A Controlled Trial to Improve Care for Seriously Ill Hospitalized Patients

The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT)

The SUPPORT Principal Investigators

Objectives.—To improve end-of-life decision making and reduce the frequency of a mechanically supported, painful, and prolonged process of dying.

Design.—A 2-year prospective observational study (phase I) with 4001 patients followed by a 2-year controlled clinical trial (phase II) with 4804 patients and their physicians randomized by specialty group to the intervention group (n=2652) or control group (n=2152).

Setting.—Five teaching hospitals in the United States.

Patients.—A total of 9105 adults hospitalized with one or more of nine life-threatening diagnoses; an overall 6-month mortality rate of 47%.

Intervention.—Physicians in the intervention group received estimates of the likelihood of 6-month survival for every day up to 6 months, outcomes of cardiopulmonary resuscitation (CPR), and functional disability at 2 months. A specially trained nurse had multiple contacts with the patient, family, physician, and hospital staff to elicit preferences, improve understanding of outcomes, encourage attention to pain control, and facilitate advance care planning and patient-physician communication.

Results.—The phase I observation documented shortcomings in communication, frequent of aggressive treatment, and the characteristics of hospital deaths: only 47% of physicians knew when their patients preferred to avoid CPR; 45% of do-not-resuscitate (DNR) orders were written within 2 days of death; 36% of patients who died spent at least 10 days in an intensive care unit (ICU); and for 50% of conscious patients who died in the hospital, family members reported moderate to severe pain at least half the time. During the phase II intervention, patients experienced no improvement in patient-physician communication (eg, 37% of control patients and 40% of intervention patients discussed CPR preferences) or in the five targeted outcomes, ie, incidence or timing of written DNR orders (adjusted ratio, 1.02; 95% confidence interval [CI], 0.90 to 1.15), physicians’ knowledge of their patients’ preferences not to be resuscitated (adjusted ratio, 1.22; 95% CI, 0.99 to 1.49), number of days spent in an ICU, receiving mechanical ventilation, or coma before death (adjusted ratio, 0.97; 95% CI, 0.87 to 1.07), or level of reported pain (adjusted ratio, 1.15; 95% CI, 1.00 to 1.33). The intervention also did not reduce use of hospital resources (adjusted ratio, 1.05; 95% CI, 0.99 to 1.12).

Conclusions.—The phase I observation of SUPPORT confirmed substantial shortcomings in care for seriously ill hospitalized adults. The phase II intervention failed to improve care or patient outcomes. Enhancing opportunities for more patient-physician communication, although advocated as the major method for improving patient outcomes, may be inadequate to change established practices. To improve the experience of seriously ill and dying patients, greater individual and societal commitment and more proactive and forceful measures may be needed.


PUBLIC HEALTH and clinical medicine during this century have given Americans the opportunity to live longer and more productive lives, despite progressive illness. For some patients, however, this progress has resulted in prolonged dying, accompanied by substantial emotional and financial expense. Many Americans today fear they will lose control over their lives if they become critically ill, and their dying will be prolonged and imperious. This has led to an increasingly visible right-to-die movement. Two years after voters in California and Washington State narrowly defeated referenda on physician-assisted euthanasia, Oregon voters approved physician prescription of lethal medications for persons with a terminal disease. Physicians and ethicists have debated whether to use cardiopulmonary resuscitation and other aggressive treatments for patients with advanced illnesses. Many worry about the economic and human cost of providing life-sustaining treatment near the end of life.

For editorial comment see p 1634.

In response, professional organizations, the judiciary, consumer organizations, and a president’s commission have all advocated more emphasis on realistically forecasting outcomes of life-sustaining treatment and on improved communication between physician and patient. Statutes requiring informed consent and communication, like the Patient Self-Determination Act, have been passed. Advance care planning and effective ongoing communication among clinicians, patients, and families are essential to achieve these goals. Previous studies indicate, however, that communication is often absent or occurs only during a crisis. Physicians today often perceive death as failure; they tend to be too pessimistic regarding prog-
noses, and they provide more extensive treatment to seriously ill patients than they would choose for themselves.

Phase I of the Study to Understand Prognoses and ICU Decisions—SUPPORT confirmed barriers to optimal management and shortfalls in patient-physician communication. The phase II intervention sought to address these deficiencies by providing physicians with accurate predictive information on future functional ability, survival probability for each day up to 6 months, and patient preferences for end-of-life care; a skilled nurse augmented the care team to elicit patient preferences, provide prognoses, enhance understanding, enable palliative care, and facilitate advance planning. We hypothesized that increased communication and understanding of prognoses and preferences would result in earlier treatment decisions, reductions in time spent in undesirable states before death, and reduced resource use. This article describes the effect of the SUPPORT intervention on five specific outcomes: physician understanding of patient preferences, incidence and time of documentation of do-not-resuscitate (DNR) orders; pain time spent in an intensive care unit (ICU), constipation, or receiving mechanical ventilation before death; and hospital resource use (Figure 1).

