American Journal of Respiratory and Critical Care Medicine/AJRCCM

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Journal:	*American Journal of Respiratory and Critical Care Medicine*
Manuscript ID:	Blue-201006-1004OC.R1
Manuscript Type:	OC - Original Contribution
Date Submitted by the Author:	28-Jul-2010
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Key Words:	cluster randomized trial, critical care, withdrawal of life support, end-of-life care, palliative care

Effect of a quality-improvement intervention on end-of-life care in the intensive care unit: A randomized trial

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Running title: Integrating Palliative and Critical Care

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Funding: Funded by the National Institute of Nursing Research (R01 NR05226)

Running title: Integrating palliative and critical care

Manuscript Word Count: 3297

Descriptor number: 2.12 End of Life: Critical Care

Trial Registration: Registered at www.clinicaltrials.gov (NCT00685893).

At a Glance Commentary: 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. We evaluated the effectiveness of a quality-improvement intervention to improve ICU end-of-life care by conducting a cluster-randomized trial randomizing 12 hospitals. We found this intervention was associated with no improvement in quality of dying or quality of care and no change in ICU length of stay prior to death. Improving ICU end-of-life care will likely require interventions with more direct contact with patients and family.

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ABSTRACT

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 ICU end-of-life care.

Methods: We conducted a cluster-randomized trial randomizing 12 hospitals. The intervention targeted clinicians with 5 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 (5/2004-2/2008). We used robust regression models to test for intervention effects, controlling for site, patient, family, and nurse characteristics.

Results: All hospitals completed the trial with 2318 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 non-significant increase in ICU days prior to death after the intervention (HR=0.9; p=0.07). Among patients undergoing withdrawal of mechanical ventilation, there was no change in time from admission to withdrawal (HR=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 prior to 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 family.

Abstract Word Count: 250

Key Words: cluster randomized trial, critical care, withdrawal of life support, end-of-life care, palliative care.

INTRODUCTION

The 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 (PTSD)[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 prior to 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 multi-faceted, 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 prior to 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 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, multi-faceted 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 non-teaching 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 Appendix). 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 Appendix).

Outcome Evaluation

In order 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 three weeks after initial distribution followed by a second set of materials to non-respondents after five 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 0-10 ratings, divided by the number of items completed (providing implicit imputation of the respondent's mean response for missing data), and recalibrated to range 0-100, with higher scores indicating higher quality dying. We also examined a single-item 0-10 quality-of-dying rating that has been associated with ICU palliative care.[23]

The 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 0-100 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 co-reviewed 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 CPR in the last hour of life, DNR 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, 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 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] While 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]

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 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 pre-intervention and post-intervention data from the 12 randomized hospitals (see Appendix).

Although outcomes based on family surveys and medical records represented independent observations, those based on nurse surveys were non-independent 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 non-independence, 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 non-independence, 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/non-response, 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 Appendix).

RESULTS

Sample and response rates

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

For the randomized trial, there were 2318 eligible patients with 1239 patients in the baseline and 1079 in the follow-up period (Table 1). Charts were abstracted for 2238 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 1924 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 1269 patients and received completed surveys for 636 (50%) of those patients (Figure 1B). One hundred and 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 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" prior to 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 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 pre-intervention to post-intervention outcomes for all 12 sites gave results similar to those for the randomized trial (see Appendix).

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 Appendix). 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

Since 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 prior to death presumably due to earlier decision-making about withdrawal of life support.[8-11] We saw no significant change in the number of ICU days prior to 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 non-responding family members showing that non-response bias results in an over-estimation 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 prior to 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 intra-institutional 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 multi-faceted 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 U.S. 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 multi-faceted, 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.

ACKNOWLEDGEMENTS

This study was funded by a grant from the National Institute of Nursing Research (R01 NR05226; PI: JR Curtis). The funding agency had no role in design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript. Dr. Curtis had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. All authors have no financial interests or relationships that could constitute a potential conflict of interest.

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Table 1: Characteristics of patients in intervention and control hospitals during the baseline and follow-up periods

Characteristics	Intervention Group (n=1183)		Control Group (n=1135)	
	Baseline (n=669)	Follow-up (n=514)	Baseline (n=570)	Follow-up (n=565)
Mean age in years (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)

Table 2: Characteristics of family members who completed surveys for patients in intervention and control hospitals during the baseline and follow-up periods

Characteristics	Intervention Group (n=421)		Control Group (n=401)	
	Baseline (n=239)	Follow-up (n=182)	Baseline (n=187)	Follow-up (n=214)
Mean age in years (SD)	60.9 (15.2)	58.1 (14.5)	57.5 (14.8)	59.3 (14.5)
% Male (n)	30.5 (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

Characteristics	Intervention Group (n=165[a])		Control Group (n=144[a])	
	Baseline (n=123)	Follow-up (n=71)	Baseline (n=68)	Follow-up (n=106)
Mean age in years, 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 yrs CC nursing, 2008 (SD)	15.7 (8.9)	12.6 (8.6)	17.4 (11.7)	14.5 (9.9)

a 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.

Table 4: Study outcomes

Outcomes: Questionnaires	Intervention Group Baseline Mean(SD){%}	Intervention Group F/U Mean(SD) {%}	Control Group Baseline Mean(SD){%}	Control Group F/U Mean(SD){%}	b[HR]{OR}[a]	95% CI	*P*
Family-assessed: 822 family members (N1, N2)[b]							
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
QOD 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[c] (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)[b]							
QODD total score[d] (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[e]							
Chart-abstractions: 2238 patients (N1, N2)[b]							
Days in ICU (2250, 2250)	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 (1053, 1036)[f]	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 hours (2238, 2238)	{78.3}	{59.8}	{76.3}	{72.8}	{0.50}	0.34, 0.73	<0.001
Prognosis discussed, 1st 72 hours (2238, 2238)	{43.6}	{29.8}	{38.3}	{32.2}	{0.69}	0.48, 0.98	0.04
Palliative care consult (2234, 1350)[g]	{9.5}	{10.2}	{1.3}	{2.5}	{0.52}	0.18, 1.51	0.23
Spiritual care provided (2236, 2236)	{50.7}	{57.4}	{36.7}	{34.8}	{1.33}	0.91, 1.94	0.15
Social work assistance (2236, 2236)	{37.7}	{37.8}	{35.4}	{28.5}	{1.73}	1.16, 2.58	0.008
Avoided CPR in last hour of life (2236, 2236)	{87.1}	{89.4}	{89.4}	{87.2}	{1.64}	0.96, 2.80	0.07
DNR orders at death (2236, 2195)[h]	{82.7}	{76.0}	{82.1}	{74.1}	{1.09}	0.71, 1.67	0.68

