Effect of a Quality-Improvement Intervention on End-of-Life Care in the Intensive Care Unit

A Randomized Trial

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***Rationale*: Because of high mortality, end-of-life care is an important component of intensive care.**
***Objectives*: We evaluated the effectiveness of a quality-improvement intervention to improve intensive care unit (ICU) end-of-life care.**
***Methods*: We conducted a cluster-randomized trial randomizing 12 hospitals. The intervention targeted clinicians with five components: clinician education, local champions, academic detailing, clinician feedback of quality data, and system supports. Outcomes were assessed for patients dying in the ICU or within 30 hours of ICU discharge using surveys and medical record review. Families completed Quality of Dying and Death (QODD) and satisfaction surveys. Nurses completed the QODD. Data were collected during baseline and follow-up at each hospital (May 2004 to February 2008). We used robust regression models to test for intervention effects, controlling for site, patient, family, and nurse characteristics.**
***Measurements and Main Results*: All hospitals completed the trial with 2,318 eligible patients and target sample sizes obtained for family and nurse surveys. The primary outcome, family-QODD, showed no change with the intervention ($P = 0.33$). There was no change in family satisfaction ($P = 0.66$) or nurse-QODD ($P = 0.81$). There was a nonsignificant increase in ICU days before death after the intervention (hazard ratio = 0.9; $P = 0.07$). Among patients undergoing withdrawal of mechanical ventilation, there was no change in time from admission to withdrawal (hazard ratio = 1.0; $P = 0.81$).**
***Conclusions*: We found this intervention was associated with no improvement in quality of dying and no change in ICU length of stay before death or time from ICU admission to withdrawal of life-sustaining measures. Improving ICU end-of-life care will require interventions with more direct contact with patients and families.**
Clinical trial registered with www.clinicaltrials.gov (NCT00685893).

Keywords: cluster randomized trial; critical care; withdrawal of life support; end-of-life care; palliative care

AT A GLANCE COMMENTARY

Scientific Knowledge on the Subject

Because of high mortality, end-of-life care is an important component of intensive care, and yet studies suggest the current quality of this care is often poor.

What This Study Adds to the Field

We evaluated the effectiveness of a quality-improvement intervention to improve intensive care unit (ICU) end-of-life care by conducting a cluster-randomized trial randomizing 12 hospitals. We found that this intervention was associated with no improvement in quality of dying or quality of care and no change in ICU length of stay before death. Improving ICU end-of-life care will likely require interventions with more direct contact with patients and families.

The intensive care unit (ICU) is a common setting for death, and most ICU deaths are preceded by a decision to withhold or withdraw life-sustaining therapies (1, 2). Therefore, end-of-life care is an important component of ICU care. There is compelling evidence of problems with the quality of end-of-life care in the ICU (3–6). For example, many patients die with moderate or severe pain (3, 4), and physicians are often unaware of patients' preferences regarding end-of-life care (7). Family of ICU patients have a high prevalence of symptoms of anxiety, depression, and post-traumatic stress disorder (5) and report physician and nurse behaviors that increase their burden (6).

There have been several studies suggesting that interventions to improve communication in the ICU can improve end-of-life care and reduce ICU days before death (8–11). To date, only one intervention study has examined patient- or family-centered outcomes: a randomized trial from France demonstrated that a proactive ICU family conference and a bereavement pamphlet produced dramatic reductions in psychological symptoms among family members 3 months after a death in the ICU (12). However, how best to implement these findings into practice is unclear.

In an effort to improve end-of-life care in the ICU, we developed a multifaceted, interdisciplinary, quality-improvement intervention. We previously published a single-center, before–after study showing the intervention was associated with improved nurse ratings of quality of dying and reduced ICU length of stay before death but no significant change in family ratings of quality of dying (13). To further evaluate this intervention, we conducted a cluster-randomized trial randomizing hospitals to intervention or usual care. Because our intervention targeted hospitals, a clustered-trial design enabled us to deliver the intervention throughout hospitals. We evaluated the intervention using the primary outcome of families' ratings of quality of dying as well as family satisfaction with care, nurse-assessed

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quality of dying, ICU length of stay, duration of time to withdrawal of mechanical ventilation, and nine chart-based elements of palliative care. Some of the results of this study have been reported previously in the form of an abstract (14).

