Effect of Ethics Consultations on Nonbeneficial Life-Sustaining Treatments in the Intensive Care Setting: A Randomized Controlled Trial

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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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For editorial comment see p 1208.
Several retrospective studies have examined the outcomes of ethics consultations. 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 al 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, Scheider et al 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.

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 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 comfort 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 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

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).

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available within 24 hours and con- 
ducted in a timely manner depending 
on the circumstances.

Although no standardized protocol 
was in place, each site followed a gen- 
eral process model of ethics consulta- 
tion, 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 re- 
sponsible for the patient consented to the 
ethics consultation. At the time of the first 
meeting, the ethics consultants ob- 
tained informed consent from the pa- 
tient, surrogate, family, or intimate friend 
to conduct an ethics consultation ac- 
cording to the procedures at each site and 
and to conduct a follow-up interview. The person asked to provide consent was ei- 
ther the patient (if that person had de-
cision-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 consider- 
ation were interviewed;

(3) Ethical diagnosis, that is, the eth- 
ics consultant framed the issues in eas-
ily understood ethical terms with the 
involved parties, drawing on relevant 
supporting material, including hospi-
tal policy, published ethical consen-
sus statements, statutes, and case law;

(4) Recommendations of the next 
steps, including measures for further 
meetings to improve communication 
(sharing information, dealing with emo-
tional discomfort and grieving, correct-
ing misunderstandings) ranging from 
team-only meetings with selected par-
ticipants to a formal conference involv-
ing the full ethics committee. At a mini-

mum, the consultant saw to it that the 
following areas of importance were ad-
dressed: relevant medical factors, the 
patient’s known or inferred values and 
preferences, quality of life consider-
atations, and other contextual factors of 
importance. The consultant helped arti-
culate consensus or disagreement and 
either facilitated implementing the con-
sensus or facilitated ways to address and 
resolve the disagreement;

(5) Documentation of the consulta-
tion in the patient’s medical record, iden-
tifying the person requesting the con-
sultation, activities occurring prior to the 
consultation, the reason for the ethics 
consultation, the ethical issues identi-
fied in the case, the steps taken to ad-
dress those issues, the options and ethi-
cal rationales considered, the outcome, 
and the future plan;

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

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

(8) Record keeping to enhance fu-
ture learning and quality improve-
ment opportunities.

Because at the time of the study eth- 
ics consultations were not considered 
standard care, we did not seek in-
formed consent from the usual-care pa-
tients. Any effort to seek informed con-
sent from this group would have 
compromised and perhaps even invalid-
ated the study by dividing the pa-
tients into those who were predi-
posed to accepting the intervention and 
those who were not. All the institu-
tional review boards at the participat-
ing medical centers agreed that archi-
val medical record data that are coded 
could be analyzed for the purpose of 
this research.

At each participating hospital a re-
search assistant obtained demographic 
and medical data from the medical rec-
ord. These data included age, sex, eth-
nicity, payer, and major diagnosis at time 
of entry into study. Life-sustaining in-
tervention data consisted specifically of 
days in the ICU, days in the ICU spent 
receiving ventilation, days in the ICU re-
ceiving artificial nutrition and hydra-
tion, full code/comfort care orders, and 
cardiopulmonary resuscitation at-
ttempts—all prior to and after entry into 
the study. Categories of outcome of hos-
pitalization consisted of death or dis-
charge to hospice, skilled nursing facil-
ity, 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 encoun-
tered an ethics consultation note, did not 
know whether the patient had origi-
nally been assigned to the ethics con-
sultation, or was a crossover from the 
usual-care group.

When a patient in the intervention 
group died or was discharged the re-
search assistant conducted a struc-
tured and open-ended interview ei-
ther face-to-face or by telephone within 
1 to 2 weeks after the patient’s death 
or hospital discharge with the respon-
sible attending physician and nurse who 
were involved with the patient, and 1 
month after the patient’s death or hos-
pital discharge with the patient, surro-
gate, family, or intimate friend. The lat-
ter person was the one identified by the 
health care team as the most appropri-
ate decision maker.

In all cases, the persons interviewed 
had participated in the ethics consul-
tation. The interviewed persons were 
asked to respond by means of a struc-
tured Likert scale whether the consul-
tation was perceived as helpful in iden-
tifying, analyzing, and resolving ethical 
issues, and whether it was stressful, in-
formative, supportive, as well as assisting 
with communication. (Interview in-
strument available on request from the 
authors.) Because of the difficulty of ad-
dressing these emotional issues over the 
telephone with the help of an inter-
preter, interviews were limited to En-
lish-speaking persons.

