

# 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 4301 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, frequency of aggressive treatment, and the characteristics of hospital death: only 47% of physicians knew when their patients preferred to avoid CPR; 46% of do-not-resuscitate (DNR) orders were written within 2 days of death; 38% 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 comatose 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.

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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.<sup>1</sup> Many Americans today fear they will lose control over their lives if they become critically ill, and their dying will be prolonged and impersonal.<sup>2</sup> 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.<sup>3,4</sup> Physicians and ethicists have debated when to use cardiac resuscitation and other aggressive treatments for patients with advanced illnesses.<sup>5,6</sup> Many worry about the economic and human cost of providing life-sustaining treatment near the end of life.<sup>7-9</sup>

**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.<sup>2,10-16</sup> Statutes requiring informed consent and communication, like the Patient Self-determination Act,<sup>17</sup> 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.<sup>18-20</sup> Physicians today often perceive death as failure,<sup>1</sup> they tend to be too pessimistic regarding prog-

A complete list of the SUPPORT principal investigators and collaborators appears at the end of this article.

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noses,<sup>21</sup> and they provide more extensive treatment to seriously ill patients than they would choose for themselves.<sup>22</sup>

Phase I of the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT) confirmed barriers to optimal management and shortfalls in patient-physician communication.<sup>23,24</sup> The phase II intervention sought to address these deficiencies by providing physicians with accurate predictive information on future functional ability,<sup>25</sup> survival probability for each day up to 6 months,<sup>26</sup> 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), comatose, 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.<sup>21,23-28</sup>

### 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 with malignancy, coma, chronic obstructive lung disease, congestive heart failure, cirrhosis, metastatic colon cancer, and non-small cell 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, did not speak English, were admitted to the psychiatric ward, had acquired immunodeficiency syndrome, or were pregnant or sustained an acute burn, head, or other trauma (unless they later developed acute respiratory failure or multiple organ system failure).<sup>26,28</sup> 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 1989 to June 1991, and 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. Mortality 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,<sup>29,30</sup> length of stay, a modified version of the Therapeutic Intervention Scoring System,<sup>31</sup> and comorbidities from the medical records on days 1, 3, 7, 14, and 25. 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 on abstracted data.

**Interview Data.**—Patients and their designated surrogates were interviewed in the hospital between days 2 and 7 (median, day 4) and again between days 6 and 15 (median, day 12) after study enrollment, whether or not the patient remained hospitalized. The surrogate was interviewed 4 to 10 weeks after the patient's death. Among the 45% of patients who were able to communicate, the response rate for the first interview was 85%. The surrogate response rate for the first interview was 87%. For the second-week interviews, the patient response rate was 71% and the surrogate response rate was 78%. The interviews collected information on patient demographics, functional status, self-assessed quality of life, communication with physicians, frequency and severity of pain, satisfaction with medical care,<sup>32</sup> and the patient's preferences for cardiopulmo-

nary resuscitation (CPR). When a patient interview was not possible, the surrogate's responses were substituted, a strategy that mirrors clinical practice. Important elements of the patient/surrogate questionnaires were retested for reliability. Initial and repeat responses had greater than 80% agreement.

The most senior available physician acknowledging responsibility for the patient's medical decisions was interviewed in the first and second weeks after patient enrollment (median days, 3 and 11, respectively). In both interviews, we asked the physician's understanding of the patient's preferences for CPR. In the second interview, physicians assigned to the intervention were queried about its influence on the patient's care. Physician response rates were 86% for the first interview and 82% for the second interview.

### Phase II Intervention

Presented with early findings from phase I documenting substantial shortcomings in communication, decision making, and outcomes,<sup>23,24</sup> physicians at the participating institutions voiced interest in attempting change. Physician leaders and study investigators at the sites met to discuss how decision making could be improved to more closely reflect both probable outcomes and patient preferences and ways to improve patient, family, and physician communication. Physicians suggested that communication could improve if there were more reliable and prompt information generated by the study and if study personnel would make it more efficient to have conversations. In response to these suggestions, the phase II intervention aimed to improve communication and decision making by providing timely and reliable prognostic information, by eliciting 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 physician approval came with no limits. 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