METHODS

Design Overview

This study is an unblinded cluster-randomized trial of an interdisciplinary, multifaceted intervention to improve ICU clinicians' ability to provide end-of-life care to critically ill patients and their families (NCT00685893). We hypothesized that a successful intervention would result in: (*1*) improved family ratings of patient's quality of dying, (*2*) improved family satisfaction with care, (*3*) improved nurse ratings of patient's quality of dying, (*4*) reduced ICU length of stay and time to withdrawal of mechanical ventilation, and (*5*) increased provision of nine elements of palliative care. All procedures were approved by institutional review boards at all institutions.

Setting

Hospitals in Seattle or Tacoma were eligible if they had enough ICU deaths to meet sample size requirements. Of 16 eligible hospitals, 15 agreed to participate. Three hospitals were pilot sites and 12 were randomized. The 12 hospitals randomized included 1 university-affiliated hospital, 3 non–university affiliated teaching hospitals, and 8 nonteaching hospitals. We used random numbers to assign six hospitals to intervention and six to control. Study activities began May 2004 and concluded February 2008.

Intervention

The intervention targeted the clinicians and hospital, not individual patients or family members. This quality-improvement intervention was based on self-efficacy theory, which suggests that changes in clinician performance are facilitated by increasing knowledge, enhancing attitudes, and modeling appropriate behaviors (15, 16). The intervention has been described in detail (17) (*see* online supplement). In brief, the intervention promoted clinician behavior change through five components: (*1*) clinician education about palliative care in the ICU using a variety of educational approaches (grand rounds, workshops, video presentations), (*2*) identification and training of ICU clinician local champions for palliative care, (*3*) academic detailing of nurse and physician ICU directors to address individual ICU-specific barriers to improving end-of-life care, (*4*) feedback of individual ICU-specific quality data including family satisfaction, and (*5*) implementation of system supports such as palliative care order forms. The intervention occurred over 13 to 20 months at each hospital. We were able to deliver all components of the intervention at each site and clinician ratings of the educational and training components of the intervention were high (*see* online supplement).

Outcome Evaluation

To identify eligible patients, we examined hospital admission/discharge/transfer records during two time periods: a baseline period and a follow-up period after the intervention/control period. Eligible patients were those who died in an ICU or within 30 hours of transfer to another hospital location. We excluded patients in the ICU with stays shorter than 6 hours. The time restrictions allowed ICU clinicians sufficient opportunity to affect end-of-life care.

Because medical records at these sites did not provide locator information for patients' family, we sent study materials to patients' homes 4 to 6 weeks after death, addressed to "the family of" the patient, requesting response by the person most knowledgeable about the patient's end-of-life experiences. Nurse questionnaires were distributed within 72 hours of death to the hospital mailbox of the nurse caring for the patient at the time of death/transfer and the nurse from the prior shift.

Questionnaire materials included an incentive ($10 to family, coffee card to nurses), postage-paid return envelope, and questionnaire booklet. To further enhance response, we used follow-up mailings including reminder/thank-you postcards 3 weeks after initial distribution followed by a second set of materials to nonrespondents after 5 weeks (18).

Measures

Outcome measures were assessed at the individual patient level. The Quality of Dying and Death (QODD) questionnaire measures family- or clinician-assessed quality of dying. In the current trial, we used the hospital version of the instrument, which has demonstrated good reliability and validity (19–22). The nurse-assessed QODD has also shown good internal consistency and validity (21). The QODD score is a summation of available 0 to 10 ratings, divided by the number of items completed (providing implicit imputation of the respondent's mean response for missing data), and recalibrated to range 0 to 100, with higher scores indicating higher-quality dying. We also examined a single-item 0 to 10 quality-of-dying rating that has been associated with ICU palliative care (23).

The Family Satisfaction in the ICU (FS-ICU) is a reliable and valid 34-item questionnaire measuring family satisfaction with ICU care (24, 25). Scoring based on 24 items provides scores for total satisfaction, satisfaction with care, and satisfaction with decision making (26). The scoring involves recoding and recalibrating individual items to a 0 to 100 range and averaging the available recalibrated items (requiring at least 70% valid); higher values indicate higher satisfaction (26).

Chart Abstraction and Death Certificate Data

Trained chart abstractors reviewed patients' medical records using a standardized protocol and training regimen (13). Five percent of all charts were coreviewed to ensure greater than 95% agreement on all data elements. Abstraction elements included number of days in the ICU, time from ICU admission to withdrawal of mechanical ventilation, and nine elements of palliative care: occurrence of a family conference within 72 hours of ICU admission, documented discussion of patient's prognosis during a family conference in the first 72 hours, consultation with palliative care experts, involvement of a spiritual care provider, involvement of a social worker, avoidance of cardiopulmonary resuscitation in the last hour of life, Do Not Resuscitate orders in place at the time of death, documented assessment of pain in the last 24 hours, and withholding or withdrawing life support. These elements are not necessarily associated with better-quality care in all patients, but at a hospital level indicate the implementation of palliative care.

