

Effect of Ethics Consultations on Nonbeneficial Life-Sustaining Treatments in the Intensive Care Setting

A Randomized Controlled Trial

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ETHICS CONSULTATIONS HAVE been introduced into the practice of medicine during the past several decades as a way to help health care professionals, patients, and surrogates come to a decision about medical treatment where value-laden conflicts are involved. As described in a recent consensus statement:

Ethics consultation is a service provided by an individual consultant, team, or committee to address the ethical issues involved in a specific clinical case. Its central purpose is to improve the process and outcomes of patient care by helping to identify, analyze, and resolve ethical problems.¹

The consensus statement also stipulates that ethics consultations should ensure that the process of decision making is inclusive, educational, respectful of cultural values, and supportive of institutional efforts at quality improvement and appropriate resource utilization.

For editorial comment see p 1208.

Context Ethics consultations increasingly are being used to resolve conflicts about life-sustaining interventions, but few studies have reported their outcomes.

Objective To investigate whether ethics consultations in the intensive care setting reduce the use of life-sustaining treatments delivered to patients who ultimately did not survive to hospital discharge, as well as the reactions to the consultations of physicians, nurses, and patients/surrogates.

Design Prospective, multicenter, randomized controlled trial from November 2000 to December 2002.

Setting Adult intensive care units (ICUs) of 7 US hospitals representing a spectrum of institutional characteristics.

Patients Five hundred fifty-one patients in whom value-related treatment conflicts arose during the course of treatment.

Interventions Patients were randomly assigned either to an intervention (ethics consultation offered) (n=278) or to usual care (n=273).

Main Outcome Measures The primary outcomes were ICU days and life-sustaining treatments in those patients who did not survive to hospital discharge. We examined the same measures in those who did survive to discharge and also compared the overall mortality rates of the intervention and usual care groups. We also interviewed physicians and nurses and patients/surrogates about their views of the ethics consultation.

Results The intervention and usual-care groups showed no difference in mortality. However, ethics consultations were associated with reductions in hospital (−2.95 days, $P=.01$) and ICU (−1.44 days, $P=.03$) days and life-sustaining treatments (−1.7 days with ventilation, $P=.03$) in those patients who ultimately did not survive to discharge. The majority (87%) of physicians, nurses, and patients/surrogates agreed that ethics consultations in the ICU were helpful in addressing treatment conflicts.

Conclusion Ethics consultations were useful in resolving conflicts that may have inappropriately prolonged nonbeneficial or unwanted treatments in the ICU.

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Several retrospective studies have examined the outcomes of ethics consultations.²⁻⁸ Although physicians and nurses have generally been satisfied with these interventions (with 70%-95% of physicians and nurses reporting that the consultation was valuable in 1 or more aspects of patient care), satisfaction rates among patients and surrogates have been lower, in the range of 50% to 65%.

Fewer prospective studies of medical outcomes of ethics consultation have been conducted. In their single-site, non-randomized trial of unrequested ethics consultations involving patients who had spent more than 96 hours receiving continuous mechanical ventilation, Dowdy et al⁹ reported "more frequent decisions to forgo life-sustaining treatment, and reduced length of stay in the ICU [intensive care unit]" among those who had received ethics consultation compared with a previous group who had not.

In a single-site, prospective, randomized controlled trial of the effect of ethics consultations on life-sustaining treatments in response to value-laden conflicts in the intensive care setting, Scheiderman et al¹⁰ reported no difference in overall mortality between patients offered ethics consultation vs usual care. They also reported that ethics consultation was associated with significantly fewer ICU days and life-sustaining treatments in patients who ultimately did not survive to discharge. Ethics consultations were regarded favorably by most of the interviewed participants.

In this article, we report the results of a multicenter, prospective, randomized controlled intervention trial of the effect of ethics consultations on life-sustaining treatments in the adult ICUs of 7 hospitals. These hospitals were selected to represent a broad spectrum of characteristics, including community, religious, managed care, and academic institutions, with diverse patient populations. All have busy ICUs and active ethics consultation services.

