Evaluation of Prognostic Criteria for Determining Hospice Eligibility in Patients With Advanced Lung, Heart, or Liver Disease

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ECHNOLOGICAL ADVANCES IN medicine and improvements in public health have enabled Americans to live longer and to survive potentially life-threatening events such as childbirth, infectious disease, and injury. A result of these advances has been the emergence of serious chronic diseases as a major pathway toward death.

Among the most common chronic diseases are chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), and end-stage liver disease (ESLD). Together, these 3 diseases account for almost 2 million hospitalizations and more than 175 000 deaths annually.^{1,2} In contrast to incurable metastatic cancer, in which there is often a marked decline in weight and function near the end of life,3 diseases involving chronic organ failure tend to have a more erratic course and to produce death at a time that is difficult to predict. 4-6 As a result, many patients with COPD, CHF, or ESLD never experience a time during which they are

For editorial comment see p 1670.

Context Many individuals involved with care of the dying advocate expanding access to hospice care for persons with advanced lung, heart, or liver disease. However, to be eligible, these patients generally must have a prognosis for survival of less than 6 months.

Objective To test the ability of currently available criteria to identify a population with a survival prognosis of 6 months or less among seriously ill hospitalized patients with 1 of 3 commonly fatal chronic diseases.

Design Validation study using data from the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT) phase 1 (June 1989-June 1991) and phase 2 (January 1992-January 1994), with a 6-month follow-up.

Setting and Patients Consecutive sample of 2607 seriously ill patients from 5 US medical centers who were hospitalized with chronic obstructive pulmonary disease, congestive heart failure, or end-stage liver disease, and who survived to hospital discharge.

Main Outcome