Washington State releases confidential death certificate data linked by a patient identifier for research purposes. We used these records for data unavailable or incomplete in the medical record, including patient race/ethnicity, marital status, education, and cause of death.

Statistical Analyses

Analyses compared baseline-to-follow-up changes at intervention sites with baseline-to-follow-up changes at control sites, using individual-level outcomes based on intention-to-treat. We incorporated baseline data to adjust for any initial differences between patients at intervention versus control hospitals that randomization failed to address. Although hospitals, rather than patients, were randomized, neither multilevel nor clustered analyses were appropriate with only 12 clusters (27, 28). Therefore, all regression models included dummy-indicator adjustment for hospital. Also included in all models were baseline/follow-up status, the interaction between randomization and baseline/follow-up status (the primary predictor of interest), and patient covariates (age, sex, racial-ethnic minority status, cause of death). Models of family-assessed outcomes added family-member covariates (age, sex, relationship to patient, race-ethnicity); models of nurse-assessed outcomes added adjustment for nurse age. In addition to these adjustments, we adjusted models for any confounders that changed the parameter estimate for the intervention by 10% or more, selecting from the following potential confounders: patient education and marital status; length of association between patient and family member, whether patient lived with family member, family member's education, nurse sex, nurse race/ethnicity, years in critical care nursing, and whether the nurse was on duty at the time the patient died. The P level for statistical significance was 0.05.

The primary outcome was the family-QODD. Using regression analyses with our current sample size (n = 822) and controlling for

