were not constant over time, particularly with more next of kin regretting their decision to decline compared with those who had agreed to donation. When interviewed via telephone an average of 13 ± 9 days post bereavement, 20% of respondents reported they would make a different decision were they able, with more non-donors (37/138) than donors (6/147) regretting their donation decision (19). Another study found decisional regret persisted eight to 10 months post bereavement, with more non-donor (19/45) compared to donor (15/139) next of kin either regretting or being unsure they would make the same decision again (13). Decisional regret

was more likely when organ donation was discussed before next of kin were informed the patient had died, and when the first approach was by a managing health professional, such as a physician, nurse, social worker or clergy, before a formal request was made by a member of an Organ Procurement Organisation (OPO) (19). The initial approach to next of kin was found to be important because they often made their decision regarding donation at that time (20).

Communication in the ICU

Next of kin are often emotionally overwhelmed by events leading to the patient's hospitalisation, may have little time to understand the situation, and are reported to experience anxiety, depression, symptoms of traumatic stress, and fatigue (21-23). These symptoms reduce their ability to understand complex medical information (24, 25) necessary to make informed decisions when the patient is unable. For example, a review of the evidence revealed many families did not understand the patient had died when they were certified brain dead, despite agreeing to organ donation (26). Separation of the donation conversation from the certification of brain death, termed "decoupling" (27), may be an important factor in next of kins' understanding the patient is dead. Findings from a study in the United States (US) revealed 25% of requests were made when the family was informed of brain death, and of those only 35.3% (42/119) of families agreed to organ donation, whereas 60.7% (215/354) agreed when the request was decoupled from the conversation about death (12).

In Australia, the managing intensivist has traditionally assumed primary responsibility for discussing organ donation with the next of kin. They have been supported by specialist donation nurses who are trained in organ donation activities, but have not necessarily led the conversation (28). This practice is similar to that in the United Kingdom (UK), with formal requests led by managing intensivists with written consent followed up by donation specialist nurses. The Assessment of Collaborative Requesting (ACRE) study investigators compared collaborative requesting, defined as both a potential donor's managing intensivist and a donation specialist nurse participating in the request, with usual care and found the intervention did not increase consent rates for donation (29). However, the study protocol was not followed in 30% of the randomised patients. This problem resulted in more "usual care" approaches by ICU health professionals who are often time poor, with competing clinical responsibilities, and little experience or insufficient training in high quality communication regarding organ donation.

Health professionals receive little formal training in specialised communication skills required in conversations regarding end of life care and organ donation, and are often poorly prepared to understand grief reactions and to help next of kin make informed decisions (7). For example, interviews with ICU nurses, intensivists and specialist donation nurses from an ICU in Victoria, revealed they failed to raise donation with families due to their perceptions of a families' grief, with junior staff in particular reporting fear or guilt when raising the subject (30). Communication training using simulation with actors is used increasingly for health professionals to develop communication skills in deceased donation activities (31, 32). Recently in Australia the DonateLife Professional Education Program (PEP), that includes Core and Practical Family Donation Conversation workshops, was provided nationally as core training in specialised communication (1). Health professionals are able to develop skills in integrating information such as the nature of grieving and the emotional consequences to next of kin from making a decision they may regret later into the requesting conversation, and to thereby become more comfortable discussing these topics.

1.1 Study Rationale

In NSW hospitals in 2011, only half of senior available next of kin approached for consent to donate a patient's organs or tissue after death have consented. This is well below the national target of 75% (4). A potentially modifiable factor is the method of communication and language used by various health professionals when providing information to the next of kin of potential donors. Variable communication skills of health professionals who discuss organ donation may result in families making decisions they later regret, particularly if they decline donation and later feel they should have agreed. Consenting to donation may benefit some next of kin by helping with bereavement experiences over the longer term, and by helping those on transplantation waiting lists. Successful interventions for providing information and requesting consent for donation found to be effective in other countries with different medical and nursing models of care to Australia require investigation.

1.2 Intervention: Family Donation Conversation (FDC)

The intervention is a modification of current standard practice procedures for requesting consent for donation. Essential 'best practice' elements of the intervention are:

- A designated requester (DR) has prime responsibility for discussions regarding organ and/or tissue donation with the senior available next of kin of a potential donor. Primary communication with families regarding end of life management and death remain the responsibility of the managing team.
- Designated requesters may be intensivists, experienced critical care nurses, or social workers, who have completed all Family Donation Conversation workshops and the Simulation Training Program (Appendix A).
- When next of kin raise the possibility of the patient donating organs or tissue after death, the managing health professional will sensitively defer the first requesting conversation to the designated requester.
- The request for donation is separated from the conversation where next of kin are informed of the patient's death. It is important the next of kin have accepted the inevitability of death **before** donation is raised.
- Donation conversations are conducted within a family meeting, structure based on evidence-based guidelines for high quality communication regarding end of life care (28, 33-37) (see Box 1).
- The requester uses a balanced approach when discussing donation with next of kin (2).

***Box 1:** Meeting for the family donation conversation*

- **Held:** in a private room or special area for meetings.
- **Plan:** a pre-conversation action plan
  The multidisciplinary team and the designated requester will share information regarding the patient's medical and social history, family dynamics, available support for next of kin, and presence of conflict. In particular, the status of next of kin acceptance of the patient's death or inevitability of death will be discussed and roles for the various participants in the subsequent conversation will be agreed.
- **Tools:** use of effective communication techniques (38) within the meeting.
- **Transition:** the managing intensivist will introduce the designated requester to next of kin, sensitively transfer leadership of the meeting to the designated requester, and may then leave to assume usual clinical responsibilities, at their discretion.
- **Evaluation of family donation conversation:** at closure of the meeting participants, other than next of kin, will meet to verbally reflect on the process, to plan subsequent follow-up and to document the process.

2. AIM

To examine the process of organ donation decision-making, and to determine whether changes in requesting practices change rates of consent for donation and other family-based outcomes.

3. STUDY ENDPOINTS

3.1 Primary Endpoint

Consent rates for deceased organ and/or tissue donation where the potential donor had not registered their donation wishes, when requested by designated requesters using a best practice procedure for requesting consent compared to rates with current standard practice.

3.2 Secondary Endpoints

a) Health professionals' adherence rates to core elements of the intervention.
b) Identification of predictors of senior available next of kin consent or decline to donation.
c) Proportion of senior next of kin who report they regretted their final decision either to consent or to decline donation at 90 days.

4. METHODS

4.1 Design

This study design is a single arm Phase II study with current controls (i.e. current practice). Donation events will be recorded in each ICU; each unit will crossover from control to intervention status as training is received and 'designated requesters' become available.
This study entails a Quality Improvement initiative supported by a robust evaluation and a follow-up research component.

4.2 Number of Centres

The study will be conducted in the intensive care units of approximately 10 NSW hospitals where donation specialist nurses audit hospital deaths.

4.3 Sample Size

The sample size calculation was performed using requesting data from the group of potential donors who had not committed to a decision regarding donation of organs and/or tissue after death, as indicated by an absent donation intent on a register. Based on Simon's two stage design (39) 140 of these patients who can potentially have consent provided for organ donation, will provide 80% power with 95% confidence to exclude a 29% increase in consent rate in favour of a clinically worthwhile rate of 40% for the intervention.

Additionally, if in the first 46 patients who are eligible for organ donation and had not registered their preference for deceased donation in life, less than 15 have consent provided for organ donation, consideration will be given to modifying the study.

Secondary endpoints are calculated from the cohort of all patients eligible for organ and/or tissue donation. There are approximately 170 eligible patients per year from participating hospitals.

4.4 Duration

The study will commence following approval from the Human Research Ethics Committee. Each participating centre will commence data collection when ethical and local governance procedures are complete. The estimated start date is the 4 February 2013 with completion by September 2016.

5. PARTICIPANT SECTION

Participants in this study are the next of kin of patients eligible for organ and/or tissue donation, and the staff involved in each decision-making scenario.
Eligible potential donation scenarios for the intervention study period must meet all inclusion and no exclusion criteria as detailed below:

5.1 Inclusion Criteria

a) A patient who is a potential deceased organ and/or tissue donor.
   Additionally, for the primary endpoint, patients must not have registered their donation wishes.

5.2 Exclusion Criteria

a) A patient who is not medically suitable for deceased organ and/or tissue donation;
b) A patient who does not have next of kin available to participate in donation conversations;
c) An adult patient in the ICU who is able to provide first person consent for deceased donation, for example a patient with cervical spine injuries;
d) A patient who is suitable to donate only tissue after death.