METHODS

Enrollment

The hospitals that participated in the study were Montefiore Medical Center/

Weiler Division in New York City (a teaching hospital for Albert Einstein Medical School); Hennepin County Medical Center in Minneapolis, Minn (a public teaching hospital affiliated with the University of Minnesota Medical School); Swedish Covenant Hospital in Chicago, Ill (a community hospital owned by the Evangelical Covenant Church); Little Company of Mary Hospital in Torrance, Calif (a general acute care community hospital under the auspices of the Catholic church); Stanford Medical Center in Stanford, Calif (the major teaching hospital for Stanford University School of Medicine); University of California, Irvine Medical Center, Irvine (the major teaching hospital for the University of California, Irvine School of Medicine); and Southern California Permanente Medical Group, San Diego (a major hospital in the Kaiser Health Maintenance Organization).

A principal investigator was in charge of the study at each site. The overall study was coordinated by the principal investigator at the University of California San Diego (UCSD), where data analysis took place.

The study was approved by the institutional ethics committees, the institutional review boards, and the physicians and nurse chiefs of the involved services at all of the participating institutions. The ethics consultations were conducted by individuals or groups whose training and experience correspond to the advance levels of skills and knowledge recommended by the American Society for Bioethics and Humanities Core Competencies for Health Care Ethics Consultation.¹¹

Data Collection

At each hospital, nurses who made regular rounds in the ICUs were assigned to identify adult patients in whom value-laden treatment conflicts were imminent or manifest that could lead to incompatible courses of action. Criteria for such conflicts included conflicts within the health care team about whether to pursue aggressive life-sustaining treatments or com-

fort care, conflicts within the health care team about which treatments were in the patient's best interests in the absence of a qualified decision maker, conflicts over treatments regarded as futile by 1 or more members of the team, conflicts among family/friends as to who should serve as surrogate decision maker in the case of disagreement, conflicts between the health care team and family/friends about whether to pursue aggressive life-sustaining treatments or comfort care, and conflicts between team members and family/friends over treatments regarded by 1 or more members of the health care team as futile.

Once a patient was identified the principal investigator at the participating institution was notified. The principal investigator confirmed that the patient met the entry criteria and entered the patient by code into a computer program maintained at the coordinating clinical center, which assigned the patient by block-randomization by site to either the intervention (ethics consultation offered) or usual care (ethics consultation not offered). All data analyses were based on this time of study entry and this original intent-to-treat basis. Any ethics consultations requested for usual-care patients after this assignment did not alter this original assignment. Similarly, intervention patients who refused ethics consultation remained in the treatment group for purposes of analysis.

If the patient was assigned to usual care, the hospital's principal investigator did not initiate contact with the health care team. (Reassurance was provided throughout the study, however, to all those involved in patient care at each institution that anyone was free to request an ethics consultation at any time.) These patients received usual care, including family meetings or other conferences as judged to be appropriate by the health care team.

If the patient was entered into the intervention arm of the trial, the hospital's principal investigator contacted the responsible physician and sought verbal consent to arrange an ethics consultation. The consultation was made

available within 24 hours and conducted in a timely manner depending on the circumstances.

Although no standardized protocol was in place, each site followed a general process model of ethics consultation, which involved the following steps:

(1) Consultation request as defined above;

(2) Assessment of request, including confirmation that the patient qualified for the study and the attending physician responsible for the patient consented to the ethics consultation. At the time of the first meeting, the ethics consultants obtained informed consent from the patient, surrogate, family, or intimate friend to conduct an ethics consultation according to the procedures at each site and to conduct a follow-up interview. The person asked to provide consent was either the patient (if that person had decision-making capacity) or the person providing consent for the patient's ICU care. The medical record was reviewed, and those involved in the patient's care who bore on the issues under consideration were interviewed;

(3) Ethical diagnosis, that is, the ethics consultant framed the issues in easily understood ethical terms with the involved parties, drawing on relevant supporting material, including hospital policy, published ethical consensus statements, statutes, and case law;

(4) Recommendations of the next steps, including measures for further meetings to improve communication (sharing information, dealing with emotional discomfort and grieving, correcting misunderstandings) ranging from team-only meetings with selected participants to a formal conference involving the full ethics committee. At a minimum, the consultant saw to it that the following areas of importance were addressed: relevant medical factors, the patient's known or inferred values and preferences, quality of life considerations, and other contextual factors of importance. The consultant helped articulate consensus or disagreement and either facilitated implementing the consensus or facilitated ways to address and resolve the disagreement;

(5) Documentation of the consultation in the patient's medical record, identifying the person requesting the consultation, activities occurring prior to the consultation, the reason for the ethics consultation, the ethical issues identified in the case, the steps taken to address those issues, the options and ethical rationales considered, the outcome, and the future plan;

(6) Follow-up by the ethics consultant to provide ongoing support to the process;

(7) Evaluation, as described in this study; and

(8) Record keeping to enhance future learning and quality improvement opportunities.

