Decision making and satisfaction with care in the pediatric intensive care unit: Findings from a controlled clinical trial

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Objective: **To facilitate critical decision making and improve satisfaction with care among families of patients in a pediatric intensive care unit.**

Design: **Prospective observational study followed by a nonrandomized controlled trial of a clinical intervention to identify conflicts and facilitate communication between families and the clinical team.**

Setting: **The pediatric intensive care unit of a Boston teaching hospital.**

Patients: **A total of 127 patients receiving care in the pediatric intensive care unit in 1998–1999 and their families.**

Interventions: **Interviews were conducted with surrogates and decisionally capable older children concerning the adequacy of information provided, understanding, communication, and perceived decisional conflicts. Findings were relayed to the clinical team, who then developed tailored follow-up recommendations.**

Measurements and Main Results: **A survey administered to surrogates at baseline and day 7 or intensive care unit discharge measured satisfaction with care. Information on patient acuity and hospital stay were extracted from medical records and hospital databases. Wilcoxon rank-sum tests and incidence rate comparisons were used to assess the impact of the intervention on satisfaction and sentinel decision making, respectively. Incidence rates of care plan decision making, including decisions to adopt a comfort-care-only plan and decisions to forgo resuscitation, were lower among families who received the intervention. The intervention did not significantly affect satisfaction with care.**

Conclusions: **Prospectively screening for and intervening to mitigate potential conflict did not increase decision making or parental satisfaction with the care provided in this pediatric intensive care unit. (Pediatr Crit Care Med 2004; 5:40–47)**

KEY WORDS: intensive care unit; end of life; critical care; children; pediatric; decision making

The provision of intensive care to a critically ill child often requires ongoing decision making about the appropriate course and goals of care. Parents' unfulfilled expectations about the outcome of their child's illness are inherently difficult feelings to transcend, especially when the illness leads to significant morbidity or death. Such circumstances present a heightened potential for conflicts between clinicians and parents. Significant disagreements can have consequences for the management of the patient including diminished trust in the clinical team, paralysis in decision making, dissatisfaction with care, and litigation. For clinicians, conflicts with families can result in feelings of frustration, anger, loss of control, and career dissatisfaction.

To prevent the unraveling of trust and effective decision making in the pediatric intensive care unit, ethicists and policymakers have suggested that clinicians must redouble efforts to improve communication and engage in shared decision making with parents. Yet clinicians find little guidance from the literature on interventions targeted to decision-making processes in pediatric critical care. Although the pediatric critical care literature contains reports of observational studies documenting the frequency of decisions to forgo life-sustaining treatments (1–5) or describing the attitudes of pediatric critical care physicians and nurses (6, 7), little is known about satisfaction and decision making among pediatric intensive care unit (PICU) families, and no trials of clinical interventions to improve satisfaction or facilitate decision making about life-sustaining treatment have been conducted.

We hypothesized that an intervention that actively screens for cases at high risk for conflict in the PICU, coupled with procedures to tailor a specific response to identified problems, would have the greatest chance of improving deliberative decision making and increasing satisfaction with care. We anticipated that the intervention would increase rates of explicit decisions by PICU families to limit life-sustaining treatments, but also recognized the possibility that critically ill patients and their families may desire more aggressive care than the conventional wisdom among clinicians would suggest (8). The intervention was designed to be neutral between these options.

MATERIALS AND METHODS

Study Design. The project on Care Improvement for the Critically Ill was organized in 1997 by a consortium from the intensive

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care units (ICUs) at the Harvard-affiliated teaching hospitals (Appendix). The project team included the medical director and nurse manager of seven adult ICUs and one PICU and an ethicist from each of four hospitals. Phase I of the study, conducted from November 1998 to March 1999, was a prospective observational study that examined baseline decision-making patterns and satisfaction with the care in the ICU. Phase II, conducted from June through November 1999, was a controlled clinical trial to test a clinical intervention to improve decision making and satisfaction.

Setting. The Care Improvement for the Critically Ill study was conducted in eight ICUs (one pediatric and seven adult surgical and medical) at four hospitals. The pediatric patients discussed in this study were located at Children's Hospital, Boston. Results for the adult ICUs are reported elsewhere (9). The study protocol was approved by the institutional review board at Children's Hospital. Informed consent for participation in the interviews was obtained from the patient's surrogate, and patients at least 14 yrs of age who were conscious and coherent were approached for assent.

Subject Selection. Phases I and II of the study utilized identical enrollment and data collection methods. All patients admitted to the ICU during each study period were eligible for enrollment. In each phase, a group of study "cases" was selected consisting of patients deemed at high risk for conflict in decision making during their ICU stay due to a) absence of both decisional capacity and an identified surrogate; b) existence of conflict within the clinical team, within the family, and/or between the team and family as to major goals of therapy; c) length of stay greater than the 85th percentile for the PICU (8 days); or d) ICU admission due to an iatrogenic event (Fig. 1). Screening decisions were made by the clinical team. A trained research assistant verbally administered the screening tool to the clinical team for each patient each morning on bedside rounds, querying the team as to whether any of the screening criteria were met.