Pain assessment (2238, 2238)	{79.2}	{82.2}	{77.2}	{78.9}	{1.06}	0.67, 1.68	0.81
Life support withheld or withdrawn (2224, 2224)	{72.3}	{69.8}	{68.7}	{72.9}	{0.73}	0.50, 1.06	0.10

a 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 multi-predictor 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.

b N1 = number of respondents with valid data on the outcome variable; N2 = number of respondents included in the multi-predictor 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.

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

d 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.

e 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.

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

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

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

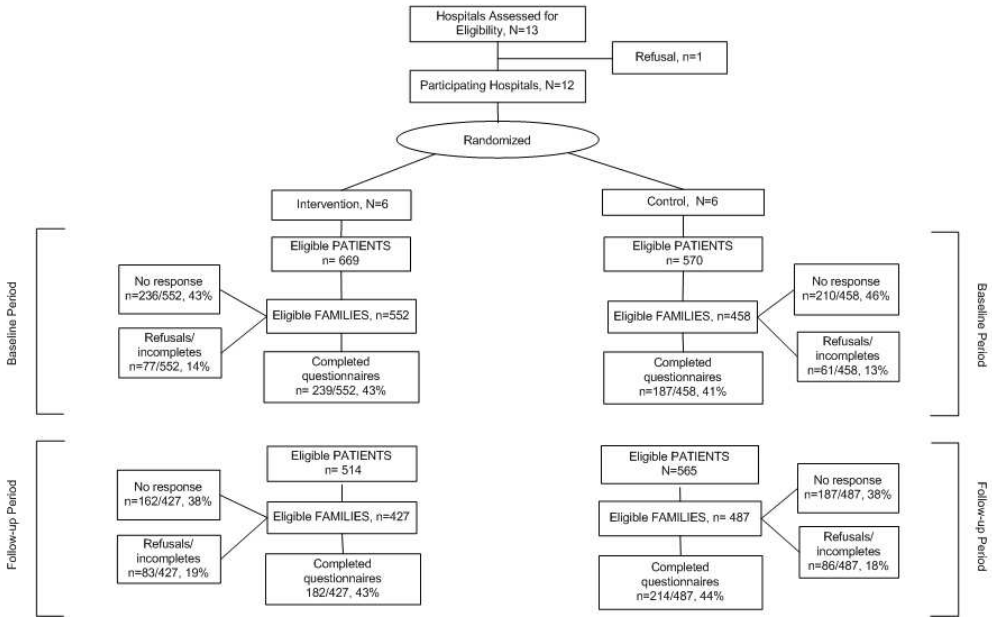
Table 5: Assessing discriminant ability of outcome measures – differences in family-assessed outcomes for different types of end-of-life care at the time of death

Family-Assessed Outcome	Patient group at time of death	Mean	SD	Median	Effect Size[a]	*P*[b]
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		

a Effect size is derived from the difference between survey score means (comfort care – full support) divided by the standard deviation of the baseline survey score.

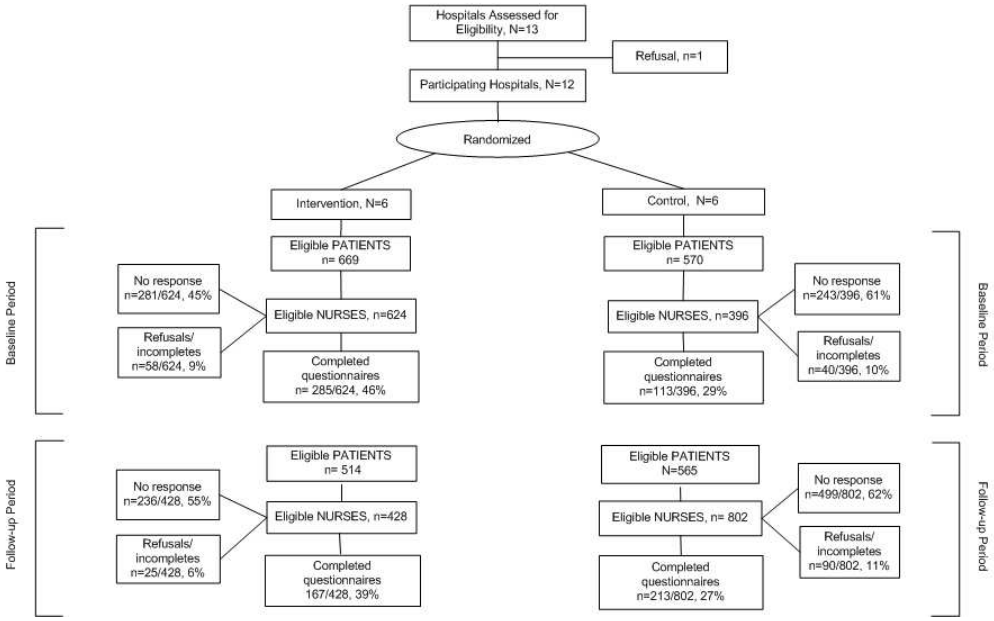
b Probabilities for differences between the two patient groups were based on Mann-Whitney Z-approximations.

Figure 1A: Family Sample



Family sample

Figure 1B: Nurse Sample



Nurse sample

ONLINE REPOSITORY: APPENDIX

Integrating Palliative and Critical Care: Randomized Trial of a Quality Improvement Intervention

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Funding: Funded by the National Institute of Nursing Research (RO1NR05226)..

