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Effects of a Personalized Web-Based Decision Aid for Surrogate Decision Makers of Patients With Prolonged Mechanical Ventilation A Randomized Clinical Trial

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Abstract

Background—Treatment decisions in intensive care units (ICUs) are common and difficult for surrogate decision makers and often lead to decisional conflict, psychological distress, and treatments misaligned with patient preferences.

Objective—To determine whether a decision aid about prolonged mechanical ventilation improved prognostic concordance between surrogate decision makers and clinicians compared with a usual care control.

Design—Multicenter, parallel, randomized, clinical trial. ([ClinicalTrials.gov: NCT01751061](https://clinicaltrials.gov/ct2/show/study/NCT01751061))

Setting—13 medical and surgical ICUs at 5 hospitals.

Participants—Adult patients receiving prolonged mechanical ventilation and their surrogates, ICU physicians, and ICU nurses.

Intervention—A Web-based decision aid provided personalized prognostic estimates, explained treatment options, and interactively clarified patient values to inform a family meeting. The control group received information according to usual care practices followed by a family meeting.

Measurements—The primary outcome was improved concordance on 1-year survival estimates, measured with the clinician–surrogate concordance scale (range, 0 to 100 percentage points; higher scores indicate more discordance). Secondary and additional outcomes assessed the experiences of surrogates (psychological distress, decisional conflict, and quality of communication) and patients (length of stay and 6-month mortality). Outcomes assessors were blinded to group allocation.

Results—The study enrolled 277 patients, 416 surrogates, and 427 clinicians. Concordance improvement did not differ between intervention and control groups (mean difference in score change from baseline, −1.7 percentage points [95% CI, −8.3 to 4.8 percentage points]; $P = 0.60$). Surrogates' postintervention estimates of patients' 1-year prognoses did not differ between intervention and control groups (median, 86.0% [interquartile range {IQR}, 50.0%] vs. 92.5% [IQR, 47.0%]; $P = 0.23$) and were substantially more optimistic than results of a validated prediction model (median, 56.0% [IQR, 43.0%]) and physician estimates (median, 50.0% [IQR, 55.5%]). Eighty-two intervention surrogates (43%) favored a treatment option that was more aggressive than their report of patient preferences. Although intervention surrogates had greater

reduction in decisional conflict than control surrogates (mean difference in change from baseline, 0.4 points [CI, 0.0 to 0.7 points]; $P = 0.041$), other surrogate and patient outcomes did not differ.

Limitation—Contamination among clinicians could have biased results toward the null hypothesis.

Conclusion—A decision aid about prolonged mechanical ventilation did not improve prognostic concordance between clinicians and surrogates, reduce psychological distress to surrogates, or alter clinical outcomes. Decision support in acute care settings may require greater individualized attention for both the cognitive and affective challenges of decision making.

Prolonged mechanical ventilation affects 400 000 U.S. patients annually and is associated with high mortality, functional and cognitive disability, caregiver burden, and health care costs exceeding \$35 billion (1, 2). These patients typically lack decisional capacity, so family members must make challenging decisions between life-prolonging therapy and comfort-focused care, including withdrawal of life support (3).

Although experts encourage shared decision making for such preference-sensitive decisions to choose a treatment plan that is most consistent with a patient's values (4–6), clinicians often fail to adequately elicit patient treatment preferences, provide guidance about the surrogate's role, disclose likely long-term outcomes, and discuss the option of comfort-focused care (7–13). As a consequence, family members struggle to make good surrogate decisions in the setting of heightened emotional distress and conflicting priorities (14). Ineffective communication can result in the default provision of aggressive life support, which may conflict with patient preferences (15) and lead to psychological distress among family members (16).

Decision aids can improve the quality of decision making by providing relevant information, helping set realistic expectations, and aligning choice with personal values (17). However, no clinical trials have tested decision aids in an acute care setting or among surrogates in intensive care units (ICUs). In this multicenter, randomized, clinical trial, we examined whether a personalized, Web-based decision aid about goal-of-care choices in prolonged mechanical ventilation (vs. a usual care control) could better align expectations for prognosis between clinicians and surrogate decision makers, reduce decisional conflict and psychological distress for surrogates, and shorten length of stay by expediting the decision-making process.

Methods

Trial Design and Oversight

We did a patient-level, randomized, clinical trial between 31 December 2012 and 4 January 2017 at 5 study sites: Duke University Medical Center, Duke Regional Hospital, Harborview Medical Center, University of North Carolina at Chapel Hill, and University of Pittsburgh Medical Center. The protocol was approved by site institutional review boards and an independent data safety monitoring board, which also reviewed performance and safety at 6-month intervals. The study protocol is in Supplement 1 (available at [Annals.org](https://www.annals.org)). This trial is registered at [ClinicalTrials.gov](https://www.clinicaltrials.gov) (NCT01751061).

Trial Centers and Participants

Eligible patients were identified through daily screening of 13 medical, surgical, trauma, cardiac, and neurologic ICUs. Patient inclusion criteria were age 18 years or older, no anticipation of death or liberation from mechanical ventilation within 24 hours, and ventilation for at least 10 days—a time at which tracheotomy and surgical feeding tube placement are commonly considered (18). Patient exclusion criteria were possession of decisional capacity, lack of a surrogate, clear preference for comfort care, ventilation for more than 21 days, chronic neuromuscular disease, and imminent organ transplant (pages 3 and 4 of Supplement 2, available at [Annals.org](https://www.annals.org)); palliative care consultation was allowed. Primary surrogates were the adults who self-identified as the most involved participant in decision making, and only 1 was enrolled per patient. An unlimited number of additional surrogates were allowed. Surrogates were excluded if they needed English translation and became ineligible after randomization if patients regained capacity, were extubated, or died before the intervention. Each patient's ICU physician (attending or fellow) and bedside ICU nurse were included. Clinicians were not excluded for previous participation. All participants gave written informed consent.