A contemporaneous comparison group of patients was also selected in each study phase for the sole purpose of controlling for potential secular changes in the usual care provided in the ICUs between the two study periods. Each time a case was enrolled, the next discharged PICU patient who did not meet any of the case criteria at any point in the ICU stay was selected as a contemporaneous control.

Intervention. The clinical intervention was developed through a consultative process. After a series of meetings, including a 2-day workshop involving community representatives and experts in medical ethics and critical care (Appendix), consensus was reached on two key aspects of improving ICU care. First, clinical interventions should address conflict by encouraging family-team communication rather than promoting particular views of the "appropriate" level of care. Second, interventions should identify cases at high risk for conflict as early as possible, be adapted to the particular needs of each unit, and be developed with the input and support of the unit's medical and nursing leadership.

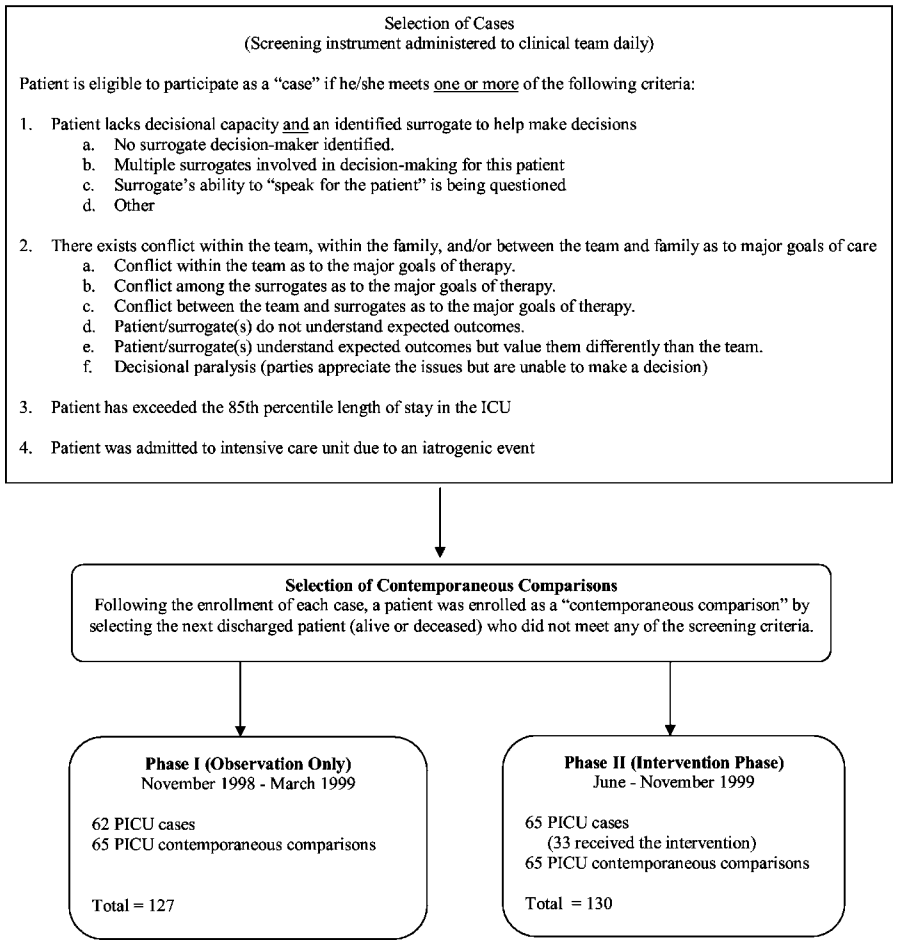

Figure 1. Study design. *PICU*, pediatric intensive care unit; *ICU*, intensive care unit.

After presentation of findings from the study's observational phase to the clinical leadership of each ICU, a four-part intervention process was developed and implemented (Fig. 2). First, patients deemed to be at high risk for conflict were screened into the study using the four-question screening tool. The four criteria were agreed on by the critical care experts (including pediatric experts) at the consensus conference. Second, a social worker assigned to each ICU performed a structured interview with the patient's surrogate (and assenting patients ≥14 yrs), focusing on the adequacy of information, communication, psychosocial support, and any perceived conflicts. Social workers were used to implement the intervention because their ordinary duties involve the elicitation of family concerns and the coordination of families and the clinical team. Additionally, we aimed to design an intervention that would be readily exportable to other ICUs without requiring additional staff to be hired.