This appendix describes the development, implementation, and ICU clinician evaluation of the multi-faceted quality improvement intervention as well as the results of the before-after analyses comparing the pre-intervention period with the post-intervention period at all hospitals involved in this randomized trial. The development and implementation of the intervention has been described previously[1] and is described in an abbreviated form in this Appendix.

CONCEPTUAL FRAMEWORK SUPPORTING THE INTERVENTION

Self-efficacy theory[2-4] has been used to guide interventions for changing a wide range of health[5, 6] and clinician behaviors.[7-9] It posits that the impetus for change resides in the individual's efficacy expectations, that is, one's "confidence in one's ability to take action and persist in action."[10] Self-efficacy, although an individual construct, does not arise out of the individual alone but comes from experience within the environment, in this case the hospital or ICU. Efficacy expectations are acquired from four primary sources: performance accomplishments, vicarious experience, verbal persuasion, and emotional state. Performance accomplishments are those personal experiences that allow mastery of a task previously felt to be difficult or feared. In this intervention, we anticipated enhancing performance accomplishments in the ICU through the use of standardized end-of-life care orders; these orders were designed to provide guidance and support for behaviors managing comfort care. Vicarious experiences include observations of other people undertaking and succeeding at tasks or skills; this may include instructors, role models, or colleagues who are skilled at these tasks. We implemented this principle through the use of local champions, educational sessions and academic detailing of the leaders in the ICU. Verbal persuasion, a change in efficacy expectations by encouragement

or persuasion by others, also supports the use of local champions, education sessions, feedback, and academic detailing. Last, the influence of emotional state on efficacy expectations suggests that addressing the anxiety that clinicians may feel in confronting death or a grief-stricken family member may be an important prerequisite for changing clinician behavior. We used educational sessions to explicitly introduce and discuss emotional aspects of providing end-of-life care.

This paradigm for understanding behavior change has been applied to clinician behavior. Using self-efficacy principles, Cabana and colleagues developed a framework to explain the empirical data on clinical guideline implementation.[7] In this framework, aspects of efficacy expectations including familiarity, awareness, agreement, outcome expectancies, self-efficacy, and motivation are associated with clinicians' willingness to adopt guidelines. These researchers also identified external supports related to environmental and organizational factors that facilitate implementation of clinical guidelines.[7] Our intervention utilized this application of self-efficacy suggested by Cabana and colleagues in which efficacy expectations are grouped as "knowledge", "attitudes" and "behavior" and are used to explain and affect clinician behavior change.

DESCRIPTION OF THE 5-COMPONENT INTERVENTION OF IPACC

Out intervention includes 5 components, each of which addresses one or more of the aspects described by self-efficacy theory as contributing to clinician behavior change.[7] The conceptual model for the development and delivery of the intervention is shown in Figure A1. Additionally, we tailored the intervention to conform to principles identified in the literature as associated with improvements in processes and outcomes of care in the ICU: 1) an effective intervention in the ICU must be multifaceted, incorporating education, protocols, and feedback directed at multiple levels of providers,[11-15] 2) nurse and respiratory therapist based protocols are

feasible and effective at changing behavior in the ICU,[16-22] and 3) the intervention must be in a format that can be exportable and generalizable to other institutions.[23]

There were no incentives provided to any clinicians for implementation of any component of the intervention. The only incentives provided to clinicians were for completion of the surveys assessing the outcomes of the intervention.

1. ICU Clinician Education

Theoretical and empirical support:

Self-efficacy theory suggests that educational efforts may affect behavior change through verbal persuasion, vicarious experiences and, when coupled with active engagement in the educational task, performance accomplishments. The model suggests knowledge, including awareness and familiarity, is important for behavior change. Although education in the form of lectures or written material has only a modest effect on clinician behavior,[12, 24] it is an important component when combined with other modalities.[14] The educational component of this intervention targets clinicians involved in end-of-life care in the ICU (physicians, nurses, social workers, respiratory therapists, and spiritual care providers) and includes Grand Rounds and discussion groups. Its goal is to provide clinicians with knowledge about providing high quality care at the end of life.

Intervention content and implementation:

The education component included a Grand Rounds lecture on palliative care principles. Although physicians were the usual targets for many Grand Rounds, nurses, social workers, and respiratory therapists and other clinicians were encouraged attend these sessions. In addition, because of the limitation of the Grand Rounds format, we produced a 40-minute teaching video

and developed a series of educational pamphlets. The lectures, video, and pamphlets addressed four topics: a) principles of decision-making about end-of-life care in the ICU; b) communication with patients and families and within the ICU team; c) pain and symptom assessment and management; and d) principles and practice of withdrawal of life support. The video content was targeted to nurses and is available online at http://depts.washington.edu/eolcare.

Medical Grand Rounds were given at the venues identified by the local champions. Sessions were advertised to nurses and other clinicians as well as physicians. The training video was shown during video discussion sessions that were interactive, allowing participant involvement in clinical scenarios. The video discussion sessions for ICU nurses and respiratory therapists were offered frequently so that all staff had an opportunity to view the video. A knowledgeable staff person, a local champion, or both proctored the video, and were available to answer questions and lead discussions. Pamphlets were distributed at this time in addition to being made available in the break-rooms and at the nursing stations.

2. Local Champions

Theoretical and empirical support:

Local champions provide the role-modeling that is an integral part of self-efficacy theory; they are able to provide input in the areas of both knowledge and attitude. In empirical research, they have been shown to play an important role in local control and implementation of quality improvement efforts.[13, 25] This approach has been successful and rewarding for nurse champions.[26] This component of the intervention provides an opportunity for local input and enhanced implementation of the intervention by providing and encouraging local support.

Therefore, the goal of the local champion component was to provide role-modeling and promote attitudinal change in the ICU. Specific tasks performed by local champions included influencing clinician behavior by sharing palliative care principles, adapting and implementing the withdrawal of life support order form, helping investigators obtain access to the ICU clinicians for the educational component, and contributing to the cultural change in the ICU by increasing the emphasis on improving palliative care.