Randomization and Treatment Groups

A password-protected computerized system randomly assigned patients and their surrogates 1:1 to either intervention or control in blocks of 4, stratifying by site. Supplement 2 describes the intervention and its conceptual model. Briefly, the interactive Web-based decision aid was designed to support surrogates and clinicians in the shared decision-making process for the provision of prolonged mechanical ventilation. It was conceptually grounded in the Ottawa Decision Support Framework, which addresses how to support individuals' decisional needs by highlighting options and risks, identifying uncertainty, and clarifying health-related values (19). It was constructed using guidelines from the International Patient Decision Aids Standards Collaboration (20) and written at a sixth-grade reading level.

The content defined prolonged ventilation, framed the decision as being among 3 options for goals of treatment (maximize comfort, aim for survival but avoid prolonged treatment, or maximize survival), described what to expect from each option, described the function of the surrogate in decision making, and elicited family support needs. An animated graphic displayed an individualized 1-year prognosis estimated from a validated clinical prediction model (21). Another graphic indicated the goal of treatment that the surrogate seemed to lean toward on the basis of an algorithm informed by his or her responses to a patient values clarification exercise integrated within the decision aid. This graphic also allowed the surrogate to move a second linear indicator of the treatment goal if they wished to more accurately reflect their own understanding of the patient's treatment preference.

On study day 1, each surrogate randomly assigned to the intervention group viewed the decision aid privately and independently on a tablet computer after a brief introduction by a trained coordinator. On completion, the decision aid summarized each surrogate's responses and the model-estimated prognosis in a 2-page document. This was given to the surrogate and clinicians for discussion in a family meeting, which was held on study day 2 and included the surrogate or surrogates, family or friends, and the enrolled physician and nurse.

Although intervention meetings were unscripted and did not specify roles for physicians and nurses, clinicians were asked to discuss the content of the decision aid summary document.

Surrogates assigned to the control group received only a family meeting on study day 2, before which no informational materials or instructions were provided to participants. In both groups, a coordinator observed each meeting as a nonparticipant, recording topics discussed on a checklist (pages 12 to 14 of Supplement 2).

Data Collection

All surrogates completed the following 4 interviews: in person at enrollment but before randomization (interview 1) and on study day 3 (interview 2) and via telephone at 3 and 6 months (interviews 3 and 4) (Figure 1 of Supplement 3, available at [Annals.org](https://www.annals.org)). Physicians and nurses completed interviews synchronous with surrogate interviews 1 and 2. Blinding during outcome assessment after randomization was ensured by use of a second coordinator at each site who was unaware of group assignment. Surrogates received \$10 per interview.

Primary Outcome

We assessed outcomes relevant to surrogates, patients, and clinicians, as detailed on pages 3 to 6 of Supplement 3 (available at [Annals.org](https://www.annals.org)). The primary outcome was score on the clinician-surrogate concordance scale (CSCS), a measure of both the alignment of prognostic expectations and the quality of information exchange among decisional participants. The CSCS is calculated as the absolute value of the difference between the surrogate's response and that of either the treating ICU physician (primary outcome) or the nurse (secondary outcome) to the question, "What percent chance do you think [the patient / your loved one] has of being alive 1 year from now if the current treatment plan is continued?" (22). Scores can range from 0 to 100 percentage points, and higher values indicate greater discordance.

Secondary and Additional Outcomes

Secondary outcomes for surrogates assessed at interviews 1 and 2 included comprehension of diagnosis, treatment, and prognosis (medical comprehension scale: range, 0 to 8 points, with higher scores indicating greater comprehension) (14) and a measure of satisfaction with clinician communication (quality of communication questionnaire: range, 0 to 110 points, with higher scores indicating better communication) (23). Surrogates also completed the Hospital Anxiety and Depression Scale (range, 0 to 42 points, with higher scores indicating greater distress) (24) and the posttraumatic stress symptom inventory (range, 10 to 70 points, with higher scores indicating greater distress) (25) at 3 and 6 months. Additional outcomes reported by surrogates included a measure of uncertainty in decision making and the options and factors contributing to that uncertainty (decisional conflict scale: range, 0 to 4 points, with higher scores indicating less conflict) (26) at interviews 1 and 2 and the patient perception of care centeredness scale (range, 12 to 48 points, with higher scores indicating greater patient-centeredness of care) (27) at 1 and 3 months. At interview 2, we assessed reasons for possible prognostic discordance, such as misunderstandings and differences in beliefs, by asking all clinicians and surrogates for their personal estimate of 1-year prognosis

and their perception of the other dyad member's estimate. We assessed patient length of stay and 6-month mortality from the medical chart and surrogate report, respectively.

Power and Statistical Analysis

The full statistical analysis plan and code are in Supplement 4 (available at [Annals.org](https://www.annals.org)). Using methods from Borm and colleagues (28) and Donner and Klar (29), we estimated that 210 patients (315 surrogates, assuming an average of 1.5 surrogates per patient) would provide 80% power to detect a mean between-group difference in CSCS score of 9 percentage points between interviews 1 and 2, assuming a baseline mean score of 50 percentage points (SD, 24), a type I error rate of 5%, a correlation between interviews of 0.5, an expectation that 50% of patients would have multiple surrogates, an intraclass correlation coefficient of 0.8 for multiple surrogates for a patient, and a 5% dropout rate before interview 2. Because we anticipated that physicians' prognostic estimates would be stable between interviews 1 and 2, the measured CSCS difference was expected to be largely due to a change in surrogates' estimates. The clinical importance of a 9-percentage point change is supported by a study of seriously ill patients whose potential willingness to receive prolonged mechanical ventilation declined substantially when prognosis worsened from 50% to 40% (30). To provide the trial with 80% power to detect clinically important differences on secondary outcomes, we inflated the sample to 280 patients (about 420 surrogates) to account for an additional 25% dropout by 6 months.