In the third part of the intervention, the social worker met with the clinical team on morning rounds and provided feedback from the family interview. In the fourth part, the clinical team selected from a list of recommendations to pursue based on the information received (one family meeting, regular family meetings, one ethics consult, regular ethics consults, social service consult, regular social service consults, pain consult, pastoral services, second medical opinion, other/specify, and no action).

Data Collection. Data were obtained through surrogate/patient interviews and medical record reviews. To measure surrogate perceptions of ICU care, on-site questionnaires were administered to surrogates at the time of study admission and at day 7 or discharge, whichever came first. The satisfaction questions, which were structured as five-point Likert scales ranging from "excellent" to "poor," were taken from well-validated instruments designed for families of critically ill patients (10). The three satisfaction queries reported in this analysis were as follows: "Overall, how would you rate the care you received while in the intensive care unit?," "Overall, how would you rate the information that has been provided about your ICU care?," and "Rate the way in which your family is

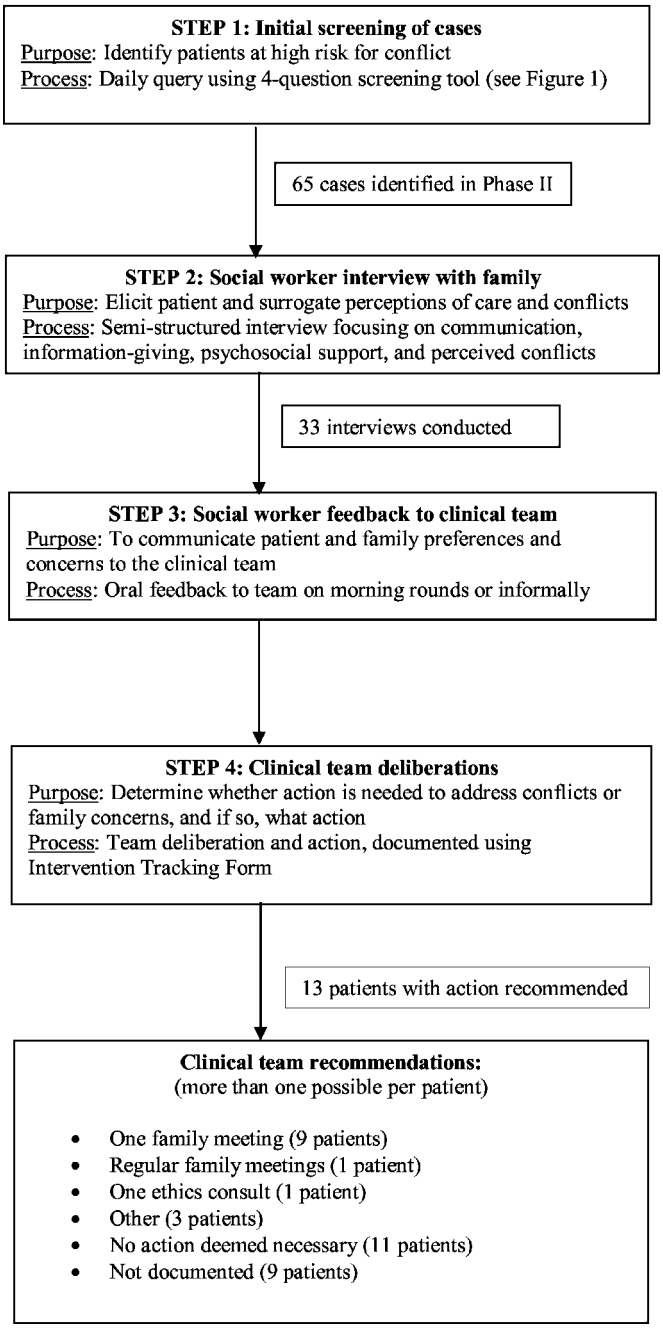

Figure 2. The intervention process.

included in treatment and care decisions." The surveys were administered by research assistants who had received a series of training sessions as well as a detailed study manual.

Additional patient data were obtained from patients' charts and hospital administrative databases. Adhering to a detailed coding protocol, research nurses with prior experience in critical care or research abstracted data from the medical record, including demographic information, Pediatric Risk of Mortality score (11), and Therapeutic Intervention Scoring System score (12, 13). In addition, the research nurses used an instrument adapted from the chart abstraction form used in the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT) (14) to evaluate the frequency of decision making about life-sustaining treatments. The information system database at each hospital was used to obtain data on discharge diagnosis-related group, International Classification of Diseases-9 classification, costs, length of stay, and discharge disposition.