Intervention content and implementation:

We identified at least one physician and several nurses in each ICU to serve as champions. We also attempted to identify social workers, spiritual care providers, and respiratory therapists. These local champions were identified through interviews with nurse and physician directors and through educating staff about what it meant to be a local champion. We assembled the local champions together and provided palliative care education using principles of adult education and discussion about what it means to be a 'change agent.' We provided information about what families need when a loved one is critically ill. Meetings with local champions allowed us to discuss barriers to quality end-of-life care in their units and strategize about ways to address those barriers.

3. Institutional Feedback

Theoretical and empirical support:

Institutional feedback is expected to influence clinician behavior through vicarious experiences and verbal persuasion and to lead to changes in clinician knowledge and attitudes. Empirically, this kind of feedback with specific data on clinical performance has been found to

be an effective stimulus to behavior change[11] and has been used successfully in the ICU setting.[16-22, 27]

Intervention content and implementation:

Feedback was based on family satisfaction with care, family assessments of the quality of dying and death (QODD), and nursing assessment of the quality of dying and death, using data collected during a baseline data collection period immediately preceding implementation of the intervention. We used previously validated questionnaires assessing each of these components of the quality of care.[28-31] The data were presented showing the proportion of family members who rated each item on the survey as "excellent."[32]

Feedback was presented in two settings. First, as part of academic detailing, ICU directors received the results. We discussed the results with the directors in an attempt to validate the findings and seek their buy-in for presenting the data more widely to the staff. As part of the education component, all ICU staff received information on their ICU's QODD scores and family satisfaction scores in comparison to the highest, lowest, and average scores from each participating hospital with the hospitals presented without identifiers.

4. Academic Detailing

Theoretical and empirical support:

Academic detailing is directed at ICU directors (nurse and physicians). Its focus is on identifying and modifying institutional barriers to the delivery of good end-of-life care. In this way, academic detailing may help change clinician behavior by facilitating performance accomplishments through the modification of institutional barriers, thereby making it easier for clinicians to practice effective behaviors. Furthermore, information provided in the academic

detailing context may influence knowledge and attitudes, as well as the organizational structure. Prior studies show that academic detailing has been effective in changing nurse[33] and physician[13, 25, 34] behavior.

Intervention content and implementation:

The academic detailing sessions were conducted one-on-one with the directors. They were similar to the education sessions, except that they focused more on identifying the ICU-specific barriers from a director's perspective and brainstorming about solutions to the barriers. These sessions had three explicit goals and one implicit goal. The explicit goals were: 1) to review the four topic areas described above under "ICU Clinician Education" using the clinician pamphlets; 2) to review the family and nursing satisfaction data for the specific unit compared to the aggregate of the other units; and 3) to elicit and discuss the institution-specific barriers to providing high quality palliative care in the ICU in each of the four topic areas and to develop solutions to address these barriers. The implicit goal of these sessions was to educate and engage these clinical leaders to serve as role models in their institutions for emphasizing and improving palliative care. Each ICU nurse and physician director was asked to schedule a 30 to 60 minute appointment with one of the investigators in order to view the data and discuss barriers.

5. External and System Supports

Theoretical and empirical support:

The implementation of order forms and distribution of informational pamphlets provide clinicians with opportunities for performance accomplishments, vicarious experiences and verbal persuasion. These experiences occur both as part of use of the forms (performance accomplishments) and also as part of the forms' development (vicarious experiences, verbal

persuasion). As summarized in the conceptual model of behavior change, the order forms encourage behavior change through institutional change. Similarly, the use of pamphlets for family members provides an institutional change that supports clinician behavior change. Empirically, forms and reminder systems have been shown to be one of the most consistently effective methods for changing clinician behavior.[11] Family pamphlet use in the ICU has been evaluated and shown to improve family comprehension and family satisfaction;[35] and physician order form use for life-sustaining treatment has been found to improve the quality of care in the nursing home setting.[36] Our own work with withdrawal of life support orders in the ICU has shown them to be well-received by clinicians and associated with increased use of analgesic and sedation medications without evidence of shortening the time for ventilator withdrawal to death.[37]

Intervention content and implementation:

We used a previously published "withdrawal of life support order form" as one of the features of this component.[37] This order form includes sections on preparations for withdrawal of life support, sedation and analgesia before and during withdrawal of life support, withdrawal of mechanical ventilation, and general principles guiding withdrawing and withholding life support. The order form was shared with local champions and ICU directors. We also encouraged ICUs to develop, adapt, or use pamphlets to provide family members with information about critical care. The family-targeted pamphlet previously shown to be effective at improving families' understanding of the patient's condition and treatments was one of the models offered for institutions to adapt.[35]

Another system support that was offered was the "Get to Know Me" poster. The poster was designed to be hung in the patients' ICU room and provide staff with information about the

patient, including a patient's likes and dislikes, personality, occupation, musical preferences and pets. It provided space for pictures brought in by the family that allowed the staff to develop an appreciation for the patient prior to critical illness. Families and staff have voiced strong appreciation of this poster.

IMPLEMENTATION OF THE INTERVENTION

We successfully implemented the intervention in all 6 of the hospitals randomized to receive the intervention and, after the randomized trial was completed, at 5 of the 6 hospitals randomized to the control group. One of the hospitals randomized to the control group closed prior to implementation of the intervention. Table A1 shows the implementation of each of the 5 components at the 6 hospitals randomized to the intervention during the randomized trial portion of the intervention. Table A2 shows the implementation of the 5 components at the 5 control hospitals that were scheduled to receive the intervention after completion of the randomized trial.

CLINICIAN EVALUATION OF INTERVENTION COMPONENTS

We asked clinicians participating in some of the educational components of the intervention (e.g., educational sessions, feedback of local quality data, local champion training sessions) to complete evaluation forms of the intervention activities. Because many of the components of the intervention were implemented by the ICU local champions at each site, it is difficult to assess the total number of clinicians reached by the intervention. In addition, some of the sessions (such as video showings) were conducted in the ICU, with clinicians encouraged to come and go as they were available, thus making assessment of their satisfaction impractical. However, we collected attendance data at the majority of the formal intervention sessions. In all

education sessions (presentations and grand rounds) at the six intervention hospitals, attendance was greater than 164 individuals. At the six intervention hospitals, 95 local champions attended the formal champion training sessions. Evaluation forms for some of the components provide an assessment of clinicians' satisfaction with the intervention. Evaluation forms were collected after the intervention assessing intervention activities were completed at each institution. These data are shown in Table A3 and suggest most clinicians were satisfied with the intervention. In addition, local champions were asked whether the local champion training sessions met the intervention's stated goals with 100% replying "yes" (65/65) and they were asked if the training session met their personal goals with 100% replying "yes" (64/64).