6. STUDY OUTLINE

6.1 Study Flow Chart

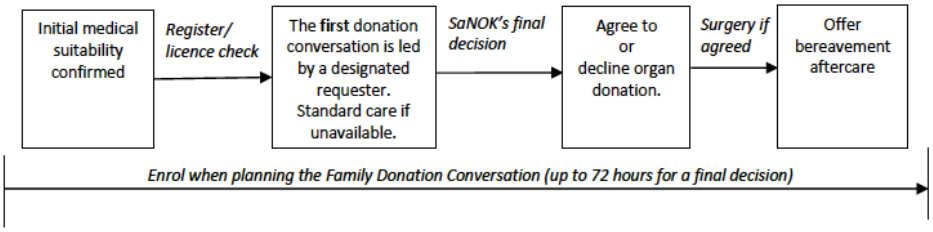

***Figure 1** Diagram of the study design*

6.2 Investigation Plan

The majority of procedures in this study are conducted routinely per normal practice.
Pre-intervention data will be collected from the approximately six month period before each site initiation visit. Data to be collected were recorded as per normal practice on hospital records, paper files and electronic databases of the NSW Organ and Tissue Donation Service and includes:

- Date of birth and date of death of those screened for organ donation;
- Final donation decision and the patient's donation intent recorded on their drivers licence and the Australian Organ Donor Register (AODR).

The intervention requires sufficient trained 'designated requesters' to be available when needed, and to lead donation conversations on a regular basis. An estimate of up to six appropriate requesters will be required from each centre to undertake specialised training (please see Appendix A). During the study period, critical care staff will be asked to complete a form to record details of request conversations and procedures. Many of these data are collected routinely as part of normal practice. All data collected for the purposes of this study will be de-identified.

Data variables required during the study recorded per normal practice are:

- Administrative data to characterise the setting such as, the number of hospital and ICU beds, availability of waiting rooms, categories of patients admitted to the ICU, areas of specialty in the ICU, medical, nursing and allied health staffing and availability, frequency of multidisciplinary ward rounds, and family meetings. These data are recorded twice, at the beginning and at completion of the study at each site.
- Data collected to characterise a potential donor's details such as: date of birth, gender, donation intent on their drivers licence and the AODR, ethnicity, religion, primary event/cause of death, details of certification of death, date of admission to the ICU, date and time procurement surgery was commenced, next of kin's relationship to the potential organ donor and their contact details. These data are recorded for each potential donor as per normal practice on paper files and electronic databases of the NSW Organ and Tissue Donation Service, and in the hospital records.

Adherence to elements of the intervention of the family donation conversation will be consecutively recorded and audited by self-report from the observations of health professionals who participated in the intervention. The role of the ICU health professional who led each initial family donation conversation (termed the 'requester') is central to this process, so for each donation conversation details of the person in this role will be collected by self-report: their demographic, training and donation experience.

- Reporting will be undertaken at the closure of the family donation conversation to minimise potential recall bias. A consensus approach will be used with equal weight given to each health professional's observations.
- The reasons stated by the next of kin for their final donation decision.

Table 3 contains a summary of procedures performed per normal practice and additional follow-up offered to the next of kin who participated in a donation conversation, regardless of their final decision to donate or not.

Table 3 Schedule of events

	STUDY PERIOD				
	Enrolment	**Allocation**	**Post-allocation**	**Mail ICD 10 weeks**	**Follow-up 90 days**
TIMEPOINT	$-t_1$	0	f_1	f_2	f_3
ENROLMENT:					
Eligibility screen	X				
Allocation		X			
Informed consent (written or verbal for D90 interview)				X	X
INTERVENTIONS:					
Usual practice		X			
First FDC led by DR		X			
Both groups offer bereavement aftercare			X		
ASSESSMENTS:					
Donation scenarios, FDC	X	X			
Endpoint: family donation decision		X			
Characteristics of SaNOK & opinions of donation decision					X

DR=designated requester; FDC=family donation conversation; ICD=informed consent document; SaNOK=senior available next of kin.

6.2.1 Follow-up

For this study we will seek consent from senior next of kin for the post-intervention follow-up interview. The Donor Family Support Coordinator will conduct a semi-structured telephone interview approximately 90 days post bereavement with senior next of kin who provide consent. In addition, with their consent, the interview with senior next of kin will be audio-recorded, although this is optional and interviews will be conducted with notes taken manually if participants do not consent to audio-recording.

A three-stage consent process will be used of:

1) Initial verbal consent to bereavement aftercare, followed by
2) Provision of a written invitation to participate in the Day 90 interview with an information sheet and consent form mailed to next of kin approximately two weeks before the proposed interview, and
3) Verbal confirmation of consent to proceed with the interview and for the audio-recording when agreed.

Data sought directly from the senior next of kin subsequent to consent are:

- Amount of bereavement support received.
- Their understanding of the information regarding organ and tissue donation.
- Their opinion of the adequacy of that information for them to make a decision.
- Whether they would make the same donation decision, and their rationale.
- Previous discussions with their relative regarding organ and tissue donation.
- Any other issue they wanted answered about donation and unanswered questions regarding their relative's care at the hospital.

Sensitive personal information including age, gender, ethnicity, religion and highest education level are asked at the end of the interview.

6.3 Study Procedure Risks

Communication with families regarding end of life decisions and organ donation is usual care in the hospital. The intervention increases the likelihood that emotionally distressed families are approached by ICU health professionals who are skilled in bereavement support and facilitation of specialised end of life decision making for organ donation. Next of kin may benefit in making decisions that are informed and this may result in reduced negative perceptions in relation to the decision process and subsequent bereavement over the longer term.

Regarding the follow-up, it is possible that contacting next of kin may cause them anxiety or distress. We plan to address this possibility in the following ways:

1) The person conducting the telephone interview at day 90 is the NSW Donor Family Support Coordinator, who is a registered nurse and a registered psychologist, and routinely follows up families who had agreed to donation. The support of this person is extended in this study to senior next of kin who declined donation. This additional support is currently not available to them under standard care.
2) Families who agreed to organ donation are routinely offered bereavement aftercare by the Donation Specialist Nurses at the hospital. When the SaNOK did not meet the Donation Specialist Nurse (DSN) the requester, hospital social worker or chaplain may offer OTDS bereavement aftercare.
3) As standard care many next of kin receive telephone support from the Donor Family Support Coordinator either at the usual 4-week follow-up call or initiate contact themselves, using the toll free number supplied by mail in the first two weeks post bereavement.
4) An invitation to participate in the Day 90 surveys will be mailed to next of kin approximately two weeks before the proposed interview so they are able to review the invitation to participate in the follow-up in their homes, and can decide at their leisure whether they wish to provide the time.
5) During telephone contact the participant can discontinue at any time should they show signs of emotional distress. The interview will be interrupted, and the participant will be given the opportunity to discontinue/continue later; options for help or support will be offered.
6) If any medical, psychological or emotional issues are disclosed during the telephone contact that require follow-up, the participant will be referred to appropriate practitioners. For help with psychological or emotional issues the interviewer, the Donor Family Support Coordinator, will negotiate follow-up support as needed by the next of kin with themselves or another registered psychologist, should that be more convenient for the participant.

6.4 Recruitment and Screening

Screening procedures for the identification of critically ill patients who are potentially suitable for deceased organ donation are per usual practice at each centre. A two stage screening procedure will be used to initially identify patients who are medically suitable for donation, and secondly to identify senior next of kin and health professionals who participated in conversations regarding the possibility of organ donation at the end of life.

A screening number will be allocated per potential donor and will be used to code data regarding actual or potential donors, their senior next of kin, requesting conversations and follow-up surveys.

6.5 Informed Consent Process

6.5.1 Intervention: Family Donation Conversation

The procedure for requesting consent for organ and tissue donation is a routine, although relatively infrequent component of end of life care for ICU health professionals. The intervention of this study is a quality improvement initiative for this process, anticipated to improve usual care by enabling it to be led by a health professional who has received specific training in supporting the bereaved and requesting organ donation, and conducted in line with current best practice. As a result the intervention offers potential benefit and only low risk as defined in the National Statement to next of kin participants (40).

We do not believe that it is necessary to seek consent from next of kin for use of patient data or for next of kin to participate in a requesting conversation as these procedures occur as part of normal standard care. The data related to this donation process are collected as part of standard care and our use of these data is consistent with the purpose for which they are collected (i.e. to support effective delivery of this aspect of care). Data collected to monitor adherence to elements of the intervention represent audit data (i.e. they represent staff adherence to best practice) and staff individuals will not be identified, other than by their designation.