Data Analysis. We analyzed the effect of the intervention on the proportion of surrogates choosing a particular care plan (do not resuscitate, comfort care, or aggressive care) and surrogate satisfaction with various dimensions of ICU care. The three care plans were not mutually exclusive: a comfort-care plan always includes a decision not to resuscitate, which may or may not be separately documented in the record. Additionally, families might choose more than one care plan over the course of an ICU stay. The groups compared in the analysis were the intervened cases from phase II vs. the nonintervened cases from phases I and II. Patients in the contemporaneous comparison groups were not intended for inclusion in the analysis because the use of length of stay as a case-selection criterion would make it impossible to control for differences in length of stay.

To verify the appropriateness of pooling data from phases I and II, we performed Student's *t*-tests, chi-square analysis, and Wilcoxon's rank-sum tests to detect differences in demographic characteristics, illness, or ICU stay between phase I cases and phase II nonintervened cases, as well as between phase I and phase II contemporaneous comparison patients. Phase I and II cases differed significantly only with respect to the percentage of families of Protestant faith ($\chi^2 = 4.51$, $p = .034$). No significant differences were observed across phases for either cases or contemporaneous comparisons with respect to severity of illness (Pediatric Risk of Mortality score, discharge diagnosis-related group weight, and Therapeutic Intervention Scoring System score), ICU length of stay, ICU mortality, insurance status, age, sex, race, reason for study entry, satisfaction-with-care ratings, or the proportion of families making various care plan decisions. Although it is not possible to completely rule out secular changes in ICU care patterns over time as a possible confounding variable without a randomized design, these findings gave us confidence that the analysis need not control for time period.

The initial sample of pediatric patients, after the exclusion of contemporaneous comparisons, consisted of 127 patients (Fig. 1). For the satisfaction models only, 42% of observations were excluded due to missing satisfaction survey data at the second sampling interval (day 7 or discharge). Data were missing for three reasons: per study rules, the surrogate was not approached because the patient died, was discharged from the ICU within 48 hrs of study admission, or there was a language barrier (n = 24); the surrogate refused to complete a follow-up questionnaire (n = 13); and the surrogate was unavailable for follow-up despite repeated attempts (n = 17). The exclusion of recently bereaved parents from follow-up data collection was mandated by the hospital's institutional review board.

The three satisfaction analyses (overall satisfaction, satisfaction with family involvement in decision making, and satisfaction with the amount of information received) were conducted for 74, 73, and 72 patients, respectively. *t*-Tests and chi-square analyses con-

Table 1. Descriptive statistics

	Intervened Cases (n = 33)	Nonintervened Cases (n = 94)
Study characteristics		
Study phase, n (%)		
Phase II	33 (100)	32 (34)
Phase I	0 (0)	62 (66)
Reason for study admission[a]		
Long length of stay	26 (79)	69 (75)
Conflict	6 (18)	18 (20)
No decisional capacity and lacks surrogate	0 (0)	0 (0)
Iatrogenic injury	0 (0)	4 (4)
Sociodemographics		
Age, mean ± SD	8.12 ± 7.64	6.24 ± 8.07
Race, n (%)		
White	27 (82)	59 (63)
Black	2 (6)	8 (9)
Other	4 (12)	26 (28)
Male, n (%)	10 (30)	47 (50)
Religion, n (%)		
Catholic	11 (44)	36 (52)
Protestant	2 (8)	18 (26)
Jewish	3 (12)	2 (3)
Other	9 (36)	13 (19)
Health status		
Died in intensive care unit, n (%)	0 (0)	14 (15)
Pediatric Risk of Mortality score, mean ± SD	10.15 ± 7.75	10.80 ± 7.96
Therapeutic Intervention Scoring System score, mean ± SD	28.12 ± 10.32	28.08 ± 11.01
Intensive care unit length of stay, mean ± SD	18.91 ± 9.18	17.08 ± 17.04

[a]More than one category possible. Data are missing for two observations.

firmed that patients excluded for missing data did not differ significantly from those retained in the sample on illness severity (discharge diagnosis-related group, Pediatric Risk of Mortality score, and Therapeutic Intervention Scoring System score), ICU length of stay, study admission criterion, age, sex, education level, or religion. Patients missing data were more likely than those included in the sample to be nonwhite ($\chi^2 = 17.44, p < .001$) and to have Medicaid insurance ($\chi^2 = 9.83, p = .01$). Additionally, because study rules precluded the collection of follow-up satisfaction for patients who died, the two groups differed on ICU mortality ($\chi^2 = 8.78, p = .004$).

We compared cases who received the intervention with those who did not on key characteristics to determine whether it was necessary to use multivariate methods. Chi-square analyses and Student's *t*-tests revealed no significant differences in discharge diagnosis-related group weight, Pediatric Risk of Mortality score, Therapeutic Intervention Scoring System score, ICU length of stay, study entry criterion, age, or race. Intervened patients were less likely than nonintervened patients to die in the ICU (two-tailed Fisher's $p = .020$), to be missing satisfaction data ($\chi^2 = 5.61, p = .018$), to be Catholic ($\chi^2 = 8.23, p = .041$), and to be female ($\chi^2 = 3.83, p = .050$). Because patients with missing satisfaction data are not included in the satisfaction models, the first two of these variables are not potentially confounding (all but three patients who died were among those with missing satisfaction data because satisfaction data were not collected at day 7 or discharge for patients who died before that date). Correlation coefficients and chi-square analyses ruled out religion and gender as potential confounders.

