Communication with Families Regarding Organ and Tissue Donation after Death in Intensive Care (COMFORT): a multicentre before-and-after study

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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.

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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

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

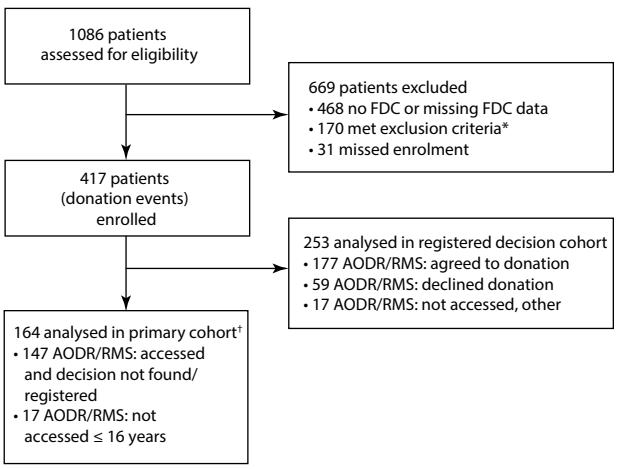
The COMFORT intervention incorporated six best-practice components for offering organ donation in the hospital setting[13] (Box).

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

	Final decision		Bivariate test	
Component	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.

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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.

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