6.5.2 Bereavement aftercare

Access to bereavement aftercare by members of the NSW Organ and Tissue Donation Service occurs routinely for next of kin who consented to donation. As a routine practice staff obtains verbal consent for this service, often before families have left the hospital. Bereavement aftercare will be extended to senior next of kin who declined donation: this is an extension of current services which has been sought by clinicians and which is possible for these participants. Verbal consent for the service will be sought from the senior next of kin or delegate who declined donation, the same approach as those who consented.

6.5.3 Follow-up interview

We feel that provision of written information about the follow-up interview at the time of donation would not be fully understood by next of kin due to emotional distress, and the timing would be inappropriate given their attention would be to procedures involved in organ donation or saying good bye to their relative.

Consent will be sought from senior next of kin for the post-intervention follow-up interview and for it to be audio-recorded. If participants do not consent to audio-recording, notes will be taken manually of interview findings by the interviewer. A three-stage process will be used of:

1) Initial verbal consent to bereavement aftercare , followed by

2) Provision of written information and obtaining written consent, and

3) Confirmation of verbal consent before conducting the interview, and for audio-recording when agreed.

The written invitation, Participant Information Sheet and Consent Form will be posted to senior next of kin who provided verbal consent to be contacted, approximately two weeks before the day-90 interview is due. A form will be included for participants to nominate a suitable day and time for the interview, or to decline contact. A pre-paid envelope, email address and toll free phone number will be provided to assist next of kin to return the information or to request further information. Should the NSW Organ and Tissue Donation Service fail to receive notification by Day 90 we will assume the posted information has not been received and the next of kin will be telephoned by the Family Support Coordinator. Verbal consent will be sought to proceed with the interview. This process will be explained in the Participant Information Sheet, so they are aware that non-response will be followed by telephone contact. Next of kin are able to change their mind at any time without affecting eligibility for ongoing bereavement support by the Family Support Coordinator.

7. SAFETY

This study does not involve investigation of therapeutic products or devices. Accordingly, adverse and serious adverse events are not anticipated and will not be collected or reported for this study.

8 STATISTICAL CONSIDERATIONS

Categorical data (e.g. details of gender, religion, ethnicity, and reasons to consent or decline donation) will be summarised by frequencies and percentages. Continuous data (e.g. age, time in family meetings) will be summarised using the mean and standard deviation. Where appropriate comparisons will be made using Chi square and t-tests. Exploratory analysis using multiple regression methods will be used as needed. A p-value of < 0.05 will be considered statistically significant.

To address the primary endpoint consent rates for deceased organ and/or tissue donation where the potential donor had not registered their decision in life, when requested by designated requesters using a best practice procedure for requesting consent, will be compared to rates with current standard practice decision processes.

To address the secondary endpoints:

a) Characteristics of the donation process including degree of staff adherence to core elements of the intervention and demographic characteristics of the potential donor and senior next of kin will be modelled to identify predictors of senior available next of kin consent to donation.
b) Health professionals' adherence rates to core elements of the intervention will be calculated
c) Numbers of next of kin who report they regretted their final decision either to consent or to decline donation at 90 days will be compared.

Content analysis will be used to systematically interpret the free text responses to open ended questions in the telephone follow-up. Audio-recordings will be transcribed, and responses read through a number of times to obtain a sense of the data. Exact words from the text that capture key ideas will be highlighted and their frequencies counted. Text will be tabulated and grouped into units of meaning, arising from text containing the key words. These units will be further reduced by condensing the text and then allocating a code that will be derived from the data and based on the representativeness of the ideas. Similar or related codes will be confirmed in a thesaurus and grouped to form categories(41).

9 CONFIDENTIALITY AND STORAGE AND ARCHIVING OF STUDY DOCUMENTS

Patient data will be de-identified and allocated a code, separate to the medical record number and donor number. The code list with patient details will be kept separately. All records are stored in a locked cabinet or password protected computer file at the NSW Organ and Tissue Donation Service, and at each site. Records for this study will be stored securely for seven years following publication of the results before destruction. Data reporting in publications will be non-identifiable and reported in aggregate form.

10 PUBLICATION AND USE OF STUDY FINDINGS

Results of this study will be presented in reports to the NSW Organ and Tissue Donation Service, will comprise part of the doctoral thesis for applicant Julie Potter, will be presented at national and international medical conferences and published in peer reviewed journals.

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APPENDIX A: SUMMARY OF TRAINING PROGRAM

The specialised communication training for designated requesters has two components, the Family Donation Conversations: Core and Practical modules(1) and the Simulation Training Program.

The training program provides staged training and sequential learning though theory and practical training. The Family Donation Conversations: Core and Practical modules, developed by the Organ and Tissue Authority (OTA), introduce specialised communication tools to assist requesters to support potential donor families in acute grief, while discussing the opportunity of organ and tissue donation.

Family Donation Conversation: Core Workshop

This two day workshop is an Australian product based on the Philadelphia Gift of Life Institute (GoLI) workshop that provide information on the advanced theory behind family donation conversations, skills and techniques to communicate with families when raising the opportunity for organ and tissue donation. The target group is health professionals responsible for requesting donation.

Family Donation Conversation: Practical Workshop

This one day follow-up practical workshop will allow participants to practice planning a family donation conversation and to manage a complex family conversation. The target group is health professionals responsible for requesting donation who have undertaken the core workshop.

Simulation Training Program

This half day workshop builds on communication skills from previous sessions. This accredited training workshop was developed in partnership with the University of Technology Sydney. The role of the designated requester and the family donation conversation are highlighted. The sessions are conducted in simulation laboratories in small groups with professional actors, with a maximum of four participants in each session. Video reflective learning is a key tool in training evaluation.

COMFORT study: Criteria for Protocol Violations

Overview

Eligibility for COMFORT is based on a designated requester approaching the family of a potential organ donor and delivering the intervention, regardless of the donation outcome.
For this study, the definition of a potential organ donor is:

- a person whose clinical condition is suspected to fulfil brain death criteria or
- a person in whom the cessation of circulatory and respiratory functions is anticipated to occur within a time frame that will enable organ recovery (1)

Inappropriate requester

The ANZICS Statement (2) describes intensive care trainees involvement in donation conversations as an observer, or the conversation leader when under supervision of the intensivist as part of training. Accordingly, for this study medical trainees e.g. from specialities of intensive care, neurosurgery and emergency medicine, who independently raise organ donation with families for the first time are defined as inappropriate requesters.

The definition of inappropriate requester is extended to include nursing and allied health professionals, Neurology/Neurosurgical Specialists and Emergency Medicine Specialists who raise organ donation with families for the first time.

Protocol Violations

1. The COMFORT intervention was not adhered to subsequent to identification of a potential organ donor.
2. Donation was raised by an inappropriate requester AND the final donation decision was made by the SaNOK before admission to the ICU / area for end-of-life care / donor management.
3. Organ donation was raised prematurely by an inappropriate requester and the patient was not a potential organ donor, regardless of the verbal donation decision by the SaNOK.

These cases are recorded on the screening log. Completion of the COMFORT case report forms (CRF) **will** be required if the person was a potential organ donor, assessed by an organ donation specialist at the hospital or the OTDS.

Exception

When a senior registrar or advanced trainee has passed their fellowship exams they are considered equivalent to an intensivist, and are to be categorised as an intensivist.
Accordingly organ donation conversations are not protocol violations in this instance and data are to be collected for COMFORT.

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Appendix 10: Case Report Form Completion Guidelines

Communication with Families regarding Organ and Tissue Donation after Death in Intensive Care Study

Short title: The COMFORT Study

Case Report Form Completion Guidelines

Version Number: 3, dated 15 November 2013

The Organ and Tissue Authority
NSW Organ and Tissue Donation Service

Table of Contents

Overview of Case Report Forms (CRF) numbers 1-7

There are 7 case report forms. The Donation Specialist Nurses (DSN) and the Research Coordinator (RC) will ensure completion of Forms 1-6. The Donor Family Support Coordinator will complete Form 7 during the follow-up interview.

Summary of Forms 1 to 7.

Form No.	Instructions
Form 1 Setting: Site Details	Completed by the DSN twice for each hospital, #1 following site initiation and #2 at completion of the study.
Forms 2-6 are completed once for each eligible potential organ and/or tissue donor in the ICU	
Form 2 Pre-conversation Action Plan	Complete this form at closure of the meeting to plan the first approach by a health professional to raise organ and/or tissue donation with the SaNOK.
Form 3 Meeting for the Family Donation Conversation	**Part A** First meeting: completed by health professionals who attended the first family donation conversation. One form to be completed **as soon as possible** following completion of the meeting. Each person will provide their own observations. **Part B** Outcome: completed when the senior next of kin provide their final decision.
Form 4 Reason(s) for the Final Donation Decision	Completed by the lead requester with the Donation Specialist Nurse. One form to be completed **as soon as possible** subsequent to notification of the final decision.
Form 5 Requester Details	Completed by the health professional who led the initial family donation conversation, and collected by the Donation Specialist Nurses. Can be completed retrospectively.
Form 6 Potential Donor Details	Completed by Donation Specialist Nurses and the Research Coordinator. Can be completed retrospectively.
Form 7 Interview with the Senior Next of Kin	Completed by the Donor Family Support Coordinator during the telephone interview with the senior next of kin.