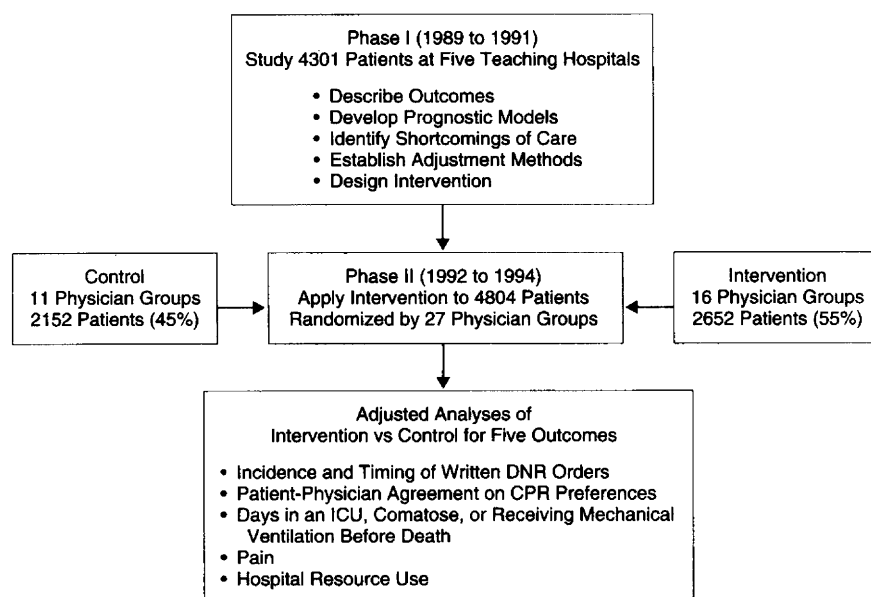


Figure 1.—Overall schematic presentation of phases I and II of the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT) project, 1989 to 1994. DNR indicates do not resuscitate; CPR, cardiopulmonary resuscitation; and ICU, intensive care unit.

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 60% 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 re-

gression model to prepare Kaplan-Meier predicted median time 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 and 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 forgo 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 comatose 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 (moderate 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  $R^2=0.93$  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 ( $\alpha=.05$ ) 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.<sup>33</sup>

## 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, practice patterns among 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.<sup>34</sup> Further details on the construction of both of these risk scores are available on request. Imputation methods for missing data have been published.<sup>25</sup> 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 Benjamini<sup>35</sup> if more than one  $P$  value was less than .05. All statistical analyses were done with UNIX S-Plus, version 3.2 software<sup>36</sup> and the Design library.<sup>37</sup>

## 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 52% with an actual 6-month survival probability of

Table 1.—Content, Recipient, and Timing of Phase II SUPPORT Intervention\*

Content	Provided to	Timing
Feedback of phase I results Benchmarking information describing phase I incidence of patient-physician communication, pain, and timing of DNR order	All intervention physicians	Early phase II
Prognostic information Survival time estimates for up to 6 mo <sup>26</sup>	Intervention physicians and medical record	Study days 2, 4, 8, 15, and 26
Prognosis for outcome for CPR if needed <sup>26</sup>	Intervention physicians and medical record	Study day 2
Survival estimates, enhanced by physician <sup>26</sup>	Intervention physicians and medical record	Study day 4
Prognosis, probability of severe disability, at 2 mo <sup>25</sup>	Intervention physicians and medical record	Study day 8
Interview information Patient and surrogate report of prognosis, preferences about CPR, advance directives, quality of life, information desires, and pain	Intervention physicians and medical record	First and second study weeks
Interview on knowledge of preferences†	Intervention physicians	Study day 10
Nurse involvement Explaining prognostic estimates and interview reports	Patient, family, staff, intervention physicians, and medical records	Study day 3 and continuously until death or 6 mo
Enhancing understanding of likely outcomes/preferences	Patient, family, staff, intervention physicians, and medical records	Study day 3 and continuously until death or 6 mo
Eliciting and documenting preferences/advance directives	Patient, family, staff, intervention physicians, and medical records	Study day 3 and continuously until death or 6 mo
Assessing pain and enabling treatment	Patient, family, staff, intervention physicians, and medical records	Study day 3 and continuously until death or 6 mo
Voicing patient/family preferences and values	Patient, family, staff, intervention physicians, and medical record	Study day 3 and continuously until death or 6 mo
Convening meetings, negotiating agreements	Patient, family, staff, intervention physicians, and medical records	Study day 3 and continuously until death or 6 mo
Encouraging planning for future decisions	Patient, family, staff, intervention physicians, and medical records	Study day 3 and continuously until death or 6 mo

\*SUPPORT indicates Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment; DNR, do not resuscitate; CPR, cardiopulmonary resuscitation; and ICU, intensive care unit.