Outcome Measures

The primary outcomes were ICU days, 
hospital days, and life-sustaining treat-
ments in those patients who did not sur-
vive to hospital discharge. Because these 
outcomes would represent a failure to 
achieve a fundamental goal of medi-
cine, we chose to call them “nonben-
eficial treatment.”10 This term is simi-
lar to but more comprehensive than the 
measure of Wenger et al12 called “un-
desirable days,” namely days in the ICU 
receiving ventilation or in coma by pa-
tients who died in the hospital. Our 
term also is similar to but distinct from 
the measure of Esserman et al,11 namely 
“potentially ineffective treatment,”

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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 χ² 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. 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) groups. 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 analysis, 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 1.** Patient Flow

<table>
<thead>
<tr>
<th>TABLE 1. Baseline Characteristics of Study Participants Including Percentage Who Did Not Survive to Hospital Discharge*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Demographics</strong></td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
</tr>
<tr>
<td>Race, No. (%)</td>
</tr>
<tr>
<td>White, non-Hispanic</td>
</tr>
<tr>
<td>African American</td>
</tr>
<tr>
<td>Hispanic</td>
</tr>
<tr>
<td>Asian</td>
</tr>
<tr>
<td>Native American</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Diagnosis, No. (%)</td>
</tr>
<tr>
<td>Pulmonary</td>
</tr>
<tr>
<td>Neurologic</td>
</tr>
<tr>
<td>Cardiovascular</td>
</tr>
<tr>
<td>Neoplastic</td>
</tr>
<tr>
<td>Metabolic</td>
</tr>
<tr>
<td>AIDS</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Surrogates, No. (%)</td>
</tr>
<tr>
<td>Family</td>
</tr>
<tr>
<td>Friend</td>
</tr>
<tr>
<td>Court</td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>Payer, No. (%)</td>
</tr>
<tr>
<td>Medicare</td>
</tr>
<tr>
<td>Private/HMO</td>
</tr>
<tr>
<td>Medicaid</td>
</tr>
<tr>
<td>Cash/CMS/Other</td>
</tr>
<tr>
<td>Died in hospital, No. (%)</td>
</tr>
</tbody>
</table>

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

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

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

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n = 173)</th>
<th>Control (n = 156)</th>
<th>Difference</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hospital</td>
<td>8.66 (9.39)</td>
<td>11.62 (16.36)</td>
<td>−2.95</td>
<td>.01</td>
</tr>
<tr>
<td>Intensive care unit</td>
<td>6.42 (6.89)</td>
<td>7.86 (10.48)</td>
<td>−1.44</td>
<td>.03</td>
</tr>
<tr>
<td>Receiving ventilation</td>
<td>6.52 (8.52)</td>
<td>8.22 (11.16)</td>
<td>−1.70</td>
<td>.03</td>
</tr>
<tr>
<td>Receiving nutrition/hydration</td>
<td>7.36 (9.46)</td>
<td>8.38 (12.14)</td>
<td>−1.03</td>
<td>.14</td>
</tr>
</tbody>
</table>

**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 unlikely 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 unknowingly would have become aware of an ethics con-

![Figure 3](https://www.jama.com/content/jama/290/9/1193.full figure.html)
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 inappropriately prolonging nonbeneficial or unwanted treatments at the end of life.

**Author Contributions:** Study concept and design: Schneiderman, Gilmer, Teetzel. Acquisition of data: Schneiderman, Gilmer, Teetzel, Dugin, Blustein, Cranford, Briggs, Komatsu, Goodman-Crews, Cohen, Young. Analysis and interpretation of data: Schneiderman, Gilmer, Teetzel, Dugin, Blustein, Cranford, Briggs, Komatsu, Cohen, Young. Drafting of the manuscript: Schneiderman, Gilmer, Teetzel. Critical revision of the manuscript for important intellectual content: Schneiderman, Gilmer, Teetzel, Dugin, Blustein, Komatsu, Goodman-Crews, Cranford, Blustein, Cohen, Young. Statistical expertise: Gilmer. Obtained funding: Schneiderman. Administrative, technical, or material support: Schneiderman, Gilmer, Teetzel, Dugin, Blustein, Cranford, Briggs, Komatsu, Goodman-Crews, Cohen, Young. Study supervision: Schneiderman. Funding/Support: This study was supported by the Agency for Healthcare Research and Quality (1 R01 HS10251).

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**REFERENCES**