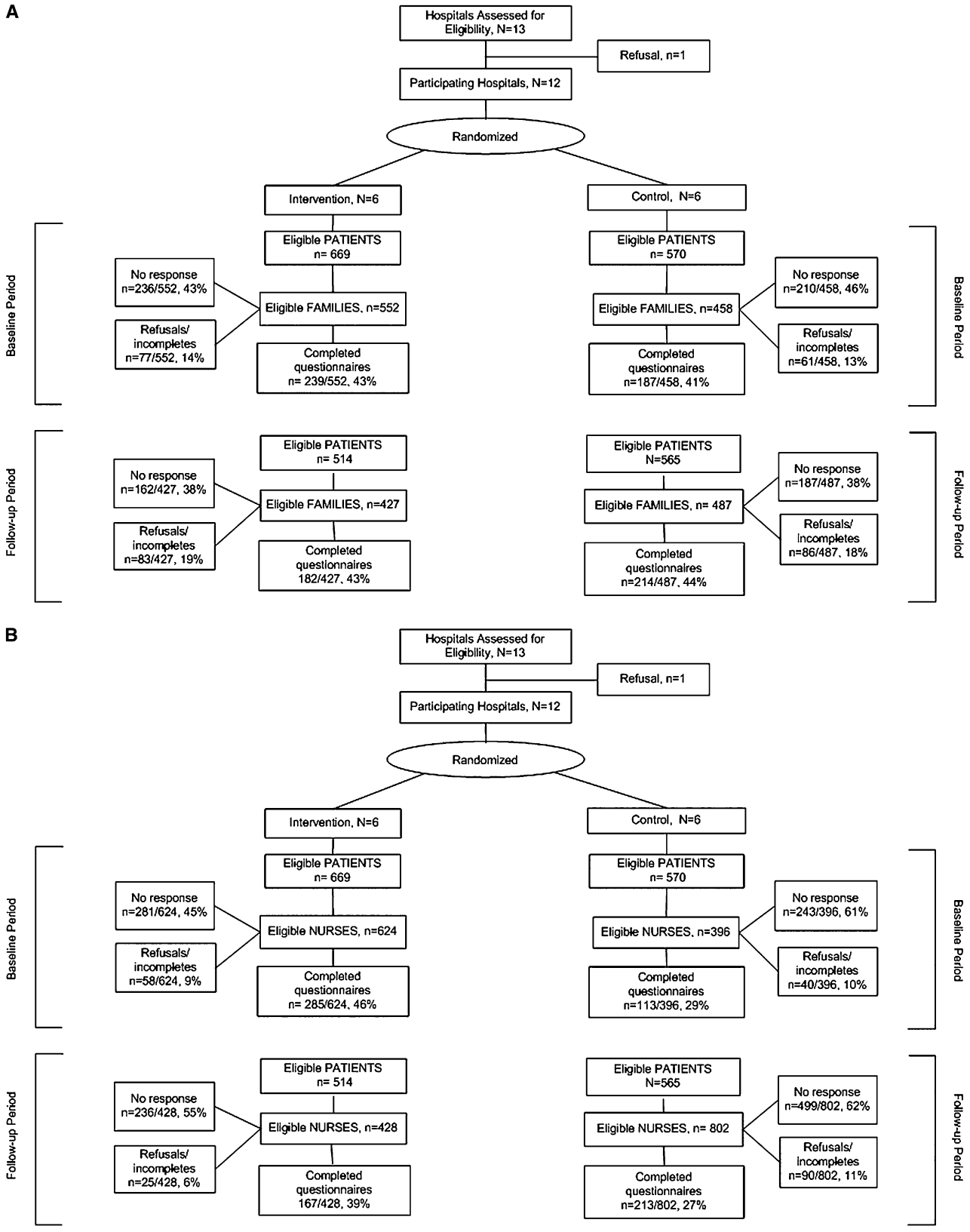

Figure 1. Development of the sample for (*A*) family members and (*B*) nurses.

hospital site, we had power of 0.87 to detect a change of 10.0 (Cohen effect size 0.4) and power of 0.62 to detect a change of 7.0 (Cohen effect size 0.3) (29, 30). Although there is not a well-defined minimal clinically significant difference for the QODD, we previously observed a 10-point difference between families who rated communication with the patient's physician as excellent and families who rated communication as poor, and a 7-point difference between patients who died in the location of their choice and patients who died elsewhere (19).

TABLE 1. CHARACTERISTICS OF PATIENTS IN INTERVENTION AND CONTROL HOSPITALS DURING THE BASELINE AND FOLLOW-UP PERIODS

	Intervention Group (*n = 1183*)		Control Group (*n = 1135*)	
Characteristics	Baseline (*n = 669*)	Follow-up (*n = 514*)	Baseline (*n = 570*)	Follow-up (*n = 565*)
Mean age, yr (SD)	71.8 (14.7)	71.1 (14.3)	70.4 (14.4)	71.0 (14.8)
% Male (n)	51.4 (344)	52.9 (272)	59.8 (341)	60.9 (344)
Race/ethnicity (n)	(668)	(513)	(570)	(565)
% White, non-Hispanic	78.0 (521)	78.2 (401)	80.0 (456)	79.3 (448)
% White, Hispanic	2.5 (17)	1.6 (8)	2.3 (13)	1.4 (8)
% Black	8.5 (57)	5.7 (29)	7.2 (41)	6.9 (39)
% Asian	7.2 (48)	10.9 (56)	8.1 (46)	9.4 (53)
% Native American	1.5 (10)	1.2 (6)	1.4 (8)	1.1 (6)
% Pacific Islander	1.0 (7)	1.0 (5)	0.2 (1)	0.5 (3)
% Mixed	1.2 (8)	1.6 (8)	0.9 (5)	1.4 (8)
Underlying cause of death (n)	(669)	(514)	(570)	(565)
% Trauma	5.2 (35)	4.3 (22)	3.9 (22)	3.9 (22)
% Cancer	13.8 (92)	11.1 (57)	19.6 (112)	19.8 (112)
% Other	81.0 (542)	84.6 (435)	76.5 (436)	76.3 (431)

To test continuous outcomes, we used robust linear regression models with full information maximum likelihood handling of missing data. For ICU length of stay and time to withdrawal of mechanical ventilation we used Cox regression, and for the elements of palliative care we used logistic regression, with these models based on cases with complete data.

Control hospitals received the intervention after the randomized trial. We confirmed findings for the randomized trial, using all preintervention and postintervention data from the 12 randomized hospitals (*see* online supplement).

Although outcomes based on family surveys and medical records represented independent observations, those based on nurse surveys were nonindependent in two ways. First, patients often had surveys completed by both the nurse at the time of death and the nurse for the prior shift; to account for this nonindependence, we selected one survey per patient, using the survey with more QODD items completed. Second, some nurses completed surveys for more than one patient; to adjust for this source of nonindependence, we clustered regressions within nurses.

Finally, we ran analyses to assess whether response bias may have influenced findings. We developed a propensity score using patient and patient-care predictors from medical and death records to predict family and nurse response/nonresponse, with backward elimination of predictors with high P values until the models retained only predictors with $P < 0.15$. From the resulting regression equations, we constructed weights for each respondent, so that the respondent sample more closely represented the full patient sample (31). We then compared family and nurse outcomes for the weighted and unweighted samples (*see* online supplement).