To test the primary hypothesis, we used a general linear model fitted with generalized estimating equations, a linear link, and an exchangeable correlation (PROC GENMOD in SAS, version 9.4 [SAS Institute]). Model parameters included indicator variables for intervention, interview 2, the interaction between intervention and interview 2, and a 4-level site variable. The mean between-group difference in CSCS score and its corresponding 95% CI and *P* value were derived from the interaction term between intervention and interview 2. The same generalized linear model was used for all other continuous secondary outcomes assessed at interviews 1 and 2, whereas indicator variables for interviews 3 and 4 were added for the 3- and 6-month outcomes. A 2-sided type I error rate of 0.05 was set for all tests; no adjustments were made for multiple comparisons. All participants were included in analyses according to their group randomization.

Role of the Funding Source

The National Institutes of Health had no role in the design or conduct of the trial, interpretation of the data, or preparation of the manuscript.

Results

Participant Characteristics

We randomly assigned 277 patients (60.1% of eligible) (Figure 1) and 416 surrogates (70.1% of eligible; 1.5 surrogates [SD, 0.87] per patient). Patients were middle-aged (mean age, 53.4 years [SD, 17.2]) and had functional limitations and chronic medical comorbid conditions (Table 1; Table 1 of Supplement 3, available at [Annals.org](https://www.annals.org)). Surrogates were generally middle-aged spouses or partners and had good health literacy and numeracy (Table

1; Table 2 of Supplement 3, available at [Annals.org](https://annals.org)). The 186 physicians had a mean age of 38.3 years (SD, 9.1), and most were male ($n = 110$ [61.5%]) (Table 3 of Supplement 3, available at [Annals.org](https://annals.org)). The 241 nurses had a mean age of 35.0 years (SD, 10.8), and most were female ($n = 184$ [81.8%]).

Intervention Delivery

The decision aid was completed by 192 surrogates (91.4%) in sessions lasting a mean of 33.4 minutes (95% CI, 24.2 to 42.7 minutes) (Table 4 of Supplement 3, available at [Annals.org](https://annals.org)). Family meetings were held for 252 patients (92%) and did not differ in length between the intervention and control groups (mean, 29.1 minutes [SD, 27.8] vs. 29.5 minutes [SD, 19.6], respectively; $P = 0.90$). The decision aid was mentioned during meetings by 37 physicians (29.8%) and 30 surrogates (24.2%). However, clinicians in almost all intervention meetings discussed 1 or more of its core components, including diagnosis ($n = 117$ [94.4%]), treatment ($n = 121$ [97.6%]), and prognosis ($n = 112$ [90.3%])—frequencies similar to those in control meetings (Table 5 of Supplement 3, available at [Annals.org](https://annals.org)). Compared with control meetings, intervention meetings more frequently included discussion of 1-year outcomes (66 meetings [52%] vs. 48 meetings [39%]) and postdischarge patient needs (88 meetings [71%] vs. 75 meetings [59%]).

Most intervention surrogates ($n = 97$ [50.5%]) seemed to lean toward an intermediate treatment option for their loved one on the basis of their report of patient values. However, nearly half of surrogates ($n = 90$ [46.9%]) adjusted the goals calculated by the decision aid algorithm to reflect a different final treatment option (Figure 2). The most common adjustments were toward aggressive care (which increased from $n = 9$ to $n = 39$) and away from comfort-focused care with a hope for survival (which decreased from $n = 46$ to $n = 11$).

Primary Outcome

Improvement in mean physician CSCI score did not differ significantly between the intervention and control groups (difference, -1.7 percentage points [CI, -8.3 to 4.8 percentage points]; $P = 0.60$) (Table 2; Table 6 of Supplement 3, available at [Annals.org](https://annals.org)). Similarly, nurse CSCI scores (secondary outcome) did not differ by treatment group (difference, 0.8 percentage point [CI, -6.5 to 8.0 percentage points]; $P = 0.84$). Postintervention 1-year prognostic estimates by intervention and control surrogates did not differ by treatment group (median, 86.0% [interquartile range {IQR}, 50.0%] vs. 92.5% [IQR, 47.0%]; $P = 0.23$) (Figure 2 of Supplement 3, available at [Annals.org](https://annals.org)). These prognoses by surrogates were substantially more optimistic than prediction model results (median, 57.0% [IQR, 45.0%] for intervention vs. 54.0% [IQR, 39.0%] for control; $P = 0.76$; overall median, 56.0% [IQR, 43.0%]) and physicians' prognoses (median, 50.0% [IQR, 55.0%] vs. 53.0% [IQR, 69.0%]; $P = 0.60$; overall median, 50.0% [IQR, 55.5%]) (Figure 3 of Supplement 3, available at [Annals.org](https://annals.org)). Prognostic discordance was explained by surrogates' misunderstandings about and conscious disagreements with physician beliefs (Figures 4 and 5 of Supplement 3, available at [Annals.org](https://annals.org)). Although change in surrogates' prognostic beliefs did not differ by group, intervention surrogates had more accurate mean estimates than control surrogates of physicians' prognostic beliefs (median difference, 57.2

percentage points [IQR, 34.6 percentage points] vs. 66.8 percentage points [IQR, 36.4 percentage points]; $P = 0.023$) (Table 7 of Supplement 3, available at [Annals.org](https://annals.org)).

Secondary Outcomes

Intervention primary surrogates had greater reduction in decisional conflict than control surrogates (mean difference in change on decisional conflict scale, 0.4 points [CI, 0.0 to 0.7 points]; $P = 0.041$). However, intervention and control primary surrogates did not differ in medical comprehension (mean difference in change on medical comprehension scale, 0.3 points [CI, -0.1 to 0.7 points]; $P = 0.184$) or communication (mean difference in change on quality of communication questionnaire, -2.9 points [CI, -6.9 to 1.1 points]; $P = 0.149$) (Table 2). Surrogates' total scores on the Hospital Anxiety and Depression Scale and posttraumatic stress symptom inventory also did not differ at 3 and 6 months (Table 3; Table 8 of Supplement 3, available at [Annals.org](https://annals.org)).