†Physician interview on day 10 was for evaluation, not part of the intervention.

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 (278 [29%]) died before discharge.

Among all phase I patients who died during the index hospitalization (n=1150), 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 (38%) spent at least 10 days in an ICU, and 46% received mechanical ventilation within 3 days of death. In the second week, 22% of patients reported being 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 varied from 5 to 9. The proportion of patients reporting moderate to severe pain at least half the time varied by a factor of 2.7, from 12% to 32% across study institutions. The predicted median number of days until a DNR order was written for a standard patient varied by a factor of 3.5, from 73 days for patients on a surgical service to 22 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 24% 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 4804 patients, 2152 assigned to usual medical care and 2652

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. She talked directly with the patient or family in most cases (eg, with 84% concerning prognosis, 77% about pain, 63% about likely outcomes or resuscitation, and 73% concerning written advance directives). For patients in the hospital for 7 or more days after qualifying for the study, the median number of SUPPORT nurse contacts with the patient, family, or physician was four and the mean was six. Documentation in the progress notes of discussions about patients' preferences with regard to resuscitation was increased from 38.5% in phase I to 50.3% among phase II intervention patients.

The patient's physician received at least one prognostic report for 94% of patients, and the report was put in the medical record of 80%. The patient's physician received at least one printed report of patient or surrogate understanding and preferences in 78% 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 2534 intervention patients was the same as for the 2208 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 1480 intervention patients who had patient or surrogate and matching physician interviews, compared with 1159 control patients (adjusted ratio, 1.22; 95% CI, 0.99 to 1.49). The number of days spent in an ICU, comatose, or receiving mechanical ventilation before death for the 680 intervention patients who died in the hospital was the same as for the 530 control patients (adjusted ratio of median days, 0.97; 95% CI, 0.87 to 1.07).

Table 2.—Characteristics of 9105 SUPPORT Patients, 1989 to 1994\*

	Total		Phase II	
	Phase I (n=4301)	Phase II (n=4804)	Control Group (n=2152)	Intervention Group (n=2652)
Median age, y	65	65	64	66
Sex, % female	43.0	44.3	43.0	45.4
Race, %				
White	79.5	79.0	82.1	77
Black	15.3	15.4	11.5	19
Other	5.3	5.6	6.4	5.0
Annual income <\$11 000, %	59.1	53.1	48.9	57
Education high school or more, %	53.4	59.0	63.2	56
Primary insurance, %				
Private	29.2	29.6	32.7	27.1
Medicare	53.8	56.0	53.5	57.9
Medicaid	11.8	10.8	11.2	10.6
None	5.3	3.6	2.6	4.4
Disease class, %				
Acute organ system failure†	42.9	49.6	52.8	47
Chronic disease‡	34.4	28.8	25.0	31.8
Nontraumatic coma	5.7	7.3	5.9	8.4
Cancer§	16.9	14.4	16.3	12.9
Mean ADL Scale score	1.6	1.5	1.5	1.5
Median APS of APACHE III  #	33	32	32	32
SUPPORT 6-mo mean survival estimate	0.52	0.52	0.51	0.52
Hospital mortality, %	26.7	25.2	24.6	25.6
6-mo Mortality, %	48.0	45.6	43.8	47.1
Median hospital charges, \$ thousands	21	29	33	27

\*SUPPORT indicates Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment.

†Includes acute respiratory failure and multiple organ system failure with or without sepsis.

‡Includes end-stage cirrhosis and acute exacerbations of severe congestive heart failure or severe chronic obstructive pulmonary disease.

§Includes colon cancer with liver metastases and stage III or stage IV non-small cell lung cancer.

||Measured on the third study day.

¶ADL indicates activities of daily living score from 0 to 7, with each point representing an impairment in basic function, reflecting patient status 2 weeks before admission.

#APS indicates acute physiology score; and APACHE III, Acute Physiology, Age, Chronic Health Evaluation III.<sup>29</sup> The APS varies from 0 to 252 with a higher score indicating greater physiological instability and risk of death.