Because at the time of the study ethics consultations were not considered standard care, we did not seek informed consent from the usual-care patients. Any effort to seek informed consent from this group would have compromised and perhaps even invalidated the study by dividing the patients into those who were predisposed to accepting the intervention and those who were not. All the institutional review boards at the participating medical centers agreed that archival medical record data that are coded could be analyzed for the purpose of this research.

At each participating hospital a research assistant obtained demographic and medical data from the medical record. These data included age, sex, ethnicity, payer, and major diagnosis at time of entry into study. Life-sustaining intervention data consisted specifically of days in the ICU, days in the ICU spent receiving ventilation, days in the ICU receiving artificial nutrition and hydration, full code/comfort care orders, and cardiopulmonary resuscitation attempts—all prior to and after entry into the study. Categories of outcome of hospitalization consisted of death or discharge to hospice, skilled nursing facility, or home. Detailed review of the medical record included examination of physicians' orders, progress notes, and nurses' notes. The research assistants were blinded to which study arm the pa-

tient belonged to, and if they encountered an ethics consultation note, did not know whether the patient had originally been assigned to the ethics consultation, or was a crossover from the usual-care group.

When a patient in the intervention group died or was discharged the research assistant conducted a structured and open-ended interview either face-to-face or by telephone within 1 to 2 weeks after the patient's death or hospital discharge with the responsible attending physician and nurse who were involved with the patient, and 1 month after the patient's death or hospital discharge with the patient, surrogate, family, or intimate friend. The latter person was the one identified by the health care team as the most appropriate decision maker.

In all cases, the persons interviewed had participated in the ethics consultation. The interviewed persons were asked to respond by means of a structured Likert scale whether the consultation was perceived as helpful in identifying, analyzing, and resolving ethical issues, and whether it was stressful, informative, supportive, as well as assisting with communication. (Interview instrument available on request from the authors.) Because of the difficulty of addressing these emotional issues over the telephone with the help of an interpreter, interviews were limited to English-speaking persons.

Outcome Measures

The primary outcomes were ICU days, hospital days, and life-sustaining treatments in those patients who did not survive to hospital discharge. Because these outcomes would represent a failure to achieve a fundamental goal of medicine, we chose to call them "nonbeneficial treatment."¹⁰ This term is similar to but more comprehensive than the measure of Wenger et al¹² called "undesirable days," namely days in the ICU receiving ventilation or in a coma by patients who died in the hospital. Our term also is similar to but distinct from the measure of Esserman et al,¹³ namely "potentially ineffective treatment,"

which is defined as a prolonged ICU stay that ends in the patient's death within 100 days of discharge from the hospital. We hypothesized that ethics consultation would serve to reduce ICU days in those patients who would not have survived to hospital discharge, but would have no effect on this outcome among those who did survive. We also hypothesized that ethics consultation would not increase mortality relative to usual care and that the reduction in ICU days and treatments in patients who did not survive hospitalization would be achieved through interventions that are viewed as beneficial by all the involved parties.