Definition of meetings

Form 2: Pre-conversation action plan

This is the meeting between the requester and the managing team to:

- Negotiate roles in the family donation conversation.
- Agree on the method of introducing the requester and other team members to the family.

Information is shared regarding the patients' medical and social history, family dynamics, and outcomes of previous meetings. The requester may discuss the use of communication tools, such as silence, and the way they plan to use that technique in the meeting.

Form 3: First meeting to discuss organ donation " the family donation conversation"

This is a meeting convened by ICU health professionals to raise organ donation with the SaNOK for the first time. Include data from family meetings convened to inform the SaNOK the patient had died, or death was inevitable, when organ donation was subsequently discussed during that meeting (unplanned). This meeting may take place in the Emergency Department or the Intensive Care Unit.

Additional notes

Header details

Header details on each form include: the form number, a pre-allocated centre number, first initial of the first name and surname of the patient, and a pre-allocated COMFORT study number beginning with the centre number.

Study number

Study number: each patient is identified by a 5-digit code generated specifically for this study that is different to their medical record number or donor number.

- The first two numerals are the pre-allocated centre number.
- The remaining numerals are allocated sequentially at each centre for every patient who fulfils all inclusion and no exclusion criteria. These numbers will begin with a leading zero. For example the study number of the first eligible patient from site # 06 will be 06001, the next 06002 and so on.

The details of all patients who are allocated a study number will be recorded on the site enrolment log. This log remains at the hospital and will be reviewed for monitoring purposes.

Date of enrolment

Select the date of the pre-conversation planning meeting on Form 2.

General completion

Check boxes may be ticked ☑ (paper form) or ☒ (electronic form).
Mistakes: draw a single line through the incorrect entry, write the correct information next to it, initial and date the correction e.g ~~36~~ 39 $^{12/05/13}$

Completed forms

Scanned copies of each form can be forwarded by:

- Email to the generic clinical email address at the NSW Organ and Tissue Donation Service (clinical.otds@sesiahs.health.nsw.gov.au).

Original forms will be retained securely at each hospital. Forms will be entered into a secure database maintained by the NSW Organ and Tissue Donation Service.

Data Dictionary

Form 1: Setting site details	
This form is completed twice for each hospital, #1 following site initiation and #2 at completion of the study.	
Header	Pre-allocated centre number.
1.1-1.6	Answer with respect to the most recent available administrative data. A large intensive care unit (ICU) (e.g. "a hot floor") typically includes separate specialty units such as neurosurgical, cardiothoracic and general ICUs. Answer all questions with respect to the ICU as a single entity.
1.7	Patients are categorised per the primary diagnosis present on their admission to the ICU and which led to the ICU admission. These categories are the same as those used in routine data collection for the ANZICS Adult Patient Database. General medical (non-operative): patient was admitted directly to the ICU from a general ward or Emergency Department (including transfers from another hospital). General surgical (operative): patient was admitted directly to the ICU from operating theatres. Both medical and surgical: admits both categories.
1.8	An area of specialty includes medical and surgical conditions. Please select all that apply.
1.9-1.21	Answer with respect to the most recent available administrative, staffing and personnel data. Answer all questions with respect to the ICU as a single entity.
1.15-1.16	A day equals a 24 hour period.
1.18	Include only those who have completed and were awarded any post-registration critical care nursing qualifications.
1.22-1.26	Document the number and availability of people in the position. Include people who are seconded or "acting" in a position. During hours =office hours, the equivalent to a day shift and may commence anytime from 07:00 to 09:00 hours. After hours includes evenings, overnight and weekends. If in doubt record hours staff enter on their timesheets.
1.27	Document the opinion of the ICU Director. Record the designation of the professional group, e.g intensivists, Donation Specialist Medical.
1.28	Document the opinion of the ICU Nurse Unit Manager(s) or another key person as appropriate. An example of a special group is those nurses who have completed an Australasian Donor Awareness Program (ADAPT) workshop and who volunteer for allocation to potential organ donors.
1.29-1.32	Answer with respect to the most recent available administrative data.
1.33	Date the form was completed.

Form 2: Pre-conversation action plan	
Complete this form at closure of the planning event/meeting by health professionals to agree on the approach to raising organ donation with next of kin of a potential organ donor. Complete once for each potential donor who fulfils all inclusion and no exclusion criteria.	
Header	Complete the patient initials and study number per the instructions under "Additional notes".
2.1	Date and time the planning meeting started. A best estimate within 10 mins of the actual time is acceptable. Does not include the time of screening activities such as checking the registers.
2.2	Select the designation of each health professional who was either consulted via telephone or who physically attended the pre-conversation planning meeting. Each category equals one person. If there are > 1 of a category complete details in 'other, specify'. Select an individual's primary designation with respect to medical management of the patient. For an individual with multiple categories for example: • Intensivist (managing the patient) who is a Donation Specialist Medical (DSM) and a designated requester (DR), select intensivist (managing the patient). • Intensivist (not managing the patient) who may be a DSM and who will be the DR today, select designated requester. • Donation Specialist Nurse (DSN) who will be the DR today, select designated requester.
2.3	Select one option. Select an individual's primary designation with respect to medical management of the patient. In addition to the explanation in 2.2, if the Donation Specialist Nurse is a nominated DR at another hospital **and** will lead the family meeting today, select designated requester.
2.4	Record the documented time of the meeting in the medical notes. When documentation is lacking, obtain the time verbally from participants in that meeting. News regarding the inevitability of death is typically delivered to the family following consensus between referring and managing teams that withdrawing or withholding of intensive therapies is in the patient's best interests. Do not record the date and time of previous family conversations convened for the purpose of delivering bad news such as a poor prognosis.
2.5-2.6	Refers to discussions led by a health professional with the family. Complete with the available data. May be updated if previous discussions are revealed subsequently. Record designation, not the person's name. For example, RN (bedside), ICU registrar, or ED registrar.
2.7	Select each topic discussed. This list may be used as a checklist to assist planning.
2.8	Select if a pre-conversation action plan event did not occur.
2.9	Record the first time the Donation Specialist Nurse met the family of the potential donor face to face. A best estimate within 10 mins is acceptable. This time may be before, during or after the first family donation conversation. This includes the time the DSN met the family when they were the DR. Leave blank if the DSN never met the family.

Form 3: Meeting for the family donation conversation	
Header	Repeat the patient initials and study number used on Form 2.
Part A	*Complete this section at closure of the first family meeting, usually when health professionals are evaluating the outcome of the family donation conversation. It is distracting for all present if the clinician actually writes notes during the family meeting.* ***Obtain observations from all health professionals who attended the meeting.***
3.1	Date and time the meeting for this first family donation conversation started, and was completed 'stopped'.
3.2	Select the location of this meeting. Select "Other, and specify telephone if the consent was provided over the telephone. For example if the SaNOK was overseas.
3.3	Select one option and complete the details of this person in Form 5. Record the designation of the requester who actually led the first meeting to discuss organ donation. Select an individual's primary designation with respect to medical management of the patient. For an individual with multiple categories for example: • Intensivist (managing the patient) who is a Donation Specialist Medical (DSM) and a designated requester (DR), select intensivist (managing the patient). • Intensivist (not managing the patient)who may be a DSM and who was the DR today, select designated requester. • Donation Specialist Nurse (DSN) who was the DR today, select designated requester.
3.4	Select one item. Yes, the requester was introduced in relation to their role in organ donation. No, the requester was introduced "blinded" in relation to their role in general terms. For example, to support families with end of life decisions. NA, the designated requester was not introduced by the managing team, and introduced themself. NA, another member of the managing team led the meeting.
3.5 3.5.1 3.5.2 3.5.3	The managing intensivist is responsible for the potential donor's medical management. Select one of Yes, No or NA and complete details. Yes, record the time the intensivist left before the meeting closed N=No, did not leave the meeting, and select the main reason from the list: • Also a designated requester. • Led the meeting because a DR was unavailable. • Stayed to answer clinical management questions. • Stayed to observe the method of communication or to mentor a DR. or specify other reason NA=not applicable-select if the managing intensivist did not attend this meeting.