RESULTS

Sample and Response Rates

Of the 16 eligible hospitals, 15 participated (94%), including three nonrandomized pilot sites. All 12 randomized hospitals completed the trial and had sufficient numbers of patients and respondents, based on a predetermined goal of at least 25 family and 25 nurse surveys per hospital per time period.

For the randomized trial, there were 2,318 eligible patients with 1,239 patients in the baseline and 1,079 in the follow-up period (Table 1). Charts were abstracted for 2,238 patients (97%). Patients in the intervention group were significantly less likely than those in the control group to be male (52 vs. 60%, $P < 0.001$) and to have died with cancer (13 vs. 20%, $P < 0.001$).

We sent questionnaires to homes of 1,924 patients, and 822 (43%) of their families completed them (Figure 1A, Table 2). Family response was more likely if patients were older, married, or non-Hispanic white ($P < 0.001$). Family response rates also differed by hospital ($P = 0.003$).

We distributed questionnaires to nurses of 1,269 patients and received completed surveys for 636 (50%) of those patients (Figure 1B). One hundred sixty-five nurses returned one or more questionnaires for patients at intervention sites and 144 nurses returned one or more questionnaires for patients at the control sites (Table 3). Patients were more likely to have a nurse survey returned if they were younger ($P = 0.008$), had longer hospital stays ($P = 0.007$), and died in intervention hospitals

TABLE 2. CHARACTERISTICS OF FAMILY MEMBERS WHO COMPLETED SURVEYS FOR PATIENTS IN INTERVENTION AND CONTROL HOSPITALS DURING THE BASELINE AND FOLLOW-UP PERIODS

	Intervention Group (*n = 421*)		Control Group (*n = 401*)	
Characteristics	Baseline (*n = 239*)	Follow-up (*n = 182*)	Baseline (*n = 187*)	Follow-up (*n = 214*)
Mean age, yr (SD)	60.9 (15.2)	58.1 (14.5)	57.5 (14.8)	59.3 (14.5)
% Male (n)	30 (72)	36.9 (66)	32.2 (58)	26.3 (55)
Race/ethnicity (n)	(232)	(177)	(181)	(207)
% White, non-Hispanic	89.7 (208)	85.3 (151)	84.5 (153)	84.5 (175)
% White, Hispanic	1.3 (3)	1.1 (2)	1.1 (2)	2.4 (5)
% Black	2.2 (5)	4.0 (7)	5.0 (9)	2.9 (6)
% Asian	2.6 (6)	4.5 (8)	5.0 (9)	6.3 (13)
% Native American	0.4 (1)	1.1 (2)	0.6 (1)	1.0 (2)
% Pacific-Islander	0.9 (2)	0.6 (1)	0.0 (0)	0.5 (1)
% Mixed	3.0 (7)	3.4 (6)	3.9 (7)	2.4 (5)
% Patient's spouse (n)	48.3 (114)	40.0 (72)	43.3 (78)	46.9 (98)

TABLE 3. CHARACTERISTICS OF NURSES WHO COMPLETED SURVEYS FOR PATIENTS IN INTERVENTION AND CONTROL HOSPITALS DURING THE BASELINE AND FOLLOW-UP PERIODS

	Intervention Group (*n* = *165*)		Control Group (*n* = *144*)	
Characteristics	Baseline (*n* = *123*)	Follow-up (*n* = *71*)	Baseline (*n* = *68*)	Follow-up (*n* = *106*)
Mean age, yr, 2008 (SD)	48.4 (9.7)	46.4 (10.6)	48.9 (10.6)	45.6 (10.0)
% Male (n)	8.1 (10)	9.9 (7)	8.8 (6)	11.3 (12)
% Racial/ethnic minority (n)	21.1 (26)	23.9 (17)	13.2 (9)	25.5 (27)
Mean yr CC nursing, 2008 (SD)	15.7 (8.9)	12.6 (8.6)	17.4 (11.7)	14.5 (9.9)

Definition of abbreviation: CC = critical care.

The sum of the number of nurses completing baseline and follow-up surveys is larger than the total nurses in the intervention group because some nurses completed surveys during both time periods.

during the baseline period or in control hospitals during the follow-up period ($P < 0.001$). Nurse response rates also differed by hospital ($P < 0.001$).

Outcomes

The intervention was not associated with significant change in any of the family-assessed or nurse-assessed outcomes (Table 4). To test for a possible intervention effect on these outcomes among patients who received palliative care, we repeated the analyses using only patients who transitioned to "comfort measures only" before death. The results for this group were similar.