These findings supported a conclusion that it was not necessary to use multiple regression to control for confounding variables. Instead, we tested the effect of the intervention on satisfaction using Wilcoxon's rank-sum test. In testing the effect on care plan decision making, we controlled for differences in ICU length of stay among cases by performing an incidence rate comparison. We used the "ir" command in the STATA statistical package, which calculates point estimates and confidence intervals for the incidence rate ratio and difference for two comparison groups using person-time data.

RESULTS

Patient Characteristics. A total of 124 pediatric patients were enrolled in phase I of the study, and 130 were enrolled in phase II (Fig. 1). Of these, 62 were enrolled as cases in phase I and 65 were designated cases in phase II, for a total of 127 cases. Descriptive statistics for these cases are presented in Table 1.

The intervention was only implemented for 33 of the 65 eligible phase II cases, due to a constellation of reasons. Surrogates were frequently unavailable in the ICU or by phone, making interviews difficult. The social worker's duty hours were limited to weekdays from 8 am to 4 pm, and a few patients died so quickly after study enrollment that she may not have been on duty during the short window of time in which intervention could have occurred. The social worker was asked to perform study duties on top of her usual duties with no payment for additional duty hours, and stretching her resources in this manner may have resulted in some loss of study duties to fulfill her regular responsibilities. The social worker's competing obligations did not limit the effect of the intervention for those who received it, but may have been partially responsible for the incomplete implementation of the intervention among eligible cases.

Effect of the Intervention on Care Plan Decision Making. We examined whether the intervention affected rates of decision making about life-sustaining treatments by comparing the frequency of decisions to adopt particular care plans among the intervened group and the nonintervened group using an incidence rate analysis (Table 2). The frequency of decisions to adopt a comfort-care-only plan was significantly lower in the intervened group (none of 33 families) than in the nonintervened group (ten of 93 families). The difference in incidence rates was statistically significant ($p = .034$).

A trend toward significance ($p = .098$) was observable with respect to the incidence rates of decisions to forgo resuscitation in the intervened vs. nonintervened groups. Seven nonintervened families chose to forgo resuscitation, but none of the intervened families did. The intervention also produced a nonsignificant decrease in the incidence of decisions to adopt an aggressive care plan (8 vs. 2 patients, $p = .59$).

Effect of the Intervention on Satisfaction with Care. We examined the effect of the intervention on three dimensions of surrogate satisfaction with care at day 7 or discharge: overall satisfaction, satisfaction with the amount of family involvement in decision making (involvement), and satisfaction with the amount of information received (information) (Table 3). Mean overall satisfaction scores were slightly higher for intervened patients than for nonintervened patients (4.81 vs. 4.73). Eighty-four percent of intervened patients gave an "excellent" satisfaction rating compared with 65% of nonintervened patients. In Wilcoxon's rank-sum

test, however, the difference in ratings did not achieve statistical significance, although there was a trend toward significance ($p = .11$).

Intervened patients had slightly lower mean satisfaction scores on the other two measures (4.27 vs. 4.35 for involvement and 4.14 vs. 4.38 for information), and a smaller proportion of intervened than nonintervened patients gave "excellent" ratings for both dimensions of satisfaction. However, the difference was not statistically significant ($p = .38$ for involvement, $p = .48$ for information).

These results were robust to changes in the specification of the satisfaction variables. We collapsed categories of satisfaction ratings to create two different binary specifications (fair/poor vs. good/very good/excellent and fair/poor/good vs. very good/excellent) and compared intervened and nonintervened patients' ratings using chi-squared test and Fisher's exact tests, as appropriate. None of the differences were statistically significant.

DISCUSSION

This intervention, designed to enhance deliberative decision making about care plan orientation and improve satisfaction with care in the PICU, resulted in several unexpected findings. First, the intervention did not bring about statistically significant changes in satisfaction ratings, although some trend toward significance was observable for overall satisfaction. A likely explanation for the intervention's lack of effect on satisfaction is that—as suggested by SUPPORT findings—satisfaction with ICU care was very high to begin with. The general perception in the literature is that ICU care is plagued by problems of poor communication, inadequate involvement of families in decision making, and inadequate palliation (16–18). However, the baseline satisfaction scores we obtained from surrogates of PICU study cases before implementing the intervention (mean of 4.69 from a possible maximum of five) suggest that family satisfaction is nonetheless high.