Reported pain increased for the 1677 intervention patients and surrogates interviewed in the second week, compared with the control group (adjusted ratio, 1.15; 95% CI, 1.00 to 1.33) (Table 3). There was no change in hospital resources used for 2593 intervention patients not dead or discharged before the third study day compared with 2129 control patients (adjusted ratio of average resource use, 1.05; 95% CI, 0.99 to 1.12).

The unadjusted differences between intervention and control patients for median days until the first DNR order was written were large, especially for patients with colon cancer and non-small cell lung cancer for whom the median number of days until a written DNR order was 80% lower in intervention patients. Adjustment for baseline imbalances reduced much of the difference in each category (Table 4). The differences that persist in the cancer category are of uncertain importance, being one among multiple comparisons and being based on a small number of patients (Table 4).

Figure 2 illustrates the secular trends of each outcome in the phase II intervention and control groups, as well as in

phase I, using simulations of the physician specialty groupings used in phase II. None of the five outcomes changed significantly during the 5 years of the study. The differences between those who would have been assigned to intervention and control in phase I persisted throughout the SUPPORT study, unaffected by time or by the intervention.

### Communication and Preferences

The intervention did not change the unadjusted proportion of patients or surrogates reporting a discussion about CPR; 37% of control patients and 40% of intervention patients reported discussing their preference. Of patients who did not have such a discussion, 41% of each group said they would like to discuss CPR. Seventeen percent of control patients and 20% of intervention patients changed their resuscitation preferences to forgo CPR by the second week after enrollment, and 39% of control patients and 41% of intervention patients reported having a discussion about their prognosis with a physician. Of those who did not discuss their prognosis, 44% of control patients and 42% of intervention

Table 3.—Effect of the SUPPORT Phase II Intervention on Five Outcomes: Intervention Group vs Control Group, 1992 to 1994

	Adjusted Ratio (95% CI)
Median time until DNR order was written, d	1.02 (0.90-1.15)
DNR agreement, %	1.22 (0.99-1.49)
Undesirable states, median d	0.97 (0.87-1.07)
Pain, %	1.15 (1.00-1.33)
Resource Use, median 1993 dollars	1.05 (0.99-1.12)

\*SUPPORT indicates Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment; DNR, do not resuscitate; and CI, confidence interval.

patients reported that they would like to have such a discussion.

### Physician's Perspective on Intervention

In the second physician interview, 59% acknowledged receiving the prognostic reports and 34% acknowledged receiving the preference reports. Fifteen percent reported discussing this specific information with patients or families. Nearly a quarter of respondents (22%) said they thought the SUPPORT nurses' involvement improved patient care.

### Safety Monitoring

After adjusting for baseline differences, the 6-month mortality for phase II control patients was the same as for intervention patients (adjusted relative hazard, 0.95; 95% CI, 0.87 to 1.04). Both control (68%) and intervention (69%) patients or surrogates rated their care as excellent or very good.

### COMMENT

Findings from phase I of SUPPORT documented many shortcomings of care. The SUPPORT patients were all seriously ill, and their dying proved to be predictable, yet discussions and decisions substantially in advance of death were uncommon. Nearly half of all DNR orders were written in the last 2 days of life. The final hospitalization for half of patients included more than 8 days in generally undesirable states: in an ICU, receiving mechanical ventilation, or comatose. Families reported that half of the patients who were able to communicate in their last few days spent most of the time in moderate or severe pain. Based on a study in a defined population at our Wisconsin site, we estimate that patients meeting SUPPORT criteria account for approximately 400 000 admissions per year in the United States and that another 925 000 people are similarly ill but would not meet SUPPORT entry requirements of being hospitalized or in intensive care.<sup>38</sup> Patients with SUPPORT illnesses and severity account for about 40% of persons dying in the defined population.

Table 4.—Effect of the SUPPORT Intervention on Five Outcomes Within the Major Disease Categories\*

	Unadjusted Outcomes				Adjusted Outcomes			
	Acute Respiratory or Multiple System Failure	Acute Exacerbation of Cirrhosis, COPD, or CHF	Coma	Advanced Lung or Colon Cancer	Acute Respiratory or Multiple System Failure	Acute Exacerbation of Cirrhosis, COPD, or CHF	Coma	Advanced Lung or Colon Cancer
Median time until DNR order was written, d								
Control	46	40	10	58	38	41	8	40
Intervention	34	45	10	14	41	50	10	21
DNR agreement, %								
Control	11	13	33	17	8	8	25	18
Intervention	13	14	21	32	9	10	18	26
Undesirable states, median d								
Control	10	9.5	6	1	11	7	6.5	1
Intervention	9	4	6	0	10	4	7	1
Pain, %								
Control	17	16	5	21	17	16	9	20
Intervention	17	18	9	23	18	16	12	26
Resource use, median 1993 dollars								
Control	36 800	9000	26 900	5700	32 700	9100	20 900	5100
Intervention	30 300	8100	19 500	5600	33 400	8900	22 000	6100

\*SUPPORT indicates Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments; COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; and DNR, do not resuscitate.