METHODS

Phase I was a prospective observational study that described the process of decision making and patient outcomes. Phase II was a cluster randomized controlled clinical trial to test the effect of the intervention. Enrollment, data collection, and interviewing were virtually identical during the two phases.

Enrollment

Qualified patients were in the advanced stages of one or more of nine illnesses: acute respiratory failure, multiple organ system failure with sepsis, multiple organ system failure without malignancy, coma, chronic obstructive lung disease, congestive heart failure, cirrhosis, metastatic colon cancer, and non-small lung cancer. Patients were excluded if they were younger than 18 years, were discharged or died within 48 hours of qualifying for the study, were admitted with a scheduled discharge within 72 hours, died not speak English, were admitted to the psychiatric ward, had acquired immunodeficiency syndrome, were pregnant or sustained an acute burn, head, or other trauma (unless they subsequently developed acute respiratory failure or multiple organ system failure). Nurses trained in the SUPPORT eligibility criteria reviewed hospital admissions and ICU patients daily to identify newly qualified patients. Phase I enrolled patients from June 1988 to June 1992. Phase II enrolled patients from January 1992 through January 1994. Patients were recruited from five medical centers: Beth Israel Hospital, Boston, Mass; MetroHealth Medical Center, Cleveland, Ohio; Duke University Medical Center, Durham, NC; Marshfield Clinic/St Joseph’s Hospital, Marshfield, Wis; and the University of California at Los Angeles Medical Center. An independent committee monitored potential adverse events, including 6-month mortality for intervention patients and changes in patient satisfaction with medical care. Morality follow-up to 6 months was complete for all phase I patients. In phase II, 22 patients (0.5%) were unavailable for follow-up at a median of 80 days.

Data Collection Methods

Data collection was based on both concurrent and retrospective medical record reviews and on interviews with patients, patient surrogates (defined as the person who would make decisions if the patient was unable to do so), and patients’ physicians.

Medical Record-Based Data.—We collected physiological indicators of disease severity, length of stay, a modified version of the Therapeutic Intervention Scoring System, and comorbidities from the medical records on days 1, 3, 7, 14, and 28. The permanent medical record was retrospectively reviewed for discussions or decisions concerning 18 important issues, such as the use of dialysis, withdrawal from a ventilator, and DNR orders. Reliability testing on 10% of the medical records showed at least 90% agreement between abstracted data and documenting patient and family preferences and understanding of disease prognosis and treatment, and by providing a skilled nurse to help carry out the needed discussions, convene the meetings, and bring to bear the relevant information. The elements of the intervention and their timing are presented in Table 1. In each case, the nurse was free to shape her role so as to achieve the best possible care and outcome. For example, she sometimes engaged in extensive emotional support. Other times, she mainly provided information and ensured that all parties heard one another effectively. All of the nurses’ involvement required approval of the attending physicians. In virtually all cases, the nurse involved spoke with all members of the team. Physicians were free, however, to limit the intervention in any way that they felt was best for the patient, and there...
Objectives and Organization of SUPPORT

- Phase I (1989 to 1991)
  - Study 4301 Patients at Five Teaching Hospitals
  - Describe Outcomes
  - Develop Prognostic Models
  - Identify Shortcomings of Care
  - Establish Adjustment Methods
  - Design Intervention

Control
11 Physician Groups
2152 Patients (49%)

Phase II (1992 to 1994)
Apply Intervention to 4804 Patients
Randomized to 27 Physician Groups

intervention
16 Physician Groups
2652 Patients (52%)

Adjusted Analyses of Intervention vs Control for Five Outcomes
- Incidence and Timing of Written DNR Orders
- Patient-Physician Agreement on CPR Preferences
- Days in an ICU, Coma, or Receiving Mechanical Ventilation Before Death
- Pain
- Hospital Resource Use

Figure 1.—Overall schematic presentation of phases I and II of the Study to Understand Prognostic and Treatment Foresight for Outcomes and Rates of Treatment (SUPPORT) project, 1989 to 1994. DNR indicates do not resuscitate; CPR, cardiopulmonary resuscitation; and ICU, intensive care unit.

There was no requirement for them to share or discuss the information with the patient or family or to allow the nurse's involvement to continue. The nurse was identified on her badge and in the consent process as part of a research effort, but she had the role and appearance of a typical clinical specialist.