DEVELOPMENT OF THE PROPENSITY SCORE FOR SURVEY RESPONSE

1. Predictor Selection

We compiled a list of 32 variables for which we had values for all or most of the 2318 patients identified for the randomized trial. These variables came from hospital logs and death records for all 2318 patients and from medical records of 2238 patients for whom charts were abstracted. The list included the following variables: hospital site; died during the baseline or follow-up period; racial-ethnic minority status (white non-Hispanic vs. minority); gender; age at death; level of education; marital status at death (married or domestic partner, widowed, other); primary life-limiting diagnosis (cancer, trauma, other); number of days in hospital during final hospital stay; number of days in ICU during final stay; living will in place at time of death; designated power of attorney recorded in chart; DNR order in place at time of death; palliative care experts consulted during final ICU stay; spiritual care services provided during final ICU stay; social work services provided during final ICU stay; family conference(s) occurred during final ICU stay; prognosis discussed at family conference during final ICU stay; patient's

opinions/wishes expressed at family conference during final ICU stay; patient expressed wish to withhold or withdraw life-sustaining treatment during final ICU stay; family expressed wish to withhold or withdraw life-sustaining treatment during final ICU stay; physician recommended withholding or withdrawing life-sustaining treatment during final ICU stay; decision made to withhold or withdraw life-sustaining treatment during final ICU stay; ICU team gave the family assurance during the final ICU stay that the patient would be kept comfortable; spiritual needs discussed at a family conference during the final ICU stay; intra-family discord noted at a family conference during the final ICU stay; family-physician discord noted at a family conference during the final ICU stay; healthcare team discord noted at a family conference during the final ICU stay; CPR provided in final hour of life; pain assessed during final 24 hours of life; family member(s) present at time of death; and patient died in setting of full support.

2. Bivariate Predictors.

Separately for two dichotomous outcomes (whether a family member completed a survey for the patient, and whether at least one nurse completed a survey for the patient), we examined the bivariate associations of each of the 32 variables in the pool with family/nurse response, using Fisher's Exact Test, Pearson χ^2, or the Mann-Whitney test, depending upon the predictor's level of measurement. Based on the bivariate associations, we removed variables with bivariate *p*-values >0.20, creating an intermediate pool of potential predictors of each outcome.

3. Multi-predictor Models.

For each outcome, we then built multi-predictor logistic regression models, beginning with all predictors in the intermediate pool, and removing predictors sequentially in descending order

of *p*-value until achieving an equation in which all predictors had $p \leq 0.15$. Finally, we added each excluded variable from the intermediate pool back into the final equation, in the event that any of them had $p \leq 0.15$ when added to this smaller set of predictors.

4. Response-Propensity Measure, Based on the Final Multi-predictor Models.

Using the intercepts and slopes in the final equation for each outcome, derived in Step 3 above, we computed for each patient three values: the response logit (computed directly from the regression parameters, using the equation $\text{logit}(Y) = b_0 + b_1X_1 + ... + b_kX_k$), the response probability (computed as $\exp[\text{logit}(Y)]/\{1+\exp[\text{logit}(Y)]\}$), and the response weight (computed as 1/response probability).

5. Weighted Regression Models of Intervention Effect

Finally, we repeated the analyses of survey outcomes, applying the weights computed in Step 4 above, and compared the results with those for the unweighted analyses reported in the original manuscript. All weighted models included the same covariate adjustments as were used for the unweighted models.

RESULTS OF THE ASSESSMENT OF THE INTERVENTION WEIGHTED BY THE PROPENSITY SCORE FOR SURVEY RESPONSE

For family outcomes, the sample included 784 family members for whom a weight could be computed. As with the unweighted models, the intervention did not show a significant association with any of the family-assessed study outcomes (Table A4a). For the nurse outcomes, the sample included 628 nurses for whom a weight could be computed. Again, as

with the unweighted models, the weighted models failed to show a significant association between the intervention and either any of the nurse-assessed study outcomes (Table A4b).

RESULTS OF THE BEFORE-AFTER ANALYSES FOR 11 HOSPITALS THAT RECEIVED AN INTERVENTION

Sample and response rates

For the before-after analysis in the 11 hospitals that received the intervention (either as part of, or following, the randomized trial), there were 2567 eligible patients who died in the ICU or within 30 hours of transfer from the ICU, with 1712 patients in the pre-intervention period and 855 in the post-intervention period. This sample differs in two ways from that used for the randomized trial analyses: (1) it excludes patients who were in the randomized trial sample, but who died in the control hospital that closed before receiving the delayed intervention; (2) it includes patients who died in control hospitals after implementation of the delayed intervention that followed the randomized trial. Patient characteristics and outcome are shown in Table A5. Patients who died after the intervention were significantly less likely to have family conferences during their first 72 hours in the ICU, and were significantly more likely to receive pain assessments during their last 24 hours of life, as well as palliative care consultation and spiritual care at some point during their ICU stay.

We mailed surveys to family members of 2151 patients, and 917 (43%) of these families completed surveys. The assessment period (pre- vs. post-intervention) was not significantly associated with any family characteristics (Table A6).

We located nurses who had cared for 1410 patients, and nurses completed surveys for 677 (48%) of these patients. Of 2478 nurse surveys distributed, 823 (33%) were completed. A

total of 823 nurses were in the identified pool, and 356 (43%) completed one or more surveys (Table A7). Of the 356 nurses who completed surveys, 326 provided surveys that were used in the final analysis.