Clinical Outcomes

Intervention and control groups did not differ in the ways in which the decision-making process was operationalized, such as use of aggressive ICU treatments, mean number of days with mechanical ventilation after randomization (15.3 days [SD, 23.4] vs. 13.7 days [SD, 21.4]; $P = 0.76$), days in the hospital (42.8 days [SD, 31.6] vs. 39.4 days [SD, 27.3]; $P = 0.84$), hospital mortality (47 deaths [SD, 34.1] vs. 39 deaths [SD, 28.1]; $P = 0.28$), and 6-month mortality (56 deaths [40.6%] vs. 53 deaths [38.1%]; $P = 0.68$) (Tables 9 and 10 of Supplement 3, available at [Annals.org](https://annals.org)).

Discussion

A personalized decision aid that is grounded in theory, targets surrogate decision makers of patients with prolonged mechanical ventilation, and feeds results back to ICU clinicians before a family meeting did not increase prognostic concordance; change decisions about goals of treatment; or improve outcomes of relevance to patients, family members, and clinicians. Of note, the intervention had no effect in mitigating surrogates' remarkably high levels of prognostic optimism for a condition associated with high morbidity and mortality.

Evidence suggests that decision aids combined with clinical counseling can improve the quality of decision making for patients facing various decisions about treatment and screening (17). Accordingly, this decision aid reduced decisional conflict and improved surrogates' understanding of physicians' prognostic beliefs. Decision aids have also had notable clinical effects in populations with serious conditions, such as decreased rates of implementation of left ventricular assist devices in outpatients with congestive heart failure and decreased hospital transfer rates in nursing home residents with dementia (31, 32). We observed no effect on surrogate and patient outcomes from hospitalization to 6 months.

The decision aid's lack of effect has many potential explanations. First, the intense emotional and psychological difficulty of making end-of-life decisions for others may have blunted any benefit of a decision aid largely focused on the cognitive aspects of decision making. Experimental evidence from decision psychology indicates that strong emotions, such as fear and anxiety, substantially affect a person's ability to process information and

weigh tradeoffs between options (33). Although the intervention reduced surrogates' decisional conflict, their unaddressed emotional distress may have diminished their ability to come to terms with poor prognosis or opt for treatments focused on palliation when doing so seemed consistent with the patient's treatment preferences.

Second, the lack of intervention effect on end of life decisions may have arisen because its failure to correct surrogates' overly optimistic prognostic expectations to a more accurate awareness of outcomes whose likely incongruence with patient preferences would have influenced them to opt for comfort-focused care. Because surrogates had adequate health literacy, numeracy, and understanding of physicians' prognostic beliefs, their own prognostic estimates may also have served as "illocutionary acts"—that is, expressions distinct from comprehension with which they intended to express positive attitude, optimism, or faith; to highlight patients' unrecognized qualities of resilience; or to counter clinicians' pessimism (15, 34–36). In addition, surrogates may have considered the decision aid content but used it to confirm an existing decision when integrating it with other informational sources and optimistic bias (37). Given past research showing that few surrogates rely exclusively on physician prognostication when forming their perception of patient prognosis (38), it is also possible that the intervention simply received lower priority as an information source. Even more striking, most intervention surrogates chose a treatment option that was more aggressive than a suggestion derived from their own understanding of patient preferences. This contradiction may reflect confusion of personal and patient perspectives (39), conflation of medical care intensity and quality (40), prioritization of immediate patient well-being over likely long-term outcome (41), reluctance in the face of prognostic uncertainty to consider withdrawal of a treatment that will likely result in death (42), or simply an inadequate mechanization of the values elicitation process by the intervention.

Third, the clinical context was likely a challenge to careful decision making because of the sudden onset and rapid pace of critical illness, the proximity of possible death, the many clinicians involved with each patient, and the difficulties of deciding about life-sustaining therapy for a loved one (16). Although uncertainty about outcome may be greater earlier in the ICU course, initiating decision-making interventions before day 10 of ventilation could be important.

This trial has important implications for the design of future decision-support interventions. Improving the quality of end-of-life decisions in critical illness may require interventions that attend more carefully to both the cognitive and affective dimensions of decision making. In support of this idea, a recent intervention in which palliative care providers provided prognostic information and unstructured emotional support over 1 to 2 meetings had no effect on family members' psychological distress or length of stay for patients with chronic critical illness (43). In contrast, a recent pragmatic trial of a nurse-led intervention in the ICU that provided intensive emotional support to families and frequent family meetings improved patient-centeredness of care and reduced length of stay, although it did not improve surrogates' psychological distress (44). In our trial, only about a third of clinicians explicitly mentioned the decision aid in a family meeting. Decisional outcomes might be improved in future trials by including an intervention component designed to help clinicians learn how to effectively incorporate the decision aid into both their clinical workflow and

their conversations with surrogates (45). Ultimately, using an individualized decision-making approach in which clinicians more collaboratively provide prognostic information, explain treatment options, and give recommendations; better support surrogates' decisional role stresses; and attend to surrogates' emotions throughout the entire decisional process could provide a better decisional framework for acute illness (46).

This trial also suggests that decision aids may not alter health care use in the setting of surrogate decision making in critical illness. At a time of rising policymaker interest in shared decision making and decision aids to reduce costly interventions of unclear benefit (47, 48), caution is needed in expecting benefit from the use of decision aids alone in a hospital setting, where most health care use occurs.

This study is the first multicenter randomized trial to our knowledge to test a decision aid in an acute care setting (49). Other strengths include the decision aid's rigorous development and high usability across all age groups (50) and the study's high protocol fidelity and 6-month follow-up rate. Limitations include the fact that unmeasured physician-level effects or contamination among clinicians could have biased results toward the null hypothesis. However, only 12 physicians (6.5%) had experience with the intervention before interacting with a control surrogate (Figure 6 of Supplement 3, available at [Annals.org](https://www.annals.org)).

In conclusion, a personalized, Web-based decision aid addressing prolonged mechanical ventilation did not improve prognostic concordance between clinicians and surrogates, lessen surrogates' psychological distress, or reduce patients' hospital length of stay. Future approaches to decision support in ICU settings will likely require greater individualized attention for both the cognitive and affective challenges of decision making.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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* For 2 patients, the primary surrogate decision maker (SDM) wished to be considered an additional surrogate with equal decisional power.

All available data at each time point were included in analyses.