These findings do not dismiss the need for further attempts to improve the care provided in the PICU. High satisfaction ratings may simply reflect a good fit between parental expectations and ICU experiences or the gratitude that families feel toward clinical staff who have worked hard to help their child. Our results do suggest, however, that satisfaction ratings may be relatively uninformative as a measure of the impact of efforts to improve ICU care.

Similar findings regarding the impact of the intervention on satisfaction were obtained in the analysis of the adult surgical and medical ICU patients in this study (9). The intervention was not associated with a statistically significant change in satisfaction ratings. As in the pediatric sample, patient and family satisfaction with ICU care among adult patients and their families was very high even before the interventional phase of the study.

A second study finding was that the intervention failed to increase the incidence of any type of explicit care plan decision making in cases deemed at high risk for conflict. Rates of adoption of explicit aggressive-care plans were not significantly different between the two groups. Families who received the intervention were significantly less likely to decide to adopt a comfort-care-only care plan and somewhat less likely to decide to forgo resuscitation.

Interestingly, these results are the opposite of our findings for the adult patients in the study. For the adults, the intervention resulted in statistically significant increases in the proportion of patients/surrogates making each of the three care plan decisions: no resuscitation, comfort care, and aggressive care (9). Advanced age was found to be a strong driver of decisions to limit treatment. The age difference between the adult and pediatric samples, as well as the very different hopes and expectations that families may have for ill children, may explain the divergent findings regarding care plan decisions. The intervention may

Table 2. Effect of intervention on incidence of care plan decision making

	Nonintervened Patients (n = 93)		Intervened Patients (n = 33)		
	n	IR	n	IR	*p* Value[a]
Decision to forgo resuscitation	7	0.0044	0	0	.098
Decision to provide comfort care only	10	0.0065	0	0	.034
Decision to provide aggressive care	8	0.0052	2	0.0032	.59

IR, incidence rate.

[a]Difference in incidence rates for intervened vs. nonintervened cases; two-sided "midp" exact significance (15).

Table 3. Effect of intervention on satisfaction

	Poor		Fair		Good		Very Good		Excellent		
	n	%	n	%	n	%	n	%	n	%	*p* Value[a]
Overall satisfaction with care (n = 74)											
Nonintervened patients	0	0	0	0	3	6	14	29	32	65	.11
Intervened patients	0	0	1	4	0	0	3	12	21	84	
Satisfaction with information provided (n = 72)											
Nonintervened patients	1	2	1	2	9	19	13	28	23	49	.48
Intervened patients	1	4	2	8	5	20	6	24	11	44	
Satisfaction with involvement in decision making (n = 73)											
Nonintervened patients	3	6	1	2	6	13	11	23	27	56	.38
Intervened patients	1	4	2	8	1	4	11	44	10	40	

[a]Intervened vs. nonintervened cases; Wilcoxon's rank-sum test.

have given PICU families an opportunity to voice their wish for a miracle for their child, a desire that they may otherwise have felt they had no chance to express and that may have resulted in fewer decisions to limit care.

In seeking to understand the results for the pediatric patients, an initial question is whether the intervened patients were less in need of care limitation decisions because they were not as critically ill. Our nonrandomized study design could not ensure complete comparability of the intervened and nonintervened groups, and we did not match individual cases and contemporaneous comparisons. Although the two groups did not differ significantly on Pediatric Risk of Mortality score, Therapeutic Intervention Scoring System score, or discharge diagnosis-related group weight, we did observe a significant difference in mortality between the intervened and nonintervened groups (14 deaths among the 94 nonintervened cases vs. none among the 33 intervened cases). The baseline mortality rate of this PICU was 4%. The difference in mortality appears important in explaining the difference in care plan decisions between the two groups in light of previous research that found imminent death as the most commonly-cited justification for restricting life-sustaining treatments in the PICU (4). These findings suggest that in the PICU environment, decisions to limit treatment are usually triggered by a perception that the threshold of impending death has been reached. Indeed, in our sample, eight of the 14 patients who died in the ICU (57.1%) had a do-not-resuscitate order or comfort-care-only plan, whereas only two of the 113 patients who survived (1.8%) did.

Furthermore, for eight of the 14 deaths, the patient died within 1 day of study admission. Because these patients died before there was time to expose them to the intervention, they were analyzed in the nonintervened cohort, with the resulting imbalance in mortality between the two groups. However, even when these patients are excluded from the analysis, there remain notable (although not statistically significant) differences between the nonintervened and intervened groups in mortality (6 vs. 0, $p = .19$) and care-limitation decisions (7 vs. 0, $p = .19$).

A likely explanation for this residual difference is that the intervention did promote deliberation about care plans, but these deliberations often led to undocumented decisions to continue aggressive care. Because aggressive care is the usual practice in the PICU, decisions to continue along the default path may not have been documented explicitly. This would explain why the intervened group had lower rates of decisions to limit care, but not significantly different rates of explicit decisions to pursue aggressive care.