Building on the findings in phase I, observations of others,<sup>1-16,22,24,39-45</sup> the opinions of physicians at the five sites, and the marked variation in their baseline practices, the phase II intervention aimed to make it easier to achieve better decision making for these seriously ill patients. The intervention gave physicians reliable prognostic information and timely reports of patient and surrogate perceptions, the two most important factors cited recently by physicians when considering life-support decisions for critically ill patients.<sup>44</sup> The intervention nurse also undertook time-consuming discussions, arranged meetings, provided information, supplied forms, and did anything else to encourage the patient and family to engage in an informed and collaborative decision-making process with a well-informed physician (Table 1).

The intervention was limited by its application to a diverse group of physicians and patients, all of whom had to comply voluntarily. The intervention had to be perceived as helpful, polite, and appropriate. As an initial attempt to change outcomes for seriously ill patients, we did not seek authority to be coercive or more than minimally disruptive. As designed, however, the intervention was vigorously applied. The SUPPORT nurses were committed, energetic, and highly trained. They engaged in the care of virtually all our patients, and nearly everyone had printed reports delivered promptly.

Because we thought that changes in the decision-making processes that were not reflected in improved patient outcomes would not be worth much expense, we specified five outcomes, each indicating an important improvement in patient experience, as the main targets of the intervention.

The intervention had no impact on any of these designated targets (Tables 3 and 4). Furthermore, even though the targeted outcomes are objectives of much ethical and legal writing and of some explicit social policy (such as informed consent statutes, the Patient Self-determination Act, and guidelines on pain),<sup>10-17</sup> there were no secular trends toward improvement for intervention or control patients during the 5 years of SUPPORT data collection (Figure 2).

These results raise fundamental questions about the intent and design of this trial. Do patients and physicians see the documented shortcomings as troubling? Can enhanced decision making improve the experience of seriously ill and dying patients? Were the inevitable limitations of this project too great to draw strong conclusions?

Because there was no movement toward what would seem to be better practices, one could conclude that physicians, patients, and families are fairly comfortable with the current situation. Certainly, most patients and families indicated they were satisfied, no matter what happened to them. Physicians have their established patterns of care, and while they were willing to have the SUPPORT nurse present and carrying on conversations, physician behavior appeared unchanged. Perhaps physicians and patients in this study acknowledged problems with the care of seriously ill patients as a group. However, when involved with their own situation or engaged in the care of their individual patients, they felt they were doing the best they could, were satisfied they were doing well, and did not wish to directly confront problems or face choices.<sup>46,47</sup>

The study certainly casts a pall over

any claim that, if the health care system is given additional resources for collaborative decision making in the form of skilled professional time, improvements will occur. In phase II of SUPPORT, improved information, enhanced conversation, and an explicit effort to encourage use of outcome data and preferences in decision making were completely ineffectual, despite the fact that the study had enough power to detect small effects.

It is possible that the intervention would have been more effective if implemented in different settings, earlier in the course of illness, or with physician leaders rather than nurses as implementers. Perhaps, it would have been effective if continued for more time or tested at later end points.<sup>48</sup> However, the overall results of this study are not encouraging. No pattern emerged that implied that the intervention was successful for some set of patients or physicians or that its impact increased over time. The five hospitals had been chosen for their diversity and their willingness to undertake a substantial and controversial challenge. Yet none showed a tendency toward improvement in these outcomes.