Figure 1. Study flow diagram.

Note that 277 patients were randomly assigned, but in 1 case, 2 surrogate decision makers shared decisional responsibility and were thus listed as additional surrogate decision makers. Also, clinicians at interviews 1 and 2 are not all unique (Figure 6 of Supplement 3, available at [Annals.org](https://annals.org)). All available data at each time point were included in analyses. ICU = intensive care unit; SDM = surrogate decision maker. * For 2 patients, the primary SDM wished to be considered an additional SDM with equal decisional power.

Figure 2. Differences between decision aid-suggested preference and surrogate decision maker-corrected preference for patient goals of care.

Of the 192 surrogate decision makers (both primary and additional) who completed the decision aid, 102 (53.1%) agreed with the goal-of-care choice visually suggested by the decision aid based on his or her answers to embedded questions (see gray bar in inset screenshot). Of the 90 surrogates (46.9%) who disagreed, 82 (91.1%; orange lines) adjusted the graphic by moving the bar (changing its color to red in inset screenshot) toward a more aggressive treatment goal, whereas 8 (8.9%; green lines) adjusted it to a less aggressive treatment goal.

Table 1.

Characteristics of Patients and Surrogate Decision Makers*

Characteristic	Patients		Primary Surrogate Decision Makers			Secondary Surrogate Decision Makers			
	Total (n = 277)	Intervention (n = 138)	Control (n = 139)	Total (n = 275)	Intervention (n = 137)	Control (n = 138)	Total (n = 141)	Intervention (n = 73)	Control (n = 68)
Mean age (SD), y ^{‡‡}	53.4 (17.2)	52.9 (17.9)	54.0 (16.6)	51.2 (12.6)	49.9 (13.5)	52.6 (11.6)	44.1 (14.9)	46.7 (14.0)	41.3 (15.4)
Female, n (%)	100 (36.1)	50 (36.2)	50 (36.0)	201 (73.1)	96 (70.1)	105 (76.1)	96 (68.1)	51 (69.9)	45 (66.2)
Race/ethnicity, n (%) ^{‡‡}									
White	209 (75.5)	98 (71.0)	111 (79.9)	211 (76.7)	98 (71.5)	113 (81.9)	106 (75.2)	53 (72.6)	53 (77.9)
African American	51 (18.4)	30 (21.7)	21 (15.1)	45 (16.4)	29 (21.2)	16 (11.6)	24 (17.0)	15 (20.5)	9 (13.2)
Asian	1 (0.4)	0 (0.0)	1 (0.7)	1 (0.4)	0 (0.0)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
Native Hawaiian or other Pacific Islander	2 (0.7)	2 (1.4)	0 (0.0)	1 (0.4)	1 (0.7)	0 (0.0)	1 (0.7)	0 (0.0)	1 (1.5)
American Indian or Alaska Native	8 (2.9)	6 (4.3)	2 (1.4)	7 (2.5)	5 (3.6)	2 (1.4)	4 (2.8)	4 (5.5)	0 (0.0)
Multiethnic	5 (1.8)	2 (1.4)	3 (2.2)	4 (1.5)	1 (0.7)	3 (2.2)	4 (2.8)	1 (1.4)	3 (4.4)
Other	1 (0.4)	0 (0)	1 (0.7)	5 (1.8)	2 (1.5)	3 (2.2)	2 (1.4)	0 (0.0)	2 (2.9)
Hispanic	11 (4.0)	6 (4.3)	5 (3.6)	15 (5.5)	9 (6.6)	6 (4.3)	7 (5.0)	3 (4.1)	4 (5.9)
Marital status, n (%)									
Married or living with partner	148 (53.4)	72 (52.2)	76 (54.7)	210 (76.4)	102 (74.5)	108 (78.3)	80 (56.7)	40 (54.8)	40 (58.8)
Separated, divorced, or widowed	65 (23.4)	34 (24.6)	31 (22.3)	37 (13.4)	17 (12.4)	20 (14.4)	22 (15.6)	16 (21.9)	6 (8.9)
Single	64 (23.1)	32 (23.2)	32 (23.0)	28 (10.2)	18 (13.1)	10 (7.2)	39 (27.7)	17 (23.3)	22 (32.4)
Employment status, n (%)									
Employed (full time or part time), homemaker, or student	112 (40.4)	55 (39.9)	57 (41.0)	184 (66.9)	91 (66.4)	93 (67.4)	108 (76.6)	53 (72.6)	55 (80.9)
Unemployed (but not disabled)	24 (8.7)	13 (9.4)	11 (7.9)	17 (6.2)	7 (5.1)	10 (7.2)	6 (4.3)	4 (5.5)	2 (2.9)
Retired	64 (23.1)	31 (22.5)	33 (23.7)	54 (19.6)	30 (21.9)	24 (17.4)	18 (12.8)	11 (15.1)	7 (10.3)
Disabled	73 (26.4)	38 (27.5)	35 (25.2)	18 (6.5)	8 (5.8)	10 (7.2)	9 (6.4)	5 (6.8)	4 (5.9)
Other	4 (1.4)	1 (0.7)	3 (2.2)	2 (0.7)	1 (0.7)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
Education, n (%)									
Grade school or some high school	–	–	–	20 (7.3)	12 (8.7)	8 (5.8)	13 (9.2)	7 (9.6)	6 (8.9)