Form 3: Meeting for the family donation conversation	
3.5.4	If applicable, complete the time the DR left the meeting.
3.6	Select all that apply **and** circle "F" if raised by a family member who attended any part of this first meeting. To be completed as soon as possible after completion of the meeting. Each health professional will state their own observations or memories of the conversation with the family. Consensus does not need to be achieved between participants.
3.7	Select the designation of each health professional who attended any part of this first family donation conversation. Select categories per the definitions in 3.3.
3.8	Include family members who attended any part of this first family donation conversation. For example, include those who left before the meeting closed, or arrived after it had started. Numbers will begin with a leading zero, e.g. 01 for one person.
3.9	Record the relationship of the SaNOK to the patient. Do not record names.
3.10	If the SaNOK completed a form to delegate decision making to another record the relationship of that person, usually another family member, to the potential donor.
3.11	Select one option or complete "other, *specify*". Definite in principle consent: decision made according to the patient's values and preferences. Agreement to consider: agreement to receive more information, includes verbal assent. Initial decline "reactive no": decision made according to the circumstances or external factors, may not have received complete information regarding donation. Definite in principle decline: decision made according to the patient's values and preferences.
Part B	*Complete this section when the family makes their final donation decision. Remember to complete Form 4 with the reasons for the decision.* ***Complete with the individual who led the first conversation.***
3.12	Select one option or complete "other, *specify*". Written consent includes verbal, recorded consent via the telephone. Remember to complete Form 4 with the reason(s) for the final donation decision selected here.
3.13	Record the date and time of the final donation decision. For a written consent this will be the time the SaNOK signed the consent form or the time of the audio recording for consent via the telephone. For a decline this will be the time of the verbal decline to the requester or the Donation Specialist Nurse..
3.14	Include follow up meetings with members of the family. Count each encounter as '1'.
3.15-3.16	Select one option for 3.15 and complete 3.16 if "no" was selected.
3.17	Record the incision time documented in the confidential donor referral form or the electronic donor record for all potential donors who had procurement surgery commenced.
3.18-3.19	Complete when the final donation decision at 3.12 was revoked at the hospital. Document the reason for revocation stated by the family.

Form 4: Reason(s) for the final donation decision	
*This form is completed prospectively when the senior available next of kin has made their **final** donation decision. Complete once for each potential donor who fulfils all inclusion and no exclusion criteria. Complete **either** 4.1 or 4.2.*	
Header	Repeat the patient initials and study number used on Form 2.
4.1	Complete when the final donation decision documented on Form 3, Part B: Outcome (3.12) is a written consent. Select all reasons that apply and/or complete "other, *specify*". • Circle "S" if that reason was stated verbally by the SaNOK (or delegated decision maker). • Circle "P" if that reason was perceived by the requester.
4.2	Complete when the final donation decision documented on Form 3, Part B: Outcome (3.12) is a decline or "other". Select all reasons that apply and/or complete "other, *specify*". • Circle "S" if that reason was stated verbally by the SaNOK (or delegated decision maker). • Circle "P" if that reason was perceived by the requester.

Form 5: Requester details	
This form is for the health professional who actually led the first family donation conversation. This person was selected in the response to question 3.3. This form may be completed retrospectively.	
Header	Repeat the patient initials and study number used on Form 2.
5.1	Complete the date of birth, country of birth and gender of the requester.
5.2	Ethnicity: select one or more options. See Appendix A "Classifications of Ethnicity" for definitions.
5.3	Select one option. Select a religion from the list or prefer not to answer.
5.4	Specify the country where pre-registration health professional training was completed.
5.5	Select all options that apply **and** complete workshop attendance. Details of additional training programs or workshops not listed are to be included in "other, *specify*".
5.6	Include completed calendar years.
5.7	Count the family donation conversations per patient in the previous calendar year. For example, if the requester had led the first donation conversation with families of 6 potential organ donors, 6 would be recorded. This number does not relate to the number of meetings with each family or their final donation decision. Leading a conversation means that you are the first person to raise organ donation with a family. Leading a donation conversation to obtain more detailed information subsequent to the family providing verbal consent does not qualify.
5.8	Select all that apply or complete "other, *specify*". These categories relate to the individual.
5.9	Select either yes or no whether the requester was responsible for the potential donor's medical management when discussing donation with the SaNOK.

Form 6: Potential donor details	
This form is for the details of the potential organ donor following the final donation decision. This form may be completed retrospectively.	
Header	Repeat the patient initials and study number used on Form 2.
6.1	Complete the date of birth, country of birth and gender of the potential donor.
6.2	When the potential donor registered their decision in life please check each register where the information was sourced. Select 'Yes to donation' if agreement is found on a register for donation of all or any organs, **and** select the register(s). Select 'No to donation' if a decline for donation is found on a register, **and** select the register(s). Select not registered/not found and select register. Select registers not accessed for paediatric patients, or overseas residents.
6.3	Ethnicity: select one or more options. Details are included in "Classifications of Ethnicity" in Appendix A.
6.4-6.5	Select one option or complete "other, *specify*".
6.6	The date and time death was certified. For a decline to donation select "circulatory death criteria" **and** record the date and time death was certified.
6.7	Record the date and time of admission to the study hospital ICU. If the patient has had more than one admission to the ICU in this hospital stay, record the date and time of the ICU admission when the patient died.
Sign	The Donation Specialist Nurse to sign and date when they have checked the CRF, verified the data to the best of their knowledge and completed any omissions etc.

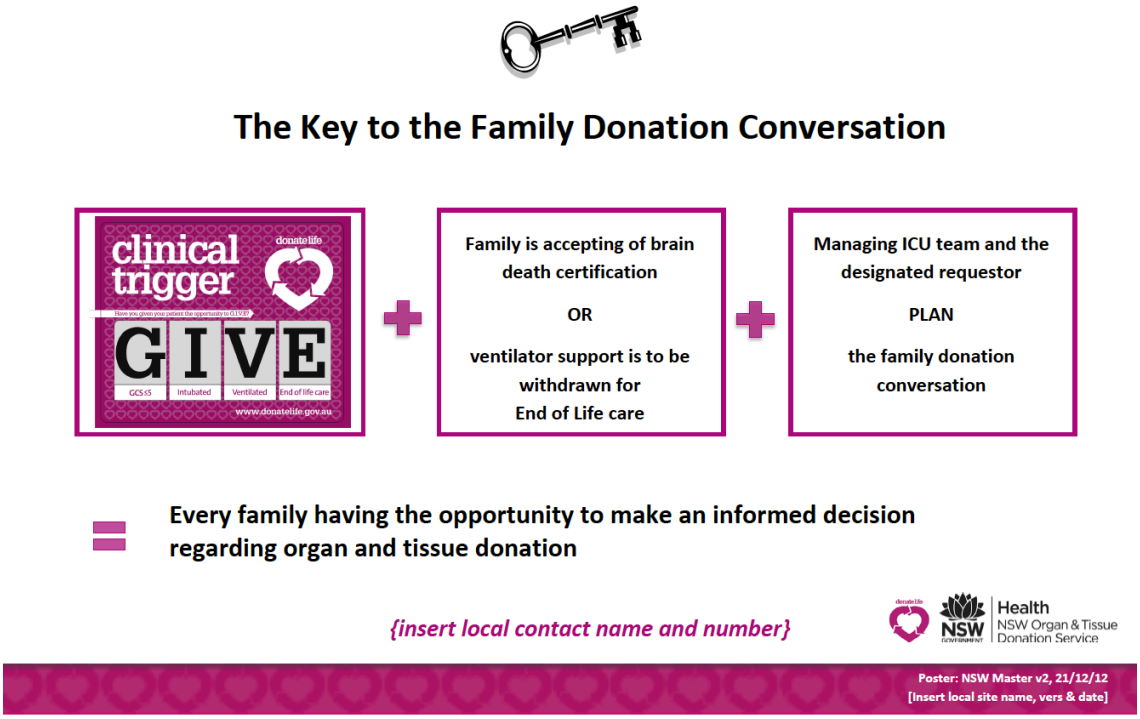
Form 7: Interview with the senior next of kin	
The information on this form is sourced from the interview with the Donor Family Support Coordinator and the SaNOK. Verbal assent is always provided by the participant before commencing the interview.	
Header	Repeat the patient initials and study number used on Form 2.
7.1-7.14	The wording of each question may be sensitively modified by the interviewer as necessary. The questions may not always be answered in sequence because people may provide the answers unsolicited during the conversation.