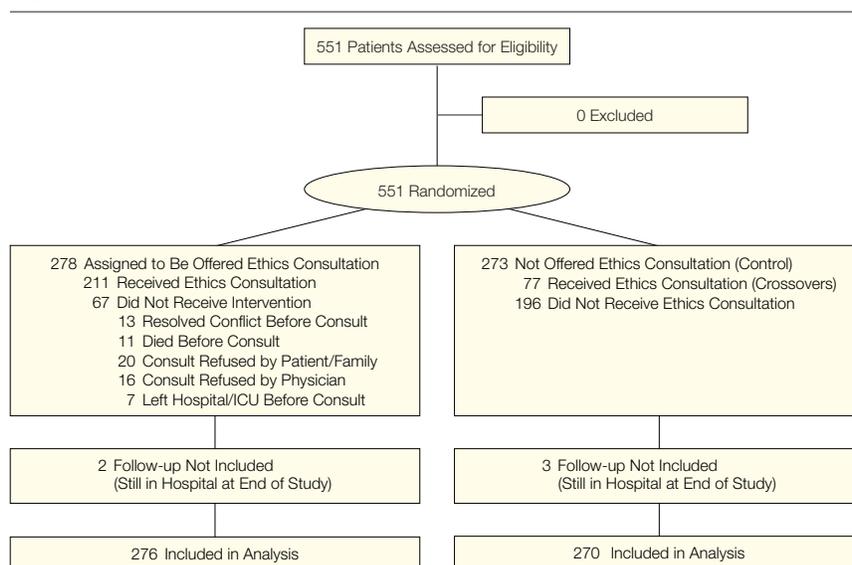
Analytic Methods

Analyses of data were carried out according to the intention-to-treat principle. The sample size was based on having a 90% power to detect a 3-day difference (SD=9.5) in ICU days among 174 intervention and 174 control patients who did not survive to discharge from the hospital. Age was compared using the *t* test, while differences between categorical baseline variables and mortality rates were compared using the χ^2 test. Distributions of days in the hospital, days in the ICU, days receiving ventilation, and days receiving artificial nutrition/hydration were substantially skewed, and thus were analyzed using nonparametric permutation.¹⁴ Analyses were performed using STATA, version 7 (STATA Corp, College Station, Tex).

RESULTS

The study enrolled a total of 551 patients between November 2000 and December 2002 (FIGURE 1). The patients included in the analysis were divided between intervention (*n*=278) and usual care (*n*=273). Sixty-seven patients in the consultation group did not receive the intervention, while 77 in the usual-care group ultimately received an ethics consultation. Two patients in the intervention group and 3 patients in the control group were not followed and included in the analysis because the study ended before they died or were discharged from the hospital. In the analy-

Figure 1. Patient Flow



sis, all patients were analyzed according to assignment group rather than treatment received.

As shown in TABLE 1, intervention (*n*=276) and usual-care (*n*=270) groups were similar with respect to age, sex, race, primary diagnosis, surrogates, and primary payer. The sample showed considerable diversity in race and primary diagnoses overall and among the participating hospitals. Most patients (91%) had a family member for a surrogate. The 2 groups showed no difference in mortality.

Among those patients who received the intervention (*n*=173), compared with control patients (*n*=156), but did not survive to discharge from the hospital (TABLE 2), hospital days (*P*=.01), days spent in the ICU (*P*=.03), and days receiving ventilation (*P*=.03) were reduced. Days receiving artificial nutrition/hydration showed no significant reduction. Among patients who survived to discharge from the hospital, hospital days, ICU days, days receiving ventilation, or days receiving nutrition/hydration (*P*>.50 for all outcomes) showed no significant differences between groups (data not shown).

FIGURE 2 shows that a pattern toward reductions of hospital and ICU days associated with patients assigned

Table 1. Baseline Characteristics of Study Participants Including Percentage Who Did Not Survive to Hospital Discharge*

Demographics	Intervention (n = 276)	Control (n = 270)
Age, mean (SD), y	67.5 (17.2)	67.5 (17.4)
Women, No. (%)	131 (47.5)	122 (45.2)
Race, No. (%)		
White, non-Hispanic	173 (62.7)	169 (62.3)
African American	41 (14.9)	38 (14.1)
Hispanic	28 (10.1)	30 (11.1)
Asian	27 (9.8)	26 (9.6)
Native American	2 (0.7)	2 (0.7)
Other	5 (1.8)	5 (1.9)
Diagnosis, No. (%)		
Pulmonary	63 (22.8)	59 (21.9)
Neurologic	62 (22.5)	57 (21.1)
Cardiovascular	46 (16.7)	37 (13.7)
Neoplastic	40 (14.5)	39 (14.4)
Metabolic	29 (10.5)	30 (11.1)
AIDS	2 (0.7)	3 (1.1)
Other	34 (12.3)	45 (16.7)
Surrogates, No. (%)		
Family	248 (89.9)	251 (93.0)
Friend	14 (5.1)	12 (4.4)
Court	6 (2.2)	3 (1.1)
None	8 (2.9)	4 (1.5)
Payer, No. (%)		
Medicare	156 (56.5)	154 (57.0)
Private/HMO	75 (27.2)	64 (23.7)
Medicaid	36 (13.0)	35 (13.0)
Cash/CMS/Other	9 (3.3)	17 (6.3)
Died in hospital, No. (%)	173 (62.7)	156 (57.8)

Abbreviations: CMS, County Medical Services; HMO, health maintenance organization.