Characteristic	Patients			Primary Surrogate Decision Makers			Secondary Surrogate Decision Makers		
	Total (n = 277)	Intervention (n = 138)	Control (n = 139)	Total (n = 275)	Intervention (n = 137)	Control (n = 138)	Total (n = 141)	Intervention (n = 73)	Control (n = 68)
High school graduate	—	—	—	56 (20.4)	30 (21.9)	26 (18.8)	28 (19.9)	11 (15.1)	17 (25.0)
Some college	—	—	—	81 (29.5)	40 (29.2)	41 (29.7)	45 (31.9)	27 (37.0)	18 (26.5)
College graduate	—	—	—	79 (28.7)	39 (28.5)	40 (29.0)	39 (27.7)	21 (28.8)	18 (26.5)
Advanced degree	—	—	—	39 (14.2)	16 (11.7)	23 (16.7)	16 (11.3)	7 (9.6)	9 (13.2)
Relationship to patient, n (%)									
Spouse or partner	—	—	—	128 (46.5)	60 (43.8)	68 (49.3)	9 (6.4)	3 (4.1)	6 (8.8)
Child	—	—	—	65 (23.6)	35 (25.5)	30 (21.7)	49 (34.8)	21 (28.8)	28 (41.2)
Parent	—	—	—	54 (19.6)	26 (19.0)	28 (20.3)	28 (19.9)	18 (24.7)	10 (14.7)
Sibling	—	—	—	22 (8.0)	11 (8.0)	11 (8.0)	25 (17.7)	13 (17.8)	12 (17.6)
Other family	—	—	—	5 (1.8)	4 (2.9)	1 (0.7)	25 (17.7)	15 (20.5)	10 (14.7)
Friend	—	—	—	1 (0.4)	1 (0.7)	0 (0.0)	5 (3.5)	3 (4.1)	2 (2.9)
Religion or faith, n (%) ^{†‡§}									
Christian	214 (77.3)	104 (75.4)	110 (79.1)	216 (78.5)	110 (80.3)	106 (76.8)	105 (74.5)	59 (80.8)	46 (67.6)
Jewish	5 (1.8)	2 (1.4)	3 (2.2)	5 (1.8)	2 (1.5)	3 (2.2)	1 (0.7)	1 (1.4)	0 (0.0)
Hindu, Buddhist, or follower of Taoism or other East Asian religion	1 (0.4)	0 (0.0)	1 (0.7)	3 (1.1)	1 (0.7)	2 (1.4)	1 (0.7)	1 (1.4)	0 (0.0)
Muslim	18 (6.5)	6 (4.3)	12 (8.6)	2 (0.7)	1 (0.7)	1 (0.7)	0 (0.0)	0 (0.0)	0 (0.0)
Other religion	38 (13.7)	25 (18.1)	13 (9.4)	19 (6.9)	5 (3.6)	14 (10.1)	6 (4.3)	0 (0.0)	6 (8.8)
None	214 (77.3)	104 (75.4)	110 (79.1)	30 (10.9)	18 (13.1)	12 (8.7)	21 (14.9)	9 (12.3)	12 (17.6)
Financial distress, n (%)									
High	—	—	—	20 (7.3)	10 (7.3)	10 (7.2)	9 (6.4)	4 (5.5)	5 (7.4)
Moderate	—	—	—	45 (16.4)	20 (14.6)	25 (18.1)	23 (16.3)	12 (16.4)	11 (16.2)
Low	—	—	—	130 (47.3)	75 (54.7)	55 (39.9)	72 (51.1)	42 (57.5)	30 (44.1)
None	—	—	—	80 (29.1)	32 (23.4)	48 (34.8)	37 (26.2)	15 (20.5)	22 (32.4)
Treated for psychological issues in the past month, n (%) ^{†‡}									
Depression	—	—	—	37 (13.5)	18 (13.1)	19 (13.8)	22 (15.6)	13 (17.8)	9 (13.2)
Anxiety	—	—	—	35 (12.7)	15 (10.9)	20 (14.5)	19 (13.5)	7 (9.6)	12 (17.6)
Posttraumatic stress disorder	—	—	—	6 (2.2)	2 (1.5)	4 (2.9)	2 (1.4)	0 (0.0)	2 (2.9)

Characteristic	Patients			Primary Surrogate Decision Makers			Secondary Surrogate Decision Makers		
	Total (n = 277)	Intervention (n = 138)	Control (n = 139)	Total (n = 275)	Intervention (n = 137)	Control (n = 138)	Total (n = 141)	Intervention (n = 73)	Control (n = 68)
Study site, n (%)									
Duke University Medical Center	81 (29.2)	41 (29.7)	40 (28.8)	80 (29.1)	41 (29.9)	39 (28.3)	43 (30.5)	25 (34.2)	18 (26.5)
Duke Regional Hospital	3 (1.1)	1 (0.7)	2 (1.4)	3 (1.1)	1 (0.7)	2 (1.4)	1 (0.7)	0 (0.0)	1 (1.5)
University of Pittsburgh Medical Center	60 (21.7)	28 (20.3)	32 (23.0)	60 (21.8)	28 (20.4)	32 (23.2)	38 (27.0)	13 (17.8)	25 (36.8)
University of North Carolina at Chapel Hill	64 (23.1)	33 (23.9)	31 (22.3)	64 (23.3)	33 (24.1)	31 (22.5)	24 (17.0)	16 (21.9)	8 (11.8)
Harborview Medical Center	49 (24.9)	35 (25.4)	34 (24.5)	68 (24.7)	34 (24.8)	34 (24.6)	35 (24.8)	19 (26.0)	16 (23.5)
Patient residence before hospitalization, n (%)									
Home	255 (92.1)	130 (94.2)	125 (89.9)	—	—	—	—	—	—
Skilled nursing facility	10 (3.6)	4 (2.9)	6 (4.3)	—	—	—	—	—	—
Inpatient rehabilitation facility	5 (1.8)	0 (0.0)	5 (3.6)	—	—	—	—	—	—
Long-term care facility	2 (0.7)	1 (0.7)	1 (0.7)	—	—	—	—	—	—
Homeless	5 (1.8)	3 (2.2)	2 (1.4)	—	—	—	—	—	—
Insurance status, n (%)									
Commercial	118 (42.6)	55 (39.9)	63 (45.3)	—	—	—	—	—	—
Medicare	100 (36.1)	53 (38.4)	47 (33.8)	—	—	—	—	—	—
Medicaid	30 (10.8)	19 (13.8)	11 (7.9)	—	—	—	—	—	—
Military	5 (1.8)	2 (1.4)	3 (2.2)	—	—	—	—	—	—
Other	2 (0.7)	1 (0.7)	1 (0.7)	—	—	—	—	—	—
None	22 (7.9)	8 (5.8)	14 (10.1)	—	—	—	—	—	—
Median limitations to activities of daily living (IQR), n ^{†§}									
Median limitations to instrumental activities of daily living (IQR), n ^{†§}	8.0 (1.0)	8.0 (1.0)	8.0 (1.0)	—	—	—	—	—	—
Mean chronic medical comorbid conditions (SD), n [†]	3.6 (2.8)	3.6 (2.8)	3.7 (2.9)	—	—	—	—	—	—
Admitting ICU, n (%)									
Medicine	141 (50.9)	71 (51.4)	70 (50.4)	—	—	—	—	—	—