There were no significant intervention effects on ICU length of stay or time from ICU admission to withdrawal of mechanical ventilation. Of the nine elements of palliative care, six were

TABLE 4. STUDY OUTCOMES

	Intervention Group*		Control Group*				
	Baseline	F/U	Baseline	F/U	b†	95% CI	*P* Value
Outcomes: questionnaires							
Family-assessed: 822 family members (N1, N2)‡							
QODD total score (808, 781)	61.8 (23.9)	61.1 (24.9)	59.9 (21.9)	63.7 (22.8)	−3.25	−9.82, 3.33	0.33
QODD single item score (768, 742)	6.6 (3.2)	6.8 (3.2)	6.8 (3.1)	6.8 (3.2)	0.43	−0.49, 1.36	0.36
Satisfaction with ICU care							
Total satisfaction§ (792, 762)	73.7 (22.9)	74.1 (22.0)	75.7 (20.2)	74.8 (20.0)	1.38	−4.75, 7.50	0.66
Satisfaction with care (789, 763)	75.0 (22.8)	75.6 (22.0)	76.3 (20.2)	75.6 (20.4)	1.49	−4.63, 7.62	0.63
Satisfaction with decision making (804, 778)	72.4 (24.7)	72.5 (23.9)	75.7 (21.5)	73.9 (21.3)	2.04	−4.53, 8.61	0.54
Nurse-assessed: 636 patients/307 nurses (N1, N2) ‡							
QODD total score‖ (632, 611)	69.28 (20.67)	69.67 (20.74)	69.10 (22.01)	68.80 (23.14)	0.92	−6.53, 8.38	0.81
QOD single-item score (565, 559)	7.30 (2.58)	7.47 (2.55)	7.60 (2.82)	7.02 (3.20)	0.63	−0.31, 1.57	0.19
Outcomes: medical record data¶							
Chart abstractions: 2,238 patients (N1, N2) ‡							
Days in ICU (2,250, 2,(250)	4.5 (6.0)	5.0 (6.3)	6.8 (11.1)	6.0 (12.3)	0.86**	0.73, 1.01	0.07
ICU days to ventilator withdrawal (1,053, 1,036)††	5.1 (5.6)	5.2 (6.2)	7.5 (11.4)	7.1 (15.1)	0.97**	0.76, 1.24	0.81
Palliative care elements							
Family conference, 1st 72 h (2,238, 2,238)	78.3	59.8	76.3	72.8	0.50‡‡	0.34, 0.73	<0.001
Prognosis discussed, 1st 72 h (2,238, 2,238)	43.6	29.8	38.3	32.2	0.69‡‡	0.48, 0.98	0.04
Palliative care consult (2,234, 1,350)§§	9.5	10.2	1.3	2.5	0.52‡‡	0.18, 1.51	0.23
Spiritual care provided (2,236, 2,236)	50.7	57.4	36.7	34.8	1.33‡‡	0.91, 1.94	0.15
Social work assistance (2,236, 2,236)	37.7	37.8	35.4	28.5	1.73‡‡	1.16, 2.58	0.008
Avoided CPR in last hour of life (2,236, 2,236)	87.1	89.4	89.4	87.2	1.64‡‡	0.96, 2.80	0.07
DNR orders at death (2,236, 2,195)§§	82.7	76.0	82.1	74.1	1.09‡‡	0.71, 1.67	0.68
Pain assessment (2,238, 2,238)	79.2	82.2	77.2	78.9	1.06‡‡	0.67, 1.68	0.81
Life support withheld or withdrawn (2,224, 2,224)	72.3	69.8	68.7	72.9	0.73‡‡	0.50, 1.06	0.10

Definition of abbreviations: CI = confidence interval; CPR = cardiopulmonary resuscitation; DNR = Do Not Resuscitate; F/U = follow=up; ICU = intensive care unit; QODD = QODD = Quality of Dying and Death survey.

* Data given as mean (SD) or %.

† Parameter estimate for the independent effect of the interaction between the hospital's intervention/control status and whether the patient died during the baseline or follow-up period. Estimates for family- and nurse-assessed outcomes were from multipredictor robust linear regression models, using a restricted maximum likelihood estimator. Estimates for length of ICU stay and time to withdrawal of ventilation were from Cox regression models, and those for dichotomous palliative care elements were from logistic regression models. All models included covariate adjustment for baseline/follow-up status, hospital, patient age, sex, racial-ethnic minority status, and cause of death. Models of family outcomes included additional adjustment for the family member's age, sex, relationship to patient, and racial-ethnic minority status. Models of nurse outcomes included additional adjustment for the nurse's age.