*All differences are statistically insignificant at *P*>.20.

to ethics consultation vs usual care was observed at all the hospitals.

Follow-up interviews were conducted with 272 nurses and physicians for 158 patients (in many cases

both physician and nurse were interviewed for the same patient) and 111 patients or surrogate decision makers who received ethics consultations (only 108 were included in the analysis because 3 patients were reported after the cutoff date for data analysis). FIGURE 3 presents the overall results of the responses to the follow-up interviews seeking subjective evaluations of the ethics consultation by the patients/surrogates. Except for 2 patients who retained decision-making capacity, interviews were with patient surrogates. Eighty-eight patient/surrogate interviews could not be conducted either because the patient was incompetent and did not have a surrogate, the surrogate could not be reached, did not speak English, or the study ended before that patient died or

was discharged. Hence, the percentage of patient/surrogate interviews, taking into account available participants, was 111 of 122 (91%).

Figure 3 also presents the overall results of the responses to the follow-up interviews seeking subjective evaluations of the ethics consultation by nurses and physicians.

Respondents had generally positive views of ethics consultations. Eighty-seven percent of both the nurses and physicians and the patients/surrogates agreed or strongly agreed that ethics consultations were helpful. More than 90% of nurses and physicians agreed or strongly agreed that they would seek them again and recommend them to others. And even though patients/surrogates found ethics consultations somewhat more stressful than

did the nurses and physicians, 80% agreed or strongly agreed that they would seek them again and recommend them to others.

Thirteen patient surrogates disagreed or strongly disagreed with the recommendations reached in the ethics consultation. Nevertheless, 6 of these stated that they would seek an ethics consultation again in similar circumstances and an additional person would recommend it to others. Eight nurses and physicians disagreed or strongly disagreed with the recommendations reached in the ethics consultation, yet 7 of these would seek an ethics consultation again in similar circumstances and recommend it to others.