Characteristic	Patients			Primary Surrogate Decision Makers			Secondary Surrogate Decision Makers		
	Total (<i>n</i> = 277)	Intervention (<i>n</i> = 138)	Control (<i>n</i> = 139)	Total (<i>n</i> = 275)	Intervention (<i>n</i> = 137)	Control (<i>n</i> = 138)	Total (<i>n</i> = 141)	Intervention (<i>n</i> = 73)	Control (<i>n</i> = 68)
Surgery	37 (13.4)	15 (10.9)	22 (15.8)	—	—	—	—	—	—
Trauma	33 (11.9)	17 (12.3)	16 (11.5)	—	—	—	—	—	—
Neurosurgery or neurology critical care	61 (22.0)	32 (23.2)	29 (20.9)	—	—	—	—	—	—
Cardiology	5 (1.8)	3 (2.2)	2 (1.4)	—	—	—	—	—	—
ICU admission source, <i>n</i> (%)									
Transfer from outside hospital	136 (49.1)	63 (45.7)	73 (52.5)	—	—	—	—	—	—
Emergency department	92 (33.2)	55 (39.9)	37 (26.6)	—	—	—	—	—	—
Hospital ward	29 (10.5)	10 (7.2)	19 (13.7)	—	—	—	—	—	—
Postoperative	20 (7.2)	10 (7.2)	10 (7.2)	—	—	—	—	—	—
Mean APACHE II score on day of enrollment (SD) [†]	23.6 (7.2)	23.8 (7.6)	23.4 (6.8)	—	—	—	—	—	—
Median ProVent model-estimated 1-y mortality (IQR) [‡]	56.0 (44.0)	57.0 (47.0)	54.0 (41.0)	—	—	—	—	—	—
Surrogate decision makers									
Mean per patient (SD), <i>n</i>	1.5 (0.87)	1.5 (0.94)	1.5 (0.81)	—	—	—	—	—	—
Primary only, <i>n</i> (%)	182 (65.7)	90 (65.2)	92 (66.2)	—	—	—	—	—	—
Primary plus 1 additional, <i>n</i> (%)	65 (23.5)	34 (24.6)	31 (22.3)	—	—	—	—	—	—
Primary plus 1 additional, <i>n</i> (%)	28 (10.1)	13 (9.4)	15 (10.8)	—	—	—	—	—	—
No primary, 1 additional, <i>n</i> (%)	2 (0.7)	1 (0.7)	1 (0.7)	—	—	—	—	—	—

APACHE II = Acute Physiology and Chronic Health Evaluation. ICU = intensive care unit; IQR = interquartile range; ProVent = Prolonged Mechanical Ventilation Prognostic Model.

* Tables 1 and 2 of Supplement 3 provide an expanded version of this table.

[†] Pages 3 to 6 of Supplement 3 provide full descriptions and citations.

[‡] Missing from surrogate decision makers: age (*n* = 5), race (*n* = 1), religion (*n* = 7), and whether treated for psychological issue (*n* = 1).

[§] Missing from patients: religion or faith (*n* = 1), activities of daily living (*n* = 1), and instrumental activities of daily living (*n* = 7).

// Not mutually exclusive.

Table 2.
Primary and Secondary Hospital-Based Outcomes Among Primary Surrogate Decision Makers*

Outcome	Intervention			Control			P Value [†]
	Estimated Mean Score at Interview 1 (95% CI)	Estimated Mean Score at Interview 2 (95% CI)	Difference (95% CI)	Estimated Mean Score at Interview 1 (95% CI)	Estimated Mean Score at Interview 2 (95% CI)	Difference (95% CI)	
Primary outcome							
CSCS (physician) [‡]	33.6 (29.3 to 38.0)	27.1 (22.8 to 31.4)	-6.6 (-11.5 to -1.6)	34.3 (29.9 to 38.8)	29.5 (25.1 to 33.9)	-4.8 (-9.1 to -0.6)	0.60
Secondary outcomes							
HADS total [§]	16.0 (14.6 to 17.3)	14.9 (13.5 to 16.3)	-1.1 (-2.0 to -0.1)	16.4 (15.0 to 17.8)	15.7 (14.2 to 17.2)	-0.7 (-1.5 to 0.1)	0.56
HADS anxiety subscale [§]	9.2 (8.5 to 9.9)	8.4 (7.7 to 9.1)	-0.8 (-1.3 to -0.3)	9.4 (8.6 to 10.1)	8.9 (8.1 to 9.6)	-0.5 (-1.0 to -0.0)	0.44
HADS depression subscale [§]	6.8 (6.1 to 7.5)	6.5 (5.8 to 7.3)	-0.3 (-0.8 to 0.3)	7.0 (6.2 to 7.8)	6.8 (6.0 to 7.6)	-0.2 (-0.7 to 0.3)	0.84
PTSS [§]	26.3 (24.3 to 28.2)	26.6 (24.5 to 28.7)	0.4 (-0.9 to 1.6)	26.8 (24.8 to 28.8)	27.0 (24.8 to 29.3)	0.3 (-1.0 to 1.5)	0.91
MCS [¶]	4.6 (4.4 to 4.9)	5.4 (5.1 to 5.7)	0.8 (0.5 to 1.1)	4.8 (4.5 to 5.0)	5.3 (5.0 to 5.6)	0.5 (0.2 to 0.8)	0.184
QOC [§]	87.8 (84.9 to 90.8)	91.9 (89.1 to 94.7)	4.0 (1.3 to 6.8)	83.4 (79.7 to 87.0)	90.3 (87.1 to 93.5)	7.0 (4.1 to 9.8)	0.149
DCS [¶]	2.5 (2.3 to 2.8)	3.4 (3.2 to 3.6)	0.9 (0.6 to 1.1)	2.8 (2.5 to 3.0)	3.3 (3.1 to 3.5)	0.5 (0.2 to 0.7)	0.041
CSCS (nurse)**	31.7 (27.2 to 36.2)	26.3 (21.4 to 31.2)	-5.4 (-11.2 to 0.3)	31.3 (27.0 to 36.2)	25.2 (20.7 to 29.6)	-6.2 (-10.6 to -1.7)	0.84