‡ N1 = number of respondents with valid data on the outcome variable; N2 = number of respondents included in the multipredictor regression model. The means, standard deviations, and percentages reported in columns 2–5 are based on N1; the slopes, confidence intervals, and probabilities reported in columns 6–8 are based on N2.

§ In addition to the standard covariates, this model included confounder adjustment for whether the patient and family member lived together.

‖ In addition to the standard covariates, this model included confounder adjustment for patient education, nurse race/ethnicity, and whether the nurse was on duty at the time of patient death or a shift earlier.

¶ For 12 patients for whom medical records were unavailable, ICU length of stay was drawn from hospital logs. All other data were drawn from the medical record.

** Hazard ratio.

†† In addition to the standard covariates, this model included confounder adjustment for patient education and marital status.

‡‡ Odds ratio.

§§ In addition to the standard covariates, this model included confounder adjustment for patient education.

TABLE 5. ASSESSING DISCRIMINANT ABILITY OF OUTCOME MEASURES: DIFFERENCES IN FAMILY-ASSESSED OUTCOMES FOR DIFFERENT TYPES OF END-OF-LIFE CARE AT THE TIME OF DEATH

Family-Assessed Outcome	Patient Group at Time of Death	Mean	SD	Median	Effect Size*	*P* Value†
QOD single-item rating	Comfort measures only	7.20	2.97	8	0.59	<0.001
	Full support	5.37	3.27	5		
QODD multi-item scale	Comfort measures only	64.31	22.68	65.84	0.45	<0.001
	Full support	53.95	23.40	52.50		
FS-ICU, satisfaction with care subscale	Comfort measures only	77.65	19.96	81.70	0.41	<0.001
	Full support	68.81	23.92	72.92		
FS-ICU, satisfaction with decision-making subscale	Comfort measures only	76.15	21.09	80.00	0.48	<0.001
	Full support	64.92	26.56	72.50		
FS-ICU total score	Comfort measures only	76.92	19.70	80.82	0.46	<0.001
	Full support	66.97	24.22	72.64		

Definition of abbreviations: FS-ICU = Family Satisfaction in the Intensive Care Unit survey; QODD = Quality of Dying and Death survey.
* Effect size is derived from the difference between survey score means (comfort care to full support) divided by the standard deviation of the baseline survey score.
† Probabilities for differences between the two patient groups were based on Mann-Whitney Z-approximations.

not significantly associated with the intervention. The intervention had a significant positive association with use of social workers ($P < 0.01$, owing to a decline in social work services at control sites during the follow-up period) and significant negative associations with occurrence of family conferences ($P < 0.001$) and discussion of patient prognosis ($P = 0.04$) during the first 72 hours.

Analyses comparing preintervention to postintervention outcomes for all 12 sites gave results similar to those for the randomized trial (*see* online supplement).

Examination for Potential Response Bias

Regression models significantly predicted the propensity for family or nurse response (pseudo-R^2 for family response = 0.06 and for nurse response = 0.10; P for both models < 0.001). However, weighted means for outcome measures showed little difference from unweighted means and the weighted analyses confirmed no significant differences associated with the intervention (*see* online supplement). For example, the weighted family-QODD mean scores of 60.3 (control baseline), 61.4 (control follow-up), 61.2 (experimental baseline), and 57.9 (experimental follow-up) were similar to means for the unweighted sample (Table 4).

Ability of the QODD and FS-ICU to Identify Differences in Care

Because this study showed no change in the QODD and FS-ICU, we also examined whether there was evidence that these outcome measures could identify differences in types of care. We compared the QODD and FS-ICU scores of patients who died after a transition to comfort measures only to scores for patients who died in the setting of full support (Table 5). These analyses demonstrate that each of these measures varied significantly between these two groups of patients with patients dying after a transition to comfort measures only having better scores with moderate Cohen effect sizes (range, 0.41–0.58).

DISCUSSION

This study suggests that this quality-improvement intervention had no effect on family- and nurse-assessed outcomes. Prior studies suggest that palliative care and family communication interventions were associated with reduced ICU length of stay before death presumably because of earlier decision-making about withdrawal of life support (8–11). We saw no significant change in the number of ICU days before death and no significant change in the time from ICU admission to withdrawal of mechanical ventilation. In addition, we examined nine elements of palliative care and found no consistent evidence to suggest the intervention increased these elements of palliative care.