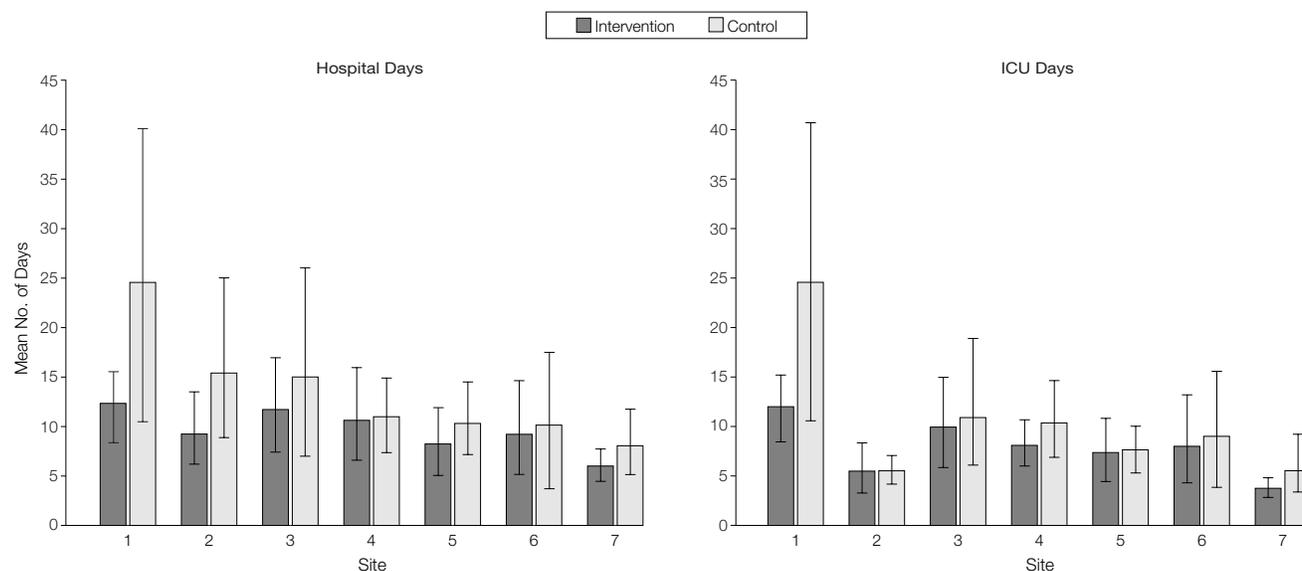
COMMENT

Our randomized, prospective, multicenter study offers several insights into the effects of ethics consultations on the care of critically ill patients. First, fears that ethics consultations would simply provide a subterfuge for “pulling the plug” were not borne out. We found no significant difference in the mortality rate between those patients who received this intervention and those who did not. On the other hand, in those pa-

Table 2. Comparison of Treatments and Days Between Ethics Consultation and Control Patients From Day of Study Entry to Day of Death in the Hospital

	Days, Mean (SD)		Difference	P Value
	Intervention (n = 173)	Control (n = 156)		
Hospital	8.66 (9.39)	11.62 (16.36)	-2.95	.01
Intensive care unit	6.42 (6.89)	7.86 (10.48)	-1.44	.03
Receiving ventilation	6.52 (8.52)	8.22 (11.16)	-1.70	.03
Receiving nutrition/hydration	7.36 (9.46)	8.38 (12.14)	-1.03	.14

Figure 2. Hospital and Intensive Care Unit (ICU) Days Associated With Patients Assigned to Ethics Consultation vs the Control



Error bars indicate 95% confidence interval.

tients who did not survive to discharge, ethics consultations were associated with a significant reduction in likely nonbeneficial treatments. Judging from their overall favorable reception by all the parties, ethics consultations were welcomed and perceived as facilitating rather than coercing decision making.

Second, these benefits were observed at all the hospitals despite their heterogeneity and diversity. Across institutions, the proportion of white patients ranged from 36% to 67%, African American from 4% to 30%, Hispanic from 7% to 23%, and Asian from 1% to 13%. The ICUs were open, closed, and mixed, the number of ICU beds ranged from 14 to 100, and the annual number of inpatients ranged from 11 300 to 24 000. The institutions included the following characteristics: a leading private research university medical center; an inner city teaching hospital with many indigent patients who tended to stay in the hospital longer than the other sites because of a lack of available follow-up facilities; affiliation with a health maintenance organization with predominantly well-

insured patients; a major county hospital with many indigent patients and a larger proportion of trauma patients than the other institutions; a small private Catholic-affiliated hospital; a state university teaching hospital; and a small, private Protestant-affiliated hospital. Ethics consultations were provided by single consultants or teams, by persons equipped with medical, doctoral, or law degrees, by social workers and theologians, by those formally schooled in ethics and philosophy, and by those who had acquired their expertise during the course of their professional career.

We acknowledge that our study has certain limitations. First, we wished to emulate as much as possible the real world circumstances for calling an ethics consultation, and hence chose an indication for entry into the study that is unavoidably subject to interpretation—conflict or potential conflict—rather than a more standardized indication, such as a specific number of hours receiving ventilation. Ethics consultations are requested far more frequently for the former reasons than the latter, however. And this choice is un-