Although the intervention appears to have resulted in families continuing along the default path, there is no reason to believe that the intervention was systematically biased in favor of aggressive care. The intervention itself did not specify a set response to parental concerns. The critical care attending physician and fellow rotated every 2 weeks, and the number of different clinicians who were involved in care decisions makes a systematic bias unlikely. Moreover, for the adult ICU patients in our study, the same intervention significantly increased decisions to adopt comfort-care plans and decisions to forgo resuscitation, as well as decisions to adopt aggressive-care plans.

A final consideration is that despite a willingness to address conflicts over life-sustaining treatments, pediatric critical care clinicians may not be able or willing to alter parents' wishes to continue aggressive care. Although most adult patients and their surrogates accept physician recommendations to limit care within a few days of the recommendation being made (19, 20), parents of critically ill children may be more resistant to such suggestions, and clinicians may not press the issue. In a previous study, 181 of 190 pediatric critical care physicians and nurses reported that even in the most contentious situations, unrestricted care continues to be provided if the family requests it (7). These findings suggest that the existing ethos in the PICU setting is one of assent to the family's wishes for continued aggressive care. In this environment, an intervention designed to identify conflicts and facilitate communication between the clinical team and the family might not result in a higher rate of care-limitation decisions. Families in our intervention group may have wanted fewer treatment limitations because death was never perceived as imminent, and clinicians ultimately may have been unable or unwilling to challenge this position.

There is little literature, in either pediatric or adult critical care, in which to situate our results. The most important previous study is the SUPPORT study, an investigation designed to enhance patient-centered decision making for several thousand critically ill adult patients. In SUPPORT, trained nurses facilitated team-family communication and gave physicians prognostic estimates for patients along with reports of patient treatment preferences, pain ratings, perceived prognosis, and desire for information. This intervention failed to effect significant change in rates of do-not-resuscitate orders, discussion of resuscitation, pain levels, physician knowledge of patients' treatment preferences, or ICU length of stay (14).

Explanations of the disappointing findings from SUPPORT have noted that the intervention relied on nurses to facilitate communication and care planning, but the culture of medicine gives nurses little authority or influence (21). Additionally, the intervention may have been implemented too late in the course of the patients' hospital stay to make a difference (22). SUPPORT also has been criticized for using outcome measures that were heavily biased toward measures of less aggressive care (8).

The failure of the intervention in our study to enhance explicit decision making (for either aggressive or palliative care) raises similar concerns. The social workers who implemented this intervention may have suffered the same limitations as the nurses in SUPPORT. Our intervention, too, was implemented late in the patient's PICU stay in many cases. Seventy-seven percent of study cases had been in the ICU $\geq$8 days at the time of study admission, and many of these had already had a long hospital stay before PICU admission. For this group, the intervention may have been implemented after particular feelings, attitudes, and behaviors had already become entrenched.

This study had other limitations. The clinical staff making recommendations in response to the social worker feedback varied over the study period due to the rotation of physicians through the PICU, which may have affected the consistency of decision making about the recommendations. The intervention was only implemented for approximately half the eligible cases, limiting the statistical power of the study. The sample size for the satisfaction models was limited by our inability to obtain satisfaction data at day 7, death, or discharge for 53 of the study

This study, which represents the first attempt to implement a clinical intervention to improve satisfaction and decision making in the pediatric intensive care unit, sheds some light on the research path ahead.

cases, which was due in part to the mandate that we not approach recently bereaved parents for interviews. This may have impacted our ability to detect an effect of the intervention on satisfaction. The small magnitude of the differences in satisfaction ratings between intervened and nonintervened cases ($mean_{intervened}$, 4.81 vs. $mean_{nonintervened}$, 4.73 for overall satisfaction) suggests, however, that the issue is not simply a lack of statistical power to detect an effect of moderate size. No statistically significant differences in satisfaction scores were observed in a multivariate analysis of a larger sample of 428 adult ICU patients enrolled in this study (9). It is possible, however, that the intervention might have had the largest effect on patients who die, and the absence of follow-up satisfaction data for these patients limited our ability to evaluate that effect.

The very high baseline satisfaction scores in the study raise a question as to whether the survey instrument may have performed poorly. However, previous studies using different instruments also found high and uniform levels of satisfaction with critical care (23–25), especially where, as here, the measure of satisfaction was specific to a particular episode of care as well as a particular type of care (25).