CSCS = clinician-surrogate concordance scale; DCS = decisional conflict scale; HADS = Hospital Anxiety and Depression Scale; MCS = medical comprehension scale; PTSS = posttraumatic stress symptom inventory; QOC = quality of communication questionnaire.

* Tables 6 and 8 of Supplement 3 describe outcomes for secondary surrogate decision makers. The CSCS score (with intensive care unit physician as the referent) ranges from 0 to 100 points, with higher scores indicating greater discordance. The HADS total score ranges from 0 to 42 points, and its subscale scores range from 0 to 21 points, with higher scores indicating greater distress. The PTSS score ranges from 10 to 70 points, with higher scores indicating greater distress. The MCS score ranges from 0 to 8 points, with higher scores indicating greater comprehension. The QOC score ranges from 0 to 11 points, with higher scores indicating better communication. The DCS score ranges from 0 to 4 points, with higher scores indicating less conflict.

[‡]From generalized linear models.

[§]134 participants in the control group and 132 in the intervention group had complete interview 1 data. 127 participants in the control group and 122 in the intervention group had complete interview 2 data.

[¶]138 participants in the control group and 137 in the intervention group had complete interview 1 data. 125 participants in the control group and 121 in the intervention group had complete interview 2 data.

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133 participants in the control group and 131 in the intervention group had complete interview 1 data. 114 participants in the control group and 110 in the intervention group had complete interview 2 data.
138 participants in the control group and 137 in the intervention group had complete interview 1 data. 124 participants in the control group and 121 in the intervention group had complete interview 2 data.
126 participants in the control group and 117 in the intervention group had complete interview 1 data. 101 participants in the control group and 94 in the intervention group had complete interview 2 data.

Table 3.
Primary and Secondary Postdischarge Outcomes Among Primary Surrogate Decision Makers*

Outcome	3 Months					6 Months				
	Intervention		Control		P Value [†]	Intervention		Control		P Value [†]
	Estimated Mean Score (95% CI)	Estimated Mean Change in Score From Interview 1 (95% CI)	Estimated Mean Score (95% CI)	Estimated Mean Change in Score From Interview 1 (95% CI)		6 mo. Estimated Mean (95% CI)	Estimated Mean Change in Score From Interview 1 (95% CI)	6 mo. Estimated Mean (95% CI)	Estimated Mean Change in Score From Interview 1 (95% CI)	
HADS total [§]	12.7 (11.3 to 14.2)	-3.2 (-4.5 to -2.0)	14.1 (12.6 to 15.6)	-2.3 (-3.6 to -1.0)	0.31	12.2 (10.6 to 13.7)	-3.8 (-5.3 to -2.3)	12.4 (11.0 to 13.9)	-4.0 (-5.1 to -2.8)	0.2 (-1.8 to 2.1)
HADS anxiety subscale [§]	7.2 (6.5 to 8.0)	-1.9 (-2.7 to -1.2)	7.9 (7.1 to 8.7)	-1.5 (-2.1 to -0.8)	0.34	6.9 (6.1 to 7.7)	-2.3 (-3.1 to -1.5)	7.0 (6.2 to 7.8)	-2.4 (-3.0 to -1.7)	0.1 (-1.0 to 1.1)
HADS depression subscale [§]	5.5 (4.6 to 6.3)	-1.3 (-2.0 to -0.6)	6.2 (5.4 to 6.9)	-0.9 (-1.6 to -0.2)	0.42	5.3 (4.4 to 6.1)	-1.5 (-2.3 to -0.7)	5.4 (4.7 to 6.2)	-1.6 (-2.3 to -0.9)	0.1 (-1.0 to 1.1)
PTSS [§]	24.8 (22.4 to 27.1)	-1.5 (-3.5 to 0.5)	26.4 (24.1 to 28.6)	-0.4 (-2.3 to 1.5)	0.42	24.5 (22.0 to 27.1)	-1.7 (-3.9 to 0.4)	25.4 (23.0 to 27.7)	-1.4 (-3.4 to 0.6)	-0.3 (-3.3 to 2.6)
PPCC	42.7 (41.5 to 44.0)	NA	41.3 (40.0 to 42.7)	NA	0.134	42.7 (41.3 to 44.1)	NA	41.8 (40.3 to 43.2)	NA	0.9 (-1.1 to 2.9)

HADS = Hospital Anxiety and Depression Scale; NA = not applicable; PPCC = patient perception of care centeredness scale; PTSS = posttraumatic stress symptom inventory.

*Tables 6 and 8 of Supplement 3 describe outcomes for secondary surrogate decision makers. The HADS total score ranges from 0 to 42 points, and its subscale scores range from 0 to 21 points, with higher scores indicating greater distress. The PTSS score ranges from 10 to 70 points, with higher scores indicating greater distress. The PPCC score ranges from 12 to 48 points, with higher scores indicating greater patient-centeredness of care.

[†]From generalized linear models.

[‡]For HADS total, HADS anxiety and depression subscales, and PTSS, *P* values are from generalized linear models. For PPCC, the *P* value is from a 2-sample *t* test.

[§]122 participants in the control group and 104 in the intervention group had complete 3-mo data. 117 participants in the control group and 101 in the intervention group had complete 6-mo data.

^{||}122 participants in the control group and 104 in the intervention group had complete 3-mo data. 117 participants in the control group and 101 in the intervention group had complete 6-mo data.