Randomization.—To limit contamination, patients were assigned to intervention or control (usual care) status based on the specialty of their attending physician. Physician specialties were divided into five groups: internal medicine, pulmonology/medical ICU, oncology, surgery, and cardiology. We used a cluster randomization scheme to assign the intervention randomly to 27 physician group/site combinations, restricted by the conditions that 50% to 80% of patients would be assigned intervention status, and that at least one intervention and one control physician specialty group be at each of the five study institutions. This resulted in 11 physician specialty groups assigned to control and 16 assigned to the intervention (Figure 1). Analyses were based on allocation to intervention (ie, intention to treat), irrespective of whether a given patient received the intervention. Investigators were blinded to the phase II results during data collection.

Analytic Methods.—Five measures were chosen to evaluate the intervention: (1) The timing of written DNR orders was analyzed with a log-normal regression model to prepare Kaplan-Meier predicted median times until the first DNR order was written. If a DNR order was not written, DNR order timing was censored at the day of death or hospital discharge. (2) Patient-physician agreement on preferences to withhold resuscitation was based on the first interview of the patient (or surrogate if the patient was unable to be interviewed) and the responsible physician. Agreement was defined as a response to a request for resuscitation from both patient and physician, analyzed with binary logistic regression, and applied to all interviewed patients or surrogates who had matching physician interviews. (3) Days spent in an ICU, receiving mechanical ventilation, or coma before death were analyzed using ordinary least-squares regression (after taking the log of 0.5 plus the number of days) and only included phase II patients who died during the index hospitalization. (4) Frequency and severity of pain analyses were based on all patients or surrogates interviewed in the second week with a combined measure (mild or severe pain all, most, or half the time) and analyzed using a single, ordinal logistic regression model. (5) Hospital resource use was defined as the log of the product of the average Therapeutic Intervention Scoring System rating and length of hospital stay after the second day of the study. In regression analyses on phase I data, this measure closely estimated hospital bills across the five study institutions (Pearson R^2 = 0.59 on log product). We used ordinary least-squares regression to model the log of resource use, which was then converted to 1993 dollars. This method allows comparisons of groups and institutions across time without having to adjust for varying hospital billing practices.

Power and Safety Calculations

Power calculations based on phase I data indicated greater than 90% power (α = 0.05) to detect a 1-day decrease in days until a DNR order was written, a 5% increase in the proportion of physicians and patients agreeing on a DNR order, a 20% decrease in undesirable days, a 10% decrease in reported pain, and a 5% decrease in resource use. Effects of the intervention on mortality rates were quantified by the estimated intervention, control hazard ratio from adjusted Cox models.²³

Adjustment Methods for Phase II Results

Because patients were assigned to intervention or control status based on a limited number of specialty groups, the resulting cohorts might be unbalanced in patient baseline risk factors. Furthermore, we measured separately the physician specialty groups in phase I differed substantially. We controlled for these expected preintervention differences using baseline multivariable risk scores that were derived by generating models to predict phase I outcomes, each of which incorporated interactions between physician specialty and hospitals.

Observed imbalances in phase II baseline patient characteristics were also adjusted using a propensity score that corrected for selection bias associated with being assigned to intervention status.²² Further details on the construction of both of these risk scores are available on request. Imputation methods for missing data have been published.²² Finally, we simulated the phase II randomization scheme on the phase I data to evaluate secular trends. To adjust for multiple outcomes, our methods prespecified adjusting confidence intervals (CIs) using the method of Hochberg and Benjamini²¹ if more than one P value was less than 0.05. All statistical analyses were done with UNISTAT Plus, version 3.2 software²⁶ and the Design Library.²⁷

RESULTS

Phase I Observations

Phase I enrolled 4301 patients (Figure 1) with a median age of 65 years and other characteristics summarized in Table 2. The mean predicted 6-month survival probability was 59% with an actual 6-month survival probability of
Table 1. Content, Recipient, and Timing of Phase II SUPPORT Interventiona

<table>
<thead>
<tr>
<th>Content</th>
<th>Provided to</th>
<th>Timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feedback of phase I results</td>
<td>All intervention physicians</td>
<td>Early phase II</td>
</tr>
<tr>
<td>Benchmarking information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Assessing phase I incidence</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time spent communicating, pain, and serum of DNA order</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Prognostic information**
- Study was estimated for up to 6 months