Outcomes

The intervention was not associated with any change in the primary outcome, the family-assessed QODD (Table A8). Similarly there was no evidence of a change in the single-item family rating of quality of dying or in family satisfaction with ICU care. There was also no evidence of an intervention effect on nurse-assessed outcomes or on the patient's length of stay in the ICU (Table A9). However, three outcomes derived from patients' medical records showed significant change after the intervention. Pain assessments during the final 24 hours of life ($p<0.001$) and consultation with palliative care experts ($p=.03$) were recorded significantly more frequently after the intervention than before, and family conferences during the patient's first 72 hours in the ICU occurred less frequently ($p<0.001$). Changes in the other six palliative care elements were nonsignificant, as were changes in length of ICU stays and time from ICU admission to ventilation withdrawal.

Figure A1: Study conceptual model for selection of the intervention components, intervention evaluation, and outcome assessment based on framework by Cabana.[7, 8]

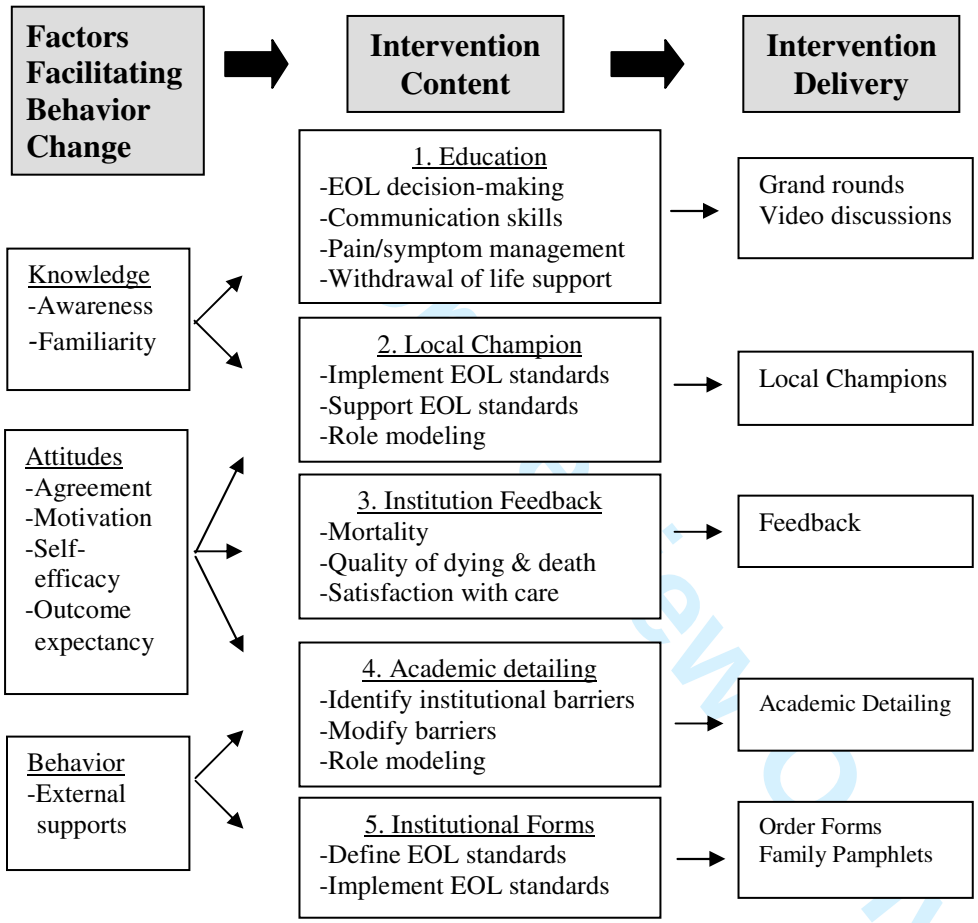

Table A1: Implementation of the intervention at the six hospitals randomized to receive the intervention (Implementation period: 2004-2007)

Component of the intervention	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6
Clinician educational sessions	4/06, 5/06, 8/06, 9/05	11/04, 10/06, 11/06	7/06, 5/07	12/05, 2/05, 4/06, 11/05	5/05, 8/05, 9/06	1/05, 6/06, 10/06
Local champion training sessions	12/05, 7/06	10/05, 5/06	4/06	6/05, 9/05, 12/05	2/06	11/06
Academic detailing with ICU nurse and physician directors	9/05, 4/07	4/05, 11/06, 1/07	2/06, 4/07	6/05	1/06	10/06, 9/07
Feedback of site-specific data	6/05, 7/05	4/05, 6/05, 8/05	1/06, 11/07	6/05	11/05, 1/06, 2/06	3/06
Systems supports	poster	poster	poster, orders	poster	poster	poster

Table A2: Implementation of the intervention at the six hospitals randomized to the control group with intention to provide the intervention after the randomized trial (Implementation period: 2005-2008)

Component of the intervention	Site 7	Site 8	Site 9	Site 10	Site 11	Site 12
		Closed				
Clinician educational sessions	9/07	N/A	1/05, 10/06	3/06, 8/07	3/07, 1/08	6/07, 7/07, 9/07
Local champion training sessions	9/07	N/A	11/06	11/06	1/08	2/07, 3/07
Academic detailing with ICU nurse and physician directors	9/07	N/A	10/06, 9/07	7/06, 12/06, 4/07	7/07, 1/08	2/07
Feedback of site-specific data	3/07, 4/07	N/A	10/06, 9/07	8/06	10/06	6/07
Systems supports	poster, orders	N/A	poster, orders	poster, orders, brochures	poster, orders, brochures	poster, orders

N/A = Not available due to hospital closure

Table A3: Ratings of the overall intervention and summary of some intervention components by ICU clinicians in 6 intervention sites assessed after the intervention.