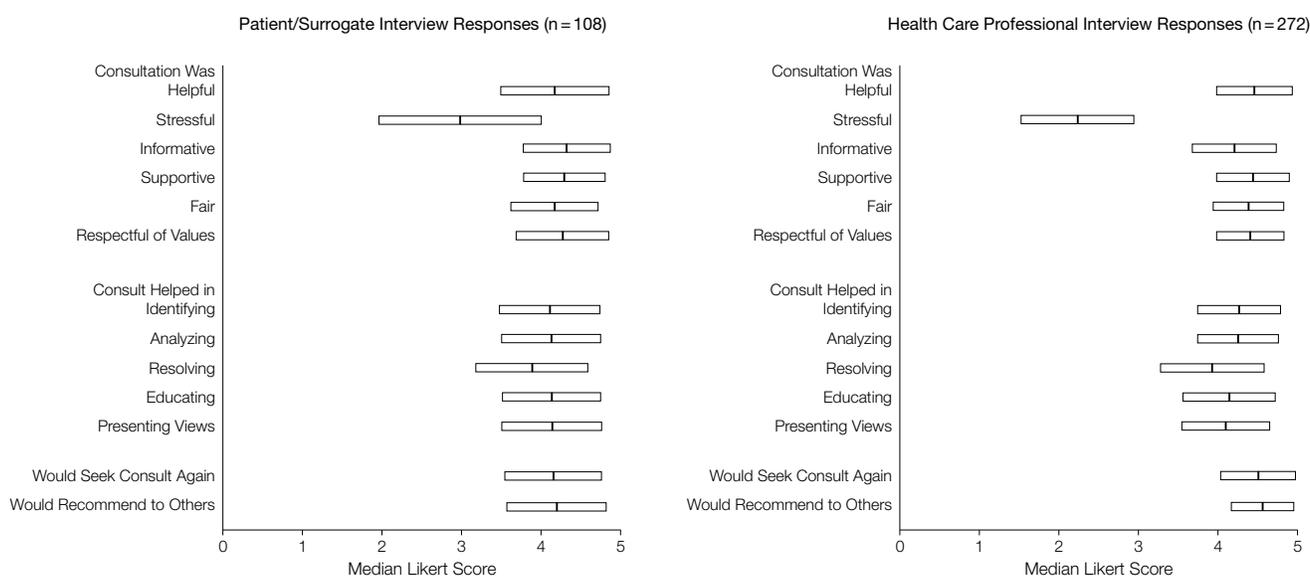
likely to lead to bias, as any ambiguity would distribute itself equally across the groups.

Second, all hospitals already had established ethics consultation services. Thus, it is not clear whether these results would extend to less skilled and experienced ethics consultation services. It also is possible that the study activity heightened the awareness of health care professionals to ethical issues within each institution. If so, we would regard that as a positive although untested additional benefit.

Third, a substantial number of patients in the usual-care group nonetheless received an ethics consultation. This reflected our ethical obligation to ensure that patient care always took precedence. Whenever there was doubt about whether a usual-care patient should be offered an ethics consultation the rule was always to offer it. It is important to emphasize, however, that these crossover patients remained in the usual-care arm for our intent-to-treat analysis.

Another limitation is that the research assistant unavoidably would have become aware of an ethics con-

Figure 3. Responses to the Follow-up Interviews Seeking Subjective Evaluations of the Ethics Consultation by Health Care Professionals and Patients/Surrogates



Likert scores are the following: 1, strongly disagree; 2, disagree; 3, neutral; 4, agree; and 5, strongly agree. Boxes indicate 25th and 75th percentile range.

sultation during the medical record review. However, the research assistant was informed that an ethics consultation would occur in both intervention and crossover patients, and thus could draw no conclusions as to which medical records represented intervention or control patients. Also, the demographic and medical treatment data transcribed were objective, and therefore less subject to interpretation and bias. As a further effort to reduce bias, none of the principal investigators or research staff had access to the accumulating data until after the study was completed. To ensure patient welfare as well as medical record confidentiality, all the raw data including completed interviews and consultation reports were secured in locked files and overseen by an independent data and safety monitoring board.

Because of the sensitivity of the issues involved we were reluctant to involve interpreters in interviews conducted by telephone. Therefore, follow-up interviews were limited to English-speaking surrogates.

We chose to limit the scope of our study to interventions in the ICU, where aggressive, high technology, burdensome medical efforts are directed principally at rescuing patients from extreme life-threatening situations, and to outcome measures occurring in a single hospitalization. Clearly, other important patient outcomes extend beyond hospitalization. A patient may be discharged from a hospital only to die a few days later in a nursing home. Other patients may have additional hospitalizations. We recommend that these longer-term outcomes be explored in future studies.

In summary, our results suggest that ethics consultations are associated with reductions in hospital and ICU days and life-sustaining treatments in those patients who ultimately will not survive to discharge. Furthermore, the majority of health care professionals and patients/surrogates agreed that ethics consultations in the ICU were helpful in addressing treatment conflicts. Hence, ethics consultations seem to be useful in resolving conflicts that may be inappro-

priately prolonging nonbeneficial or unwanted treatments at the end of life.

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