Appendix A: Classifications of Ethnicity*

- **Oceanian: Australian or New Zealander**
- **Oceanian: Aboriginal or Torres Strait Islander**
- **Oceanian: Pacific Islander (except Maori)**- includes Melanesian and Papuan, Micronesian and Polynesian peoples
- **Oceanian: New Zealand peoples, Maori**
- **North-Western European:** includes British, Irish, *Western European* (Austrian, Dutch, Flemish, French, German, Swiss, Belgian, Frisian, Luxembourg),
  and Northern European (Danish, Finnish, Icelandic, Norwegian, and Swedish).
- **Southern and Eastern European:** includes *Southern European* (Basque, Catalan, Italian, Maltese, Portugese, Spanish, and Gibraltarian),
  South Eastern European (Albanian, Bosnian, Bulgarian, Croatian, Greek, Macedonian, Moldovan, Montenegrin, Romanian, Roma/Gypsy, Serbian, Slovene, Cypriot, Vlach), and
  Eastern European (Belarusan, Czech, Estonian, Hungarian, Latvian, Lithuanian, Polish, Russian, Slovak, Ukrainian, Sorb/Wend).
- **North African and Middle Eastern:** includes *Arab* (Algerian, Egyptian, Iraqi, Jordanian, Kuwaiti, Lebanese, Libyan, Moroccan, Palestinian, Saudi Arabian, Syrian, Tunisian, Yemeni, Bahraini, Emirati, Omani, and Qatari),
  Jewish,
  Peoples of the Sudan (Bari, Darfu/Darfurian, Dinka, Nuer, South Sudanese and Sudanese),
  Other North African and Middle Eastern (Berber, Coptic, Iranian, Kurdish, Turkish, Assyrian, Chaldean, Mandaean, and Nubian).
- **South-East Asian**: includes *Mainland South-East Asian* (Anglo-Burmese, Burmese, Hmong, Khmer (Cambodian), Lao, Thai, Vietnamese, Karen, Mon, Chin,and Rohingya), and
  Maritime South-East Asian (Filipino, Indonesian, Javanese, Madurese, Malay, Sundanese, Timorese, Acehnese, Balinese, Bruneian, Kadazan, Singaporean, and Temoq).
- **North-East Asian**: includes *Chinese Asian* (Chinese and Taiwanese) and
  Other North-East Asian (Japanese, Korean, Mongolian and Tibetan).
- **Southern and Central Asian:** includes *Southern Asian* (Anglo-Indian, Bengali, Burgher, Gujarati, Indian, Malayali, Nepalese, Pakistani, Punjabi, Sikh, Sinhalese, Maldivian, Bangladeshi, Bhutanese, Fijian Indian, Kashmiri, Parsi, Sindhi, Sri Lankan, Sri Lankan Tamil, Indian Tamil, and Telugu), and
  Central Asian (Afghan, Armenian, Georgian, Kazakh, Pathan, Uzbek, Azeri, Hazara, Tajik, Tatar, Turkmen, Uighur, and Kyrgyz).
- **Peoples of the Americas:** includes *North American* (African American, American, Canadian, French Canadian, Hispanic (North American), Native North American Indian, and Bermudan), and
  South American (Argentinian, Bolivian, Brazilian, Chilean, Colombian, Ecuadorian, Guyanese, Peruvian, Uruguayan, Venezuelan, and Paraguayan),
  Central American (Mexican, Nicaraguan, Salvadoran, Costa Rican, Guatemalan, and Mayan) and
  Caribbean Islander (Cuban, Jamaican, Trinidadian (Tobagonian), Barbadian, and Puerto Rican).
- **Sub-Saharan African:** includes *Sub-Saharan African, Central and West African* (Akan, Fulani, Ghanaian, Nigerian, Yoruba, Ivorean, Liberian, Sierra Leonean, Acholi, Cameroonian, Congolese, Gio, Igbo, Krahn, Mandinka, Senegalese, Themne, and Togolese),
  Southern and East African (Afrikaner, Angolan, Eritrean, Ethiopian, Kenyan, Malawian, Mauritian, Mozambican, Namibian, Oromo, Seychellois, Somali, South African, Tanzanian, Ugandan, Zambian, Zimbabwean, Amhara, Batswana, Hutu, Masai, Tigrayan, Tigre, Zulu, Burundian, Kunama, Madi (Ma'di), Ogaden, Rwandan, Shona, Swahili, and Swazilander).

* http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/2901.0Chapter602011 (the Australian Standard Classification of Cultural and Ethnic Groups (ASCCEG) Second Edition, Revision 1)

Appendix 11: NSW Master Poster and Fact Sheet



insert Local Health District logo

Communication with Families Regarding Organ and Tissue Donation after Death in Intensive Care (COMFORT) Study

Overview:

The aim of the COMFORT study is to examine the process of organ donation decision-making and to determine whether changes in requesting practices might affect changes in consent for donation, and family outcomes. This study has been approved by the St Vincent's Hospital Human Research Ethics Committee.

Intervention:

Intensivists, experienced critical care nurses such as donation specialist nurses, and social workers from this hospital are undertaking advanced training in communicating with families regarding organ and tissue donation after death. Some of these people are selected to be a '**designated requester**', and they will have prime responsibility for family discussions regarding organ and tissue donation in the critical care environment.

- The designated requester will provide families with timely and sufficient information about the opportunity of organ and tissue donation so they can make a fully informed decision.
- A designated requester has prime responsibility for all discussions regarding organ and/or tissue donation with potential donor families.
- When next of kin raise the possibility of the patient donating organs or tissue after death, the managing team will sensitively defer the conversation to the designated requester.
- Primary communication with families concerning end of life management and death will remain the responsibility of the managing Intensive Care team.
- Structured handover to the requesting team will need to be planned.
- Donation conversations will be conducted within a family meeting, structured on evidence-based guidelines for high quality communication regarding end of life care.

Contact:

The Donation Specialist Nurse
Contact No: (insert number).

The Donation Specialist Nurse will contact the Designated Requester for family donation conversations.

Appendix 12: NSW Referrals Data Dictionary and CRF

Communication with Families regarding Organ and Tissue Donation after Death in Intensive Care study

Short title: The COMFORT Study

NSW Hospital Referrals Data Dictionary

Version 2, dated 27 September 2016

Level 6, 4 Belgrave St, Kogarah, NSW 2217 · PO Box 486, Kogarah NSW 1485
T 02 8566 1700 · F 02 8566 1755 · W nsworgandonation.org.au

All NSW Hospital Referrals

Introduction

Include data from notifications or referrals to the NSW Organ and Tissue Donation Service (OTDS) recorded on the OTDS Referral Log Form or entered in electronic databases when the patient is located in either the Emergency Department or the intensive care unit.
Do not include data from general wards, nursing homes etc.

Definition	Variable Name	Coding Instructions/Values
NSW Hospitals (audited public and private). COMFORT sites #1-9 1 = John Hunter 2 = Liverpool 3 = Prince of Wales 4 = Royal North Shore 5 = Royal Prince Alfred 6 = St George 7 = St Vincent's 8 = Tweed 9 = Children's Hospital at Westmead 10 = Albury 11 = Bankstown 12 = Blacktown 13 = Calvary (Newcastle) 14 = Campbelltown 15 = Coffs Harbour 16 = Concord 17 = Gosford 18 = Hornsby 19 = Kempsey 20 = Lidcombe 21 = Lithgow 22 = Lismore 23 = Maitland 24 = Mater (Private) 25 = Manly 26 = Mona Vale 27 = Mt Druitt 28 = Macquarie University Private 29 = Muswellbrook 30 = Nepean 31 = Newcastle Mater (Private) 32 = Orange 33 = Port Macquarie 34 = Sydney Adventist (Private) 35 = Sydney Children's 36 = Shoalhaven 37 = St Vincent's Private, Sydney 38 = St George Private 39 = Strathfield Private 40 = Sutherland 41 = Tamworth 42 = Taree 43 = Wagga 44 = Westmead 45 = Wollongong 46 = Wyong 47 = Griffith	Hosp	 1 = JHH 2 = LVP 3 = POW 4 = RNS 5 = RPA 6 = STG 7 = SVH 8 = TWD 9 = CHW 10 = ALBU 11 = BANK 12 = BLKT 13 = CALV 14 = CAMP 15 = COFF 16 = CONC 17 = GOSF 18 = HORN 19 = KEMP 20 = LIDC 21 = LITH 22 = LISM 23 = MAIT 24 = MATR 25 = MNLY 26 = MNVL 27 = MTDR 28 = MUHP 29 = MUSW 30 = NEPN 31 = NMAT 32 = ORAN 33 = PTMQ 34 = SADV 35 = SCHL 36 = SHVN 37 = STVP 38 = STGP 39 = STRP 40 = SUTH 41 = TAMW 42 = TARE 43 = WAGG 44 = WEST 45 = WGNG 46 = WYON 47 = GRIF
Numerical code for hospital in the database	HospID	Allocate per above 'Hosp'