One concern that may affect interpretation of our results was the response rate from family and nurses. The goal of the clustered trial was to assess outcomes at the hospital level and we obtained adequate samples for all outcomes at all hospitals. Furthermore, the family response rate was low in part because we sent surveys to patients' homes after death and some of these surveys may have never reached a family member. Our response rate is similar to other survey studies enrolling family after death and studies enrolling clinicians to assess end-of-life care (32–36). However, potential for response bias should be considered. We previously examined patient differences between responding and nonresponding family members showing that nonresponse bias results in an overestimation of the quality of palliative care (37). Because we have data on patient and patient-care characteristics for 97% of eligible patients, we were able to construct weights reflecting the propensity for survey response. Analyses using these weights did not alter the findings. Therefore, it seems clear that this intervention did not improve palliative care or outcomes.

Another potential explanation for lack of change in family- and nurse-assessed outcomes is that perhaps these outcomes are not sensitive to important changes. Although the QODD and the FS-ICU were developed and validated as end-of-life-care outcomes, the responsiveness of these measures is unknown. Therefore, we are unable to know for certain whether there might have been important changes that these instruments are unable to detect. However, we do have compelling data that these outcomes can differentiate quality of end-of-life care. We previously reported that family-QODD scores were 7 points higher for patients who died in the location they preferred (home or institution) as compared with patients who did not (19). In this study we found that patients who died after a transition to comfort measures only had QODD scores 10 points higher than patients who died with full support. Our study had a power of 0.62 to detect a 7-point difference and a power of 0.87 to detect a 10-point difference. It is possible that a larger sample might be needed to definitively exclude an important but smaller improvement in quality of dying. Finally, it is also possible that these instruments measure important differences in family experience, but that these family experiences are determined by many other factors over which clinician behavior may have little influence (38, 39). However, there is evidence that clinician behaviors are important determinants of family experience and may be an important target for future interventions (6, 40, 41).

The most plausible explanation for our negative results is that the intervention was ineffective. We previously published a single-center before–after study of the same intervention showing no significant improvement in family ratings of quality of dying or satisfaction with care, but an improvement in nurses' ratings of quality of dying and a significant reduction in ICU days before death (13). This prior study used the same intervention but took place at the home institution of investigators, where the intervention was easier to implement. Implementation at other sites was more challenging and may have resulted in a lower "dose." Although we delivered all five components to all intervention sites and demonstrated that ICU clinicians rated these components highly, ICU clinicians had many competing demands requiring longer implementation with less uptake of the intervention than planned. We also found that, although designed as an interdisciplinary intervention, it was difficult to transcend the silos of clinical disciplines (42).

What are the lessons from this trial? There is growing interest in improving quality and reducing costs. Although it is difficult to accomplish both of these goals with a single intervention, enhancing palliative care within acute and critical care is one approach that has generated excitement for this potential (43, 44). There is evidence that earlier and more effective communication with patients and families about end-of-life care may result in higher-quality care that minimizes ineffective life-prolonging treatments, reduces costs, and improves quality of life (8–11, 45, 46). Unfortunately, our study suggests that a quality-improvement intervention designed to educate ICU clinicians about palliative care and implemented by experts outside the institution is unlikely to have these benefits. Our findings, together with prior studies, suggest that interventions may need to be implemented from within an institution with stronger intrainstitutional support (11, 13), and that interventions may be more effective if they bring clinicians with palliative care expertise directly into the care of individual critically ill patients and their families (9, 10).

This study has additional important limitations. First, a randomized trial of hospital-based interventions requires randomizing hospitals, which is expensive and time-consuming. Our effective sample size is limited by the number of hospitals in the study. Second, randomizing hospitals resulted in unequal distribution of patient characteristics between the two groups. We used baseline data from each hospital and multivariate techniques to adjust for these differences. Third, implementation of this multifaceted intervention was complex and it is difficult to measure the "dose" delivered. Assessment of delivery of this intervention suggests all intervention components were implemented with high levels of clinician satisfaction, but we are limited in our ability to measure the degree of uptake. Fourth, this study was confined to one region of the United States and may not generalize to other regions. However, it is notable that the QODD scores from these institutions are comparable to studies done in ICUs in other areas (20, 47). Finally, given that this was a negative study, it would be informative to know if clinician attitudes were changed by the intervention. Unfortunately, we do not have data to assess this question.

In summary, our study demonstrates no effect of this multifaceted, quality-improvement intervention on family- or nurse-assessed outcomes or delivery of palliative care. Furthermore, this study suggests that efforts to improve family and nurse experiences of end-of-life care in the ICU will require an intervention with more institutional support and direct involvement in the care of individual patients and their families.

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