CONCLUSIONS

This controlled trial demonstrates some of the challenges involved in implementing interventions to improve the quality of care in pediatric intensive care units. Practical and ethical issues make randomized trials of clinical interventions in the PICU difficult to conduct, but lack of randomization complicates efforts to assess the impact of interventions. The choice of proper outcome measures, the difficulty of locating surrogates for follow-up assessments of their experience in the PICU, and the ethical issues involved in approaching parents of gravely ill children for participation in a research study pose additional challenges. Finally, the difficulty of altering or, in some cases, even determining family preferences for life-sustaining care may constitute an inherent limitation on clinicians' ability to affect patterns of care and plan decision making. This study, which represents the first attempt to implement a clinical intervention to improve satisfaction and decision making in the PICU, sheds some light on the research path ahead.

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REFERENCES

1. Ryan CA, Byrne P, Kuhn S, et al: No resuscitation and withdrawal of therapy in a neonatal and a pediatric intensive care unit in Canada. *J Pediatr* 1993; 123:534–538
2. Vernon DD, Dean JM, Timmons OD, et al: Modes of death in the pediatric intensive care unit: Withdrawal and limitation of supportive care. *Crit Care Med* 1993; 21: 1798–1802
3. Goh AYT, Lum LCS, Chan PWK, et al: Withdrawal and limitation of life support in paediatric intensive care. *Arch Dis Child* 1999; 80:424–428
4. Levetown M, Pollack MM, Cuerdon TT, et al: Limitations and withdrawals of medical intervention in pediatric critical care. *JAMA* 1994; 272:1271–1275
5. Mink RB, Pollack MM: Resuscitation and withdrawal of therapy in pediatric intensive care. *Pediatrics* 1992; 89:961–963
6. Randolph AG, Zollo MB, Wigton RS, et al: Factors explaining variability among caregivers in the intent to restrict life-support interventions in a pediatric intensive care unit. *Crit Care Med* 1997; 25:435–439
7. Burns JP, Mitchell C, Griffith TL, et al: End-of-life care in the pediatric intensive care unit: Attitudes and practices of pediatric critical care physicians and nurses. *Crit Care Med* 2001; 29:658–664
8. Lo B: End-of-life care after termination of SUPPORT. *Hastings Cent Rep* 1995; 25: S6–S8
9. Burns JP, Mello MM, Studdert DM, et al: Results of a controlled clinical trial on care improvement for the critically ill. *Crit Care Med* 2003; 31:2107-2117
10. Kristjanson L: Validity and reliability testing of the FAMCARE scale: Measuring family satisfaction with advanced cancer care. *Soc Sci Med* 1993; 36:693–701
11. Pollack MM, Ruttimann UE, Getson PR: Pediatric Risk of Mortality (PRISM) score. *Crit Care Med* 1988; 16:1110–1116
12. Cullen DJ, Civetta JM, Briggs BA, et al: Therapeutic intervention scoring system: A method for quantitative comparison of patient care. *Crit Care Med* 1974; 2:57–60
13. Keene AR, Cullen DJ: Therapeutic Intervention Scoring System: Update 1983. *Crit Care Med* 1983; 11:1–3
14. The SUPPORT Principal Investigators: A controlled trial to improve care for seriously ill hospitalized patients. *JAMA* 1995; 224: 1591–1598
15. Rothman KJ: Modern epidemiology. Boston, Little, Brown, 1986
16. Abbott KH, Sago JG, Breen CM, et al: Families looking back: One year after discussion of withdrawal or withholding of life-sustaining support. *Crit Care Med* 2001; 29:197–201
17. Rubenfeld GD, Randall CJ: End-of-life care in the intensive care unit: A research agenda. *Crit Care Med* 2001; 29:2001–2006
18. Levy MM: End-of-life care in the intensive care unit: Can we do better? *Crit Care Med* 2001; 29:N56–N61
19. Prendergast TJ, Luce JM: Increasing incidence of withholding and withdrawal of life support from the critically ill. *Am J Respir Crit Care Med* 1997; 155:15–20
20. Smedira NG, Evans BH, Cohen NH, et al: Withholding and withdrawal of life support from the critically ill. *N Engl J Med* 1990; 322:309–315
21. Emanuel L: Structured deliberation to improve decision-making for the seriously ill. *Hastings Cent Rep* 1995; 25:S14–S16
22. Danis M: Improving end-of-life care in the intensive care unit: What's to be learned from outcomes research? *New Horiz* 1998; 6:110–118
23. Ross CK, Steward CA, Sinacore JM: A comparative study of seven measures of patient satisfaction. *Med Care* 1995; 33:392–406
24. Baker R, Wu AW, Teno JM, et al: Family satisfaction with end-of-life care in seriously ill hospitalized adults. *J Am Geriatr Soc* 2000; 48:S61–S69
25. Hall JA, Dornan MC: Meta-analysis of satisfaction with medical care: Description of research domain and analysis of overall satisfaction levels. *Soc Sci Med* 1988; 27: 637–644

APPENDIX

Participants in the Harvard Project on Care Improvement for the Critically Ill.

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