Definition	Variable Name	Coding Instructions/Values
Hospital categories Categorised as a COMFORT site subsequent to the site initiation visit when recruitment commenced.	HospCats	1 = COMFORT site 2 = Other NSW
Patient date of birth Use date of birth to calculate age in years last birthday at referral.	PDoB	Enter using dd.mmm.yy
Patient age	PAge	Age in years at last birthday 0 = < 1 year *Leave blank if missing*
Patient gender	PGend	1 = Male 2 = Female
Primary cause of death MVA = Motor vehicle accident MBA = Motor bike accident Cyclist Pedest = Pedestrian OthrRd = Other road accident Fall OthrAccid = Other accident Gun = Gunshot Felon = Felony or crime e.g assault, specify OthrSelec = Other selected SAH = Spontaneous subarachnoid haemorrhage ICH = Other spontaneous intracranial haemorrhage CeInfarct = Cerebral infarct Hypoxia CeOedema = Cerebral oedema CeTumBen = Cerebral tumour benign CeTumMal = Cerebral tumour malignant Drown = Drowning Hang = Hanging Asthma SIDS = Sudden Infant Death Syndrome (SIDS)	PrimCausDth	1 = MVA 2 = MBA 3 = Cyclist 4 = Pedest 5 = OthrRd 6 = Fall 7 = OthrAccid 8 = Gun 9 = Felon 10 = OthrSelec 11 = SAH 12 = ICH 13 = CeInfarct 14 = Hypoxia 15 = CeOedema 16 = CeTumBen 17 = CeTumMal 18 = Drown 19 = Hang 20 = Asthma 21 = SIDS
Primary cause of death other	PrCausDthOthr	*Free text*
Summary of circumstances leading to death **CVA**: ICH, SAH, cerebral infarct **Trauma (road)**: MVA, MBA, cyclist, pedestrian **Trauma (non-road)**: fall, gunshot, felony (assault) **Hypoxia-anoxia**: hanging, drowning, asthma, cardio-respiratory arrest **Cerebral tumour**: benign, malignant **Other neuro**: meningitis, encephalitis, epilepsy, cerebral oedema **Non-neurological (other)**: e.g. overdose, SIDS, metabolic	DeathCats	0 = CVA 1 = Trauma (road) 2 = Trauma (non-road) 3 = Hypoxia-anoxia 4 = Cerebral tumour 5 = Other neuro 6 = Non-neuro

Definition	Variable Name	Coding Instructions/Values
First raised donation with the family (initiator of discussion) DR = Designated requester DSM = Donation Specialist Medical DSN = Donation Specialist Nurse ED = Emergency Department Fam = Family ICU = Intensive care unit Int = Intensivist (intensive care specialist doctor) ND = Not discussed Reg = Registrar (trainee) Sx = Surgeon Sw = Social worker	FstRsdDon	0 = ND 1 = DR 2 = DSM 3 = DSN 4 = EDSpec 5 = EDReg 6 = Fam 7 = Friends 8 = ICUReg 9 = Int 10 = NeuroReg 11 = NeuroSx 12 = Other 13 = Police 14 = Patient 15 = SW ***Leave blank if missing***
Numerical code for designation of individual in the database	FstRsdDonID	Allocate ID per above 'FstRsdDon'
First raised donation categories Include patient and friends in the group "Family raised" Inappropriate requesters include those defined in criteria for a protocol violation	FstRsdDonCats	1 = Family 2 = Donation Specialist, DR 3 = Int 4 = Inappropriate requester
Referral date	RefDate	Enter using dd.mmm.yy
Potential donation pathway Tissue only: include referrals for a patient staying in an ICU or ED, eligible for donation of tissue only after death.	DonPth	4 = Tissue only
Final organ donation decision Yes=agreed to donation (written or verbal) No= declined donation (verbal)	Final_Dec	1 = Yes 2 = No ***Leave blank if missing***
Roads & Maritime Services (RMS) Donor Register Register accessed and the potential organ donor: NF = not found or not answered Yes: agrees to all organs or selected organs (some) No: declines organ donation NAC = register not accessed by the OTDS	RMS	0 = NF 1 = Yes (All/some) 2 = No 3 = NAC
Australian Organ Donor Register (AODR) Register accessed and the potential organ donor: NF = not found or not answered Yes: agrees to all organs or selected organs (some) No: declines organ donation NAC = register not accessed by the OTDS	AODR	0 = NF 1 = Yes (All/some) 2 = No 3 = NAC

Definition	Variable Name	Coding Instructions/Values
Outcome of referral ***Reasons organ donation did not proceed i.e. potential donor not utilised donor (PTNUD)*** *System (fulfils one or more criteria)** • Brain death diagnosis not confirmed. • Circulatory death not declared within the appropriate time frame. • Logistical problems (e.g no recovery team). • Lack of suitable recipient (e.g child, blood type, serology positive). *Donor/Organ (fulfils one or more criteria)** • Medical unsuitability (e.g serology positive, neoplasia). • Haemodynamic instability/unanticipated cardiac arrest. • Anatomical, histological and/or functional abnormalities of organs. *Permission (fulfils any criteria)* • Family decline. • Patient decline. • Coroner decline. • No SaNOK and no registered decision ***Actual organ donor*** • Donation after brain death (DBD). • Intended brain dead donor (iDBD). • Donation after circulatory death determination (DCDD) • Intended DCDD. Note: intended donors have provided consent (verbal or written) AND a blood sample has been collected AND sent for tissue typing with allocation of a donor ID, but donation did not proceed. *previously included under the term "not medically suitable" (NMS)	RefOutcome	1 = Syst 2 = DonOrg 3 = Permission 4 = DBD 5 = iDBD 6 = DCDD 7 = iDCD
For COMFORT sites: enrolled in the COMFORT study	Enrol	1 = Yes 2 = No
Allocated COMFORT study number First two numerals are the pre-allocated site number. Remaining numerals are allocated sequentially by each centre.	COMFORT_ID	SSNNN

Key dates

Study site	Start date 6months pre	Date of site initiation visit
Royal Prince Alfred Hospital	01 Nov 2012	1 May 2013
John Hunter Hospital	06 Nov 2012	6 May 2013
Tweed Hospital	06 Dec 2012	6 June 2013
Liverpool Hospital	17 Dec 2012	17 June 2013
St George Hospital	16 Jan 2013	16 July 2013
Royal North Shore Hospital	29 Jan 2013	29 July 2013
St Vincent's Hospital	21 Feb 2013	21 August 2013
Prince of Wales Hospital	20 Jun 2013	21 December 2013
Children's Hospital at Westmead	30 Jan 2014	30 July 2014

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P	Q	R	S	T
1	Hosp	HospID	HospCats	PDoB	PAge	PGend	PrimCausDth	PrCausDthOthr	DeathCats	FstRsdDon	FstRsdDonID	FstRsdDonCats	RefDate	DonPth	Final_Dec	RMS	AODR	RefOutcome	Enrol	COMFORT_ID
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Appendix 13: Supplemental Tables

Table A13.1

Requester Adherence by Individual HCP by Study Site

Site No.	Designated requester	Total requesters[a]	Proportion DR
	n	*n*	(%)
1	8	29	27.6
2	9	16	56.3
3	6	12	50.0
4	10	16	62.5
5	8	18	44.4
6	8	16	50.0
7	5	8	62.5
8	4	5	80.0
9	2	5	40.0

Note: *N* = 117 individual HCPs. DR = designated requester; HCP = healthcare professional.
[a]Worked in two sites during the intervention period: designated requesters *n* = 7; managing team *n* = 1.

Table A13.2

Events/Circumstances Leading to Death (Intervention Period)

Characteristic	Value	
	n	*%*
Other intracranial haemorrhage	95	22.8
Cerebral hypoxia-anoxia	94	22.5
Subarachnoid haemorrhage	67	16.1
Fall	42	10.1
Cerebral infarct	26	6.2
Other event	20	4.8
Pedestrian	14	3.4
Hanging	13	3.1
Motor vehicle accident	10	2.4
Motor bike accident	9	2.2
Felony or crime (assault)	7	1.7
Other accident	5	1.2
Cerebral oedema	4	1.0
Drowning	4	1.0
Cyclist	3	0.7
Gunshot	2	0.5
Cerebral tumour (benign)	1	0.2
Cerebral tumour (malignant)	1	0.2

Note. *N* = 417 for the full sample.