**Prognostic for outcome for CPR II record**
- Intervention physicians and medical record
- Study day 2

**Surviving impact, enhanced**
- Intervention physicians and medical record
- Study day 4

**Surviving impact, salt**
- Intervention physicians and medical record
- Study day 8

**Intervention information**
- Patient and caregiver report of medical record
- First and second study weeks

**Intervention information**
- Nurse interview
- Patient family, staff, intervention physicians, and medical record
- Study day 3 and continuously until death or 6 mo

**Intervention information**
- Patient family, staff, intervention physicians, and medical record
- Study day 3 and continuously until death or 6 mo

**Intervention information**
- Patient family, staff, intervention physicians, and medical record
- Study day 3 and continuously until death or 6 mo

**Intervention information**
- Patient family, staff, intervention physicians, and medical record
- Study day 3 and continuously until death or 6 mo

**Intervention information**
- Patient family, staff, intervention physicians, and medical record
- Study day 3 and continuously until death or 6 mo

**Intervention information**
- Patient family, staff, intervention physicians, and medical record
- Study day 3 and continuously until death or 6 mo

**Intervention information**
- Patient family, staff, intervention physicians, and medical record
- Study day 3 and continuously until death or 6 mo

**Intervention information**
- Patient family, staff, intervention physicians, and medical record
- Study day 3 and continuously until death or 6 mo

48% (Table 2). Thirty-one percent of phase I patients with interviews preferred that CPR be withheld, but only 47% of their physicians accurately reported this preference during the first interview. Nearly half (49%) of the 960 phase I patients who indicated a desire for CPR to be withheld did not have a DNR order written during that hospitalization. Nearly one-third of these patients (2/73 [29%]) died before discharge. Among all phase I patients who died during the index hospitalization (n=1,150), 79% died with a DNR order, but 46% of these orders were written within 2 days of death. Among all phase I deaths, the median number of days spent in an ICU, comatose, or receiving mechanical ventilation was 8, more than one third (33%) spent at least 10 days in an ICU, and 66% received mechanical ventilation within 3 days of death. In the second week, 23% of patients remained in moderate to severe pain at least half the time. In interviews conducted after a patient died, surrogates indicated that 50% of all conscious phase I patients who died in the hospital experienced moderate or severe pain at least half the time during their last 3 days of life.

We found substantial variation in the five outcomes among physician specialty groups and across the five institutions. Across institutions, the median number of days spent in an ICU before death was 5 to 9. The proportion of patients reporting moderate to severe pain at least half the time was by a factor of 2:7, from 15% to 22% across study institutions. The predicted median number of days until a DNR order was written for a standard patient varied by a factor of 2.8, from 75 days for patients on a surgical service to 32 for oncology. One study institution had a predicted median time until DNR was written for a standard patient of 28 days, and another institution had a predicted median time of 49 days. Agreement on DNR varied from 8% for cardiology patients to 99% for oncology patients and from a low of 8% at one study institution to a high of 27% at another. The median number of days spent in an ICU before death ranged from 14 in the surgical specialties to 5 for patients in pulmonary/ICU and oncology services.

**Phase II Demographics**
- Phase II enrolled 4,704 patients, 2,152 assigned to usual medical care and 2,552 assigned to intervention status (Figure 1). Their characteristics were generally similar to those of phase I patients (Table 2).

**Delivery of the Intervention**
- Ninety-five percent of intervention patients received one or more patient-specific components of the intervention. The SUPPORT nurse was involved in the care of all but 133 patients, and 75 of these were patients who died or were discharged on the day of enrollment. The SUPPORT nurse communicated with the physician in virtually all cases. The patient's physician received at least one prognostic report for 94% of patients, and the report was put in the medical record of 90%. The patient's physician received at least one printed report of patient or surrogates understanding and preferences in 72% of cases.

No physician refused to receive the printed reports or to have them shared with other professional staff. The physicians for 43 patients refused to allow the SUPPORT nurse to have contact with the patient and family, and seven patients or surrogates refused to speak with the SUPPORT nurse.

**Effect of Intervention on Outcomes**
- The prevalence or timing of documentation of DNR orders for the 2,554 intervention patients was the same as for the 2,208 control patients (adjusted ratio of median time, 1.02; 95% CI, 0.90 to 1.15) (Table 3). There was a small association of the intervention with improved patient-physician DNR agreement for the 1,480 intervention patients who had patient or surrogate and matching physician interviews, compared with 1,130 control patients (adjusted ratio, 1.22; 95% CI, 0.99 to 1.56). The number of days spent in an ICU, comatose, or receiving mechanical ventilation before death for the 800 intervention patients who died in the hospital was the same as for the 530 control patients (adjusted ratio of 0.97; 95% CI, 0.81 to 1.17).