	Number of clinicians completing evaluation (n)	**Ratings by Clinicians – Percent (n)**					
Evaluation of the IPACC Intervention		**Worsened**	**About the same**	**A little better**	**Somewhat better**	**Quite a bit better**	**A great deal better**
How much have palliative care attitudes improved in the last 12 months?	170	0% (0)	31% (52)	12% (20)	21% (35)	22% (38)	13% (23)
Ratings of Intervention Components*		**Not worthwhile**	**A little worthwhile**	**Somewhat worthwhile**	**Very worthwhile**		
Educational sessions	78	0% (0)	4% (3)	23% (18)	73% (57)		
Feedback of local data	41	7% (3)	10% (4)	29% (12)	54% (22)		
Local champion training sessions	44	2% (1)	7% (3)	25% (11)	66% (29)		
Toolkit and resources	26	0% (0)	12% (3)	42% (11)	46% (12)		

*Other components were as described above and did not have evaluations routinely collected

Table A4.a Association of Intervention with Family Survey Outcomes, Weighted Models

Outcome[a]	b	95% CI for b	*P*
QODD total score	-3.47	-10.88, 3.93	0.36
QOD single item score	0.46	-0.58, 1.51	0.39
Satisfaction with ICU care			
Total satisfaction[b]	3.01	-3.74, 9.76	0.38
Satisfaction with care	2.25	-4.60, 9.10	0.52
Satisfaction with decision-making	3.64	-4.09, 11.37	0.36

a Models for all outcomes included covariate adjustment for the patient's hospital site, baseline/follow-up status, age, sex, racial-ethnic minority status, and cause of death, and the family member's age, sex, relationship to patient, and racial-ethnic minority status.

b In addition to the covariates included in all models, this model included adjustment for whether the patient and family member lived together.

Table A4.b Association of Intervention with Nurse Survey Outcomes, Weighted Models

Outcome[a]	b	95% CI for b	*P*
QODD total score[b]	0.47	-7.48, 8.41	0.91
QOD single item score	0.70	-0.31, 1.72	0.18

a Models for both outcomes included covariate adjustment for the patient's hospital site, baseline/follow-up status, age, sex, racial-ethnic minority status, education, and cause of death, and the nurse's age.

b The model for this outcome also included adjustment for patient education, nurse racial-ethnic minority status, and whether the nurse was on duty at the time of the patient's death.

Table A5: Characteristics and outcome for patients in the pre- and post-intervention time periods at 11 hospitals

Characteristics	Pre-intervention (n=1712)	Post-intervention (n=855)	*P*[a]
Mean age in years (SD)	70.74 (14.62)	70.14 (14.43)	.18
% Male (n)	57.4 (983)	56.5 (483)	.67
Race/Ethnicity (n)	(1711)	(854)	.40
% White, non-Hispanic	78.4 (1342)	78.8 (673)	
% White, Hispanic	2.0 (35)	1.5 (13)	
% Black	7.8 (134)	6.0 (51)	
% Asian	8.6 (147)	9.6 (82)	
% Native American	1.3 (22)	1.6 (14)	
% Pacific-Islander	0.6 (11)	0.7 (6)	
% Mixed	1.2 (20)	1.8 (15)	
Underlying cause of death (n)	(1712)	(855)	.22
% Trauma	4.6 (78)	5.3 (45)	
% Cancer	17.9 (306)	15.3 (131)	
% Other	77.6 (1328)	79.4 (679)	
Education (n)	(1682)	(837)	.54
% 8th grade or less	7.6 (128)	6.1 (51)	
% Some high school	8.4 (142)	9.1 (76)	
% HS diploma or GED	40.2 (676)	40.3 (337)	
% Some college	24.1 (406)	23.5 (197)	
% 4-year college degree	12.7 (214)	15.5 (130)	
% Post-college education	6.9 (116)	5.5 (46)	
Outcomes			
Days in ICU (n)	(1657)	(743)	.32
Mean (SD)	5.69 (9.91)	5.09 (7.20)	
Median (IQR)	2.61 (1.01, 6.49)	2.48 (0.91, 6.09)	
Days to ventilation withdrawal (n)	(737)	(324)	.09
Mean (SD)	6.18 (10.65)	5.26 (7.03)	

Median (IQR)	3.23 (1.29, 7.64)	2.81 (1.13, 6.22)	
% with family conference (valid n = 1647, 741)	76.4 (1258)	64.0 (474)	<.001
% with prognosis discussed (valid n = 1646, 741)	39.4 (648)	35.8 (265)	.10
% with palliative care consultation (valid n = 1645, 741)	4.9 (81)	8.9 (66)	<.001
% provided with spiritual care (valid n = 1646, 741)	41.6 (684)	47.1 (349)	.01
% provided social work assistance (valid n = 1645, 741)	35.7 (588)	38.6 (286)	.18
% without CPR in last 24 hrs of life (valid n = 1648, 740)	17.7 (292)	19.2 (142)	.39
% with DNR orders at time of death (valid n = 1634, 740)	80.0 (1308)	78.2 (579)	.32
% with pain assessment (valid n = 1641, 740)	80.0 (1312)	85.3 (631)	.002
% with life support withheld or withdrawn (valid n = 1636, 739)	71.9 (1176)	69.6 (514)	.26

a Probabilities associated with differences between the two groups are based on Mann-Whitney tests for ordinal variables, Fisher's Exact Test for dichotomous variables, and Pearson χ^2 tests for other unordered categorical variables.

Table A6: Characteristics and outcomes of families completing surveys for patients in the pre- and post-intervention time periods

Characteristics	Pre-intervention (n=617)	Post-intervention (n=300)	*P*[a]
Mean age in years (SD)	59.19 (14.73)	57.47 (14.05)	.11
% Male (n)	58.5 (361)	55.7 (167)	.43
Race/Ethnicity (n)	(595)	(285)	.92
% White, non-Hispanic	86.2 (513)	86.7 (247)	
% White, Hispanic	1.7 (10)	1.1 (3)	
% Black	3.4 (20)	3.2 (9)	
% Asian	4.5 (27)	4.9 (14)	
% Native American	0.7 (4)	1.4 (4)	
% Pacific-Islander	0.5 (3)	0.4 (1)	
% Mixed	3.0 (18)	2.5 (7)	
Education (n)	(599)	(286)	.80
% 8th grade or less	1.2 (7)	0.7 (2)	
% Some high school	2.0 (12)	2.4 (7)	
% HS diploma or GED	17.9 (107)	16.1 (46)	
% Some college	41.2 (247)	44.8 (128)	
% 4-year college degree	19.9 (119)	21.0 (60)	
% Post-college education	17.9 (107)	15.0 (43)	
% Patient's spouse (n)	46.7 (281)	43.5 (127)	.39
Outcomes			
QODD total score (n)	(607)	(293)	.75
Mean (SD)	61.50 (22.94)	62.20 (23.25)	
Median (IQR)	63.33 (47.22, 79.05)	63.33 (47.86, 80.00)	
QOD single-item rating (n)	(574)	(283)	.22
Mean (SD)	6.72 (3.15)	7.00 (3.04)	
Median (IQR)	8 (5, 9)	8 (5, 10)	
Satisfaction with ICU			
Total satisfaction (n)	(595)	(285)	.29
Mean (SD)	74.49 (21.19)	76.00 (20.61)	