SUPPORT did demonstrate, however, that issues this complex can be studied with sufficient scientific rigor to be confident of the findings. We achieved good interview response rates among seriously ill patients, their families, and physicians, widespread acceptance of the intervention in diverse hospitals, and high-quality data. Consent and confidentiality issues were complex but amenable to solution. The analytic issues required application of relatively novel approaches, but they proved effective. The study also demonstrated the need for such methods



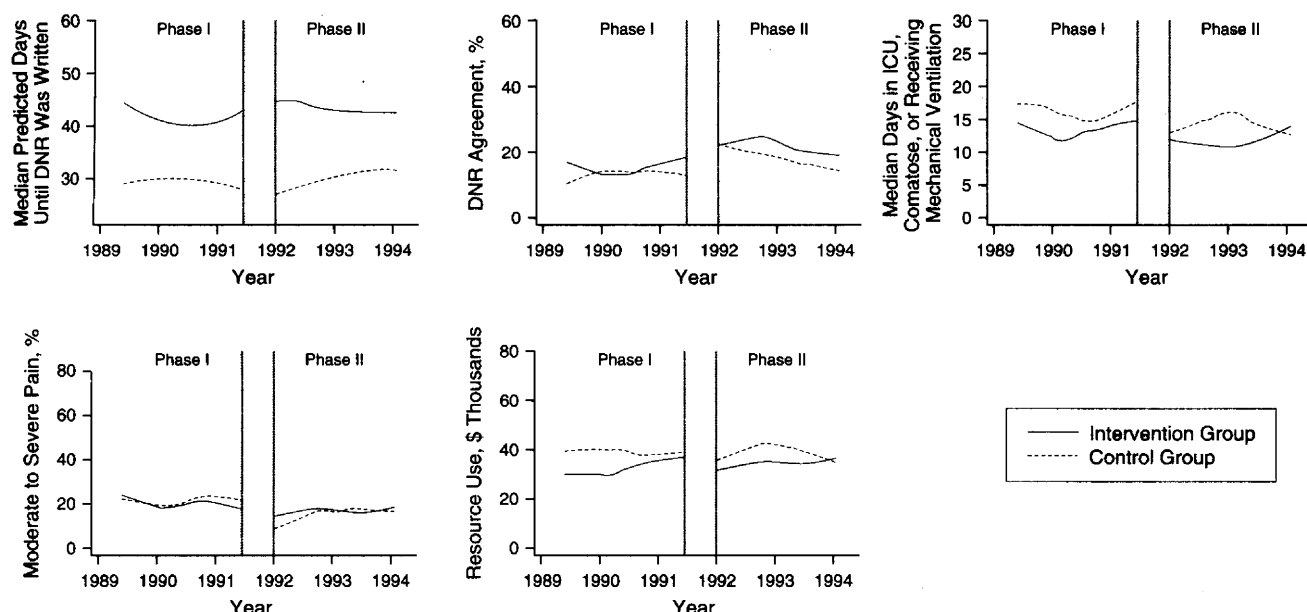


Figure 2.—Secular trends in five patient outcomes in the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT) from June 1989 through January 1994. The horizontal axes represent the years of SUPPORT (1989 to 1994). The time between phase I and phase II is represented by a space. The intervention and control group lines have been smoothed nonparametrically. The phase II results represent the actual impact of the trial, and the phase I results are the baseline or historical differences. There were no significant differences in intervention patients between phases I and II, and after adjustment, no significant differences were noted between phase II control and intervention patients for the five main outcomes. DNR indicates do not resuscitate, and ICU, intensive care unit. (See text for detailed definitions and exact sample sizes.)

when performing evaluations of complex interventions in seriously ill patients. We would have concluded that the intervention positively influenced all outcomes had we not had phase I results for baseline adjustment and phase II control patients to evaluate secular trends (Table 4 and Figure 2).

In conclusion, we are left with a troubling situation. The picture we describe of the care of seriously ill or dying persons is not attractive. One would certainly prefer to envision that, when confronted with life-threatening illness, the patient and family would be included in discussions, realistic estimates of outcome would be valued, pain would be treated, and dying would not be prolonged. That is still a worthy vision.<sup>2,49</sup> However, it is not likely to be achieved through an intervention such as that implemented by SUPPORT. Success will require reexamination of our individual and collective commitment to these goals, more creative efforts at shaping the treatment process, and, perhaps, more proactive and forceful attempts at change.

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All methods of the SUPPORT project are available to investigators for further study and implementation. Details of the day 3 survival and functional status models have been published,<sup>25,26</sup> and models for other days are available from the authors, as is technical information on baseline risk or propensity scores for SUPPORT's major targets. Requests for these materials should be sent to William A. Knaus, MD, ICU Research Unit, Box 600, University of Virginia Health Sciences Center, Charlottesville, VA 22908.

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