Table A13.3

Characteristics of Requesters Leading the First FDC (Intervention Period) by Case

Characteristics	Value		
	N	*n*	%
Country of birth: Australia	414	153	37
Religious affiliation	407		
Christianity		189	46
No religion		144	35
Non-Christian religions; non-religious beliefs		74	18
Country of pre-registration training, Australia	414		
Australia		181	44
United Kingdom		72	17
India		38	9
Other country		123	30
Designation of HCP leading the first FDC	417		
Medical HCPs			
Intensivist[a]		201	48
Donation specialist medical (all DR)		135	32
ICU Registrar (trainee)		8	2
ED staff specialist		1	0.2
Nurse and Allied Health HCPs			
Donation specialist nurse		67	16
Social worker		4	1
RN (post grad qualifications)		1	0.2
Years working in ICU	417		
≤ 4[b]		6	1
5-10		135	32
11-15		115	28
≥ 16		161	39
Total of actual FDCs led by HCPs	417		
1		42	10
2-4		120	29
≥ 5		255	61

Note. N = 417 for the full sample. DR = designated requester; FDC = family donation conversation; HCP = healthcare professional; ICU = intensive care unit; RN = registered nurse.
Total % for some categories will deviate from 100% by ± 0.1% due to rounding.
[a]Includes *n* = 58 intensivists who were also a designated requester but not a donation specialist medical;
[b] one case requester had not worked in ICU

Table A13.4

All Attendees of the First Donation Conversation (Intervention Period) by Case

Characteristic	Unregistered subsample		Full sample	
	n	%	*n*	%
HCPs attended the first FDC				
1	16	9	34	8
2	24	15	60	14
3	53	32	149	36
4	41	25	105	25
5+	30	18	69	16
Family members and friends attended				
1-2	38	23	93	22
3-5	86	52	204	49
6-9	24	15	82	20
10+	16	10	38	9
Family members attend every meeting				
Yes (only one meeting)			177	42
Yes > 1 meeting			168	40
No			72	17

Note. $N = 417$ cases for the full sample ($n = 164$ for the unregistered subsample).
FDC = family donation conversation; HCP = healthcare professional.
Total % for some categories will deviate from 100% by ± 0.1% due to rounding.

Table A13.5

FDC Attendees: Individual Family Members and Friends (Intervention Period)

Characteristics	Unregistered Subsample		Full Sample	
	M (SD)	Range	*M (SD)*	Range
Family members present	4.8 (3.5)	1, 26	4.9 (3.4)	1, 26
	n	%	*n*	%
Relationship of family members				
Spouse/partner/de facto/same sex partner	81	10	264	13
Adult children or step children	137	17	457	22
Parent (include step or adoptive parents)	139	17	280	14
Adult sibling	157	20	367	18
Adult sibling's partner	52	6	144	7
Adult children's partner	16	8	49	9
Grandparent	19	2	24	1
Extended family: uncle/aunt, nephew/ niece, grand or great nephew/niece, cousins (and partners)	59	28	151	28
Other family members or friends attended	134	17	330	16

Note. $N = 2066$ individuals for the full sample ($n = 794$ for the unregistered subsample).
Total % for some categories will deviate from 100% by ± 0.1% due to rounding.

Table A13.6.

Reasons for non-Adherence During the First Donation Conversation by Case for the Full Sample

Characteristic	Value		
	N	*n*	%
Main reason why MI led the FDC[a]	127[b]		
Answer clinical management questions		33	26.0
DR not invited/deemed not necessary or appropriate		31	24.4
DR was unavailable		31	24.4
EOL conversation led into FDC		13	10.2
"(wanted to) lead the meeting"		12	9.4
Other and unclear		7	5.5

Note. N = 154 cases led by managing team for the full sample.
DR = designated requester; EOL = end-of-life; FDC = family donation conversation; MI = managing intensivist.
[a] Additional comments from MIs:
n = 8 felt it was their responsibility;
n = 5 felt comfortable in raising donation;
n = 4 had already met family and built a rapport (existing relationship);
n = 1 their usual practice.
[b] Missing *n = 9;* and *n* = 18 not applicable (MI did not attend this meeting)

Appendix 14: Permissions to Reproduce Published Works

Paper 1 Communication with families regarding organ and tissue donation after death in intensive care (COMFORT): protocol for an intervention study. *BMC Health Services Research* 2017;(1):42. doi: 10.1186/s12913-016-1964-7.

Paper 2 Simulation-based communication skills training for experienced clinicians to improve family conversations about organ and tissue donation. *Progress in Transplantation* 2017;27(4):339-345. doi: 10.1177/1526924817731881.

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Date: 21 October 2020 at 3:57 am
To: Rebecca Winsett RPWinsett@natco1.org, Julie.Potter@health.nsw.gov.au, julespot1@gmail.com

SH

Hi Rebecca and Julie,

U0lizing your ar0cle in your disserta0on is covered under our author re-use policy found here h=ps://us.sagepub.com/en-us/nam/journal-author-archiving-policies-and-re-use Please review the informa0on provided, but no further permission is required in this case.

Congratula0ons Julie, and please let me know if you have any ques0ons or if there is any addi0onal informa0on I can provide.

Thank you,
Stephanie

From: Rebecca Winse= <RPWinse=@natco1.org>
Sent: Tuesday, October 20, 2020 9:49 AM
To: Stephanie Henkel <Stephanie.Henkel@sagepub.com>
Subject: FW: Progress in Transplanta0on - Manuscript ID PIT-16-0114 -copyright permission for inclusion in PhD thesis

[EXTERNAL]

Julie
I'm so glad you will be able to use your publica0on as part of your disserta0on and thank you for contac0ng me.
The permission to use needs to come from the publisher, so I have forwarded this to our SAGE Publishing Editor who can facilitate this for you.

Stephanie
Will you connect Julie to appropriate person/department to obtain permission to use her publica0on?
Thank you.

And Julie, congratula0ons and good luck.
All the 0me and effort to obtain your doctorate is well worth it.

Rebecca P Winse= PhD
Editor in Chief
Progress in Transplantation
rpwinse=@natco1.org

PROGRESS IN TRANSPLANTATION

From: Julie Po=er (Northern Sydney LHD) <Julie.Po=er@health.nsw.gov.au>

Paper 3 COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT) intervention: a multicentre pre-post study. *Critical Care and Resuscitation* 2018;20(4):268-276.

From: **BELLOMO, Rinaldo** Rinaldo.BELLOMO@austin.org.au
Subject: Re: Crit Care Resusc article - Potter341. Accepted article request copyright permission for PhD thesis
Date: 20 October 2020 at 9:44 am
To: Julie Potter (Northern Sydney LHD) Julie.Potter@health.nsw.gov.au

RB

Dear Julie,

I am happy to give your permission for including this article and its Pdf

Potter J, Perry L, Elliott R, O'Leary M, Aneman A, Brieva J, Cheng A, Seppelt I, Herkes R and the COMFORT investigators.
COMmunication with Families regarding ORgan and Tissue donation after death in intensive care (COMFORT) intervention: a multicentre pre-post study. *Critical Care and Resuscitation* 2018;(20):4.

in your PhD thesis.

Best regards,

Rinaldo

Rinaldo Bellomo AO
MBBS (Hons), MD, PhD, FRACP, FCICM
Professor of Intensive Care, The University of Melbourne
Professor of Medicine, Monash University
Honorary Professor of CriCcal Care Medicine, University of New South Wales
Honorary Fellow, Howard Florey InsCtute of Physiology
NHMRC PracCConer Fellow and Co-director ANZ Intensive Care Research Centre
Editor-in-Chief, CriCcal Care & ResuscitaCon
Director of Intensive Care Research, AusCn Hospital
Director of Data AnalyCcs Research and EvaluaCon (DARE) Centre
Co-director of Centre for Integrated CriCcal Care, Melbourne University
Senior Research Advisor, Royal Melbourne Hospital
Staff Specialist in Intensive Care AusCn Hospital & Royal Melbourne Hospital
& Warringal Private Hospital
Email: Rinaldo.bellomo@ausCn.org.au
Tel: +61-3-94965992; Fax: +61-3-94963932

From: Julie Po] er (Northern Sydney LHD) <Julie.Po] er@health.nsw.gov.au>
Sent: Tuesday, October 20, 2020 9:38 AM
To: ccr@cicm.org.au <ccr@cicm.org.au>; BELLOMO, Rinaldo <Rinaldo.BELLOMO@ausCn.org.au>
Cc: Julie Po] er <Julie.E.Po] er@student.uts.edu.au>
Subject: Crit Care Resusc arCcle - Po] er341. Accepted arCcle request copyright permission for PhD thesis

Dear Rinaldo

I hope this finds you well and recovering from COVID cases. I am wriCng to ask for copyright permission to include the arCcle published in your journal *Critical Care and Resuscitation* in my PhD thesis, when it is published. The thesis will be submi] ed for examinaCon by