Median (IQR)	79.17 (64.58, 91.30)	80.43 (64.43, 92.71)	
Satisfaction with care (n)	(593)	(283)	.28
Mean (SD)	75.37 (21.31)	77.06 (20.54)	
Median (IQR)	80.36 (64.29, 91.37)	82.14 (66.07, 94.23)	
Satisfaction with decision making (n)	(604)	(296)	.40
Mean (SD)	73.55 (22.86)	74.81 (22.33)	
Median (IQR)	80.00 (62.50, 91.67)	80.00 (61.46, 92.50)	

a Probabilities associated with differences between the two groups are based on Mann-Whitney tests for ordinal variables, Fisher's Exact Test for dichotomous variables, and Pearson χ^2 tests for other unordered categorical variables.

Table A7: Characteristics and outcomes for nurses who completed surveys for patients during the pre- and post-intervention time periods

Characteristics	**Pre-intervention (n=283[a])**	**Post-intervention (n=126[a])**
Mean age in years, 2008 (SD)	47.40 (10.13)	45.21 (10.95)
% Male (n[a])	10.6 (30)	9.5 (12)
% Racial/ethnic minority (n[a])	20.5 (58)	20.6 (26)
Mean yrs critical care nursing, 2008 (SD)	15.63 (9.85)	12.92 (9.85)
Outcomes		
QODD total score[b] (n[a])	(282)	(125)
Mean (SD)	69.51 (19.61)	69.43 (19.77)
Median (IQR)	70.91 (56.67, 84.23)	73.66 (60.25, 83.45)
QOD single-item rating[b] (n[a])	(267)	(118)
Mean (SD)	7.26 (2.46)	7.17 (2.46)
Median (IQR)	8 (6, 9)	8 (6, 9)

a All n's in this table represent the number of nurses, not the number of surveys. Of the 356 nurses, 230 provided surveys for the pre-intervention period only, 73 for the post-intervention period only, and 53 for both periods.

b For descriptive information related to nurse outcomes, we first computed the nurse's mean outcome score for surveys completed while the nurse was a member of each of four groups. The mean (and median) values in the table represent the mean (median) of these mean outcome scores.

Table A8: Study outcomes

Outcomes	b[a]	*P*	95% CI
Family-assessed[b]			
QODD total score	1.39	0.39	-1.78, 4.56
QOD single item score	0.41	0.06	-0.02, 0.84
Satisfaction with ICU care			
Total score	2.41	0.11	-0.53, 5.35
Satisfaction with care	2.46	0.10	-0.49, 5.40
Satisfaction with decision-making subscale	2.39	0.14	-0.75, 5.53
Nurse-assessed[c]			
QODD total score	0.41	0.84	-3.50, 4.32
QOD single item score	-0.05	0.84	-0.55, 0.45
Medical record			
Length of ICU stay,[d] (Cox coefficient)	-0.02	0.69	-0.11, 0.07
Time from ICU admit to withdrawal of ventilation,[e] (Cox coefficient)	0.05	0.45	-0.08, 0.19
Occurrence of family conference[f]	-0.57	<0.001	-0.77, -0.38
Discussion of patient's prognosis with family[g]	-0.20	0.046	-0.39, -0.004
Consultation with palliative care experts[h]	0.42	0.03	0.04, 0.80
Provision of spiritual care[i]	-0.06	0.59	-0.26, 0.15
Provision of social work assistance[j]	0.09	0.41	-0.12, 0.31
Avoidance of CPR in the last 24 hours of life[k]	0.09	0.45	-0.15, 0.33
DNR orders in place at the time of death[l]	-0.14	0.23	-0.36, 0.09
Pain assessment[m]	0.53	<0.001	0.27, 0.80
Life support withheld or withdrawn[n]	-0.11	0.27	-0.32, 0.09

a Parameter estimate for the independent effect of pre- versus post-intervention indicator after adjustment for covariates. Estimates for family- and nurse-assessed outcomes were from multi-predictor 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.

b Dataset included 917 family members.

c Clustered regression models with patients clustered under nurses. Dataset included 677 patients clustered under 326 nurses.

d Cox regression model based on 2400 patients for whom length of stay was known. Estimated hazard ratio = 0.98, 95% CI = 0.90, 1.07.

e Cox regression model based on 1061 patients who had ventilation withdrawn. Estimated hazard ratio = 1.05, 95% CI = 0.92, 1.21.
f Logistic regression model based on 2388 patients with complete data. Estimated odds ratio = 0.56, 95% CI = 0.46, 0.69.
g Logistic regression model based on 2387 patients with complete data. Estimated odds ratio = 0.82, 95% CI = 0.68, 0.996.
h Logistic regression model based on 2386 patients with complete data. Estimated odds ratio = 1.52, 95% CI = 1.04, 2.23.
i Logistic regression model based on 2387 patients with complete data. Estimated odds ratio = 0.95, 95% CI = 0.77, 1.16.
j Logistic regression model based on 2386 patients with complete data. Estimated odds ratio = 1.09, 95% CI = 0.88, 1.36.
k Logistic regression model based on 2388 patients with complete data. Estimated odds ratio = 1.10, 95% CI = 0.87, 1.39.
l Logistic regression model based on 2374 patients with complete data. Estimated odds ratio = 0.87, 95% CI = 0.70, 1.09.
m Logistic regression model based on 2381 patients with complete data. Estimated odds ratio = 1.70, 95% CI = 1.31, 2.22.
n Logistic regression model based on 2375 patients with complete data. Estimated odds ratio = 0.89, 95% CI = 0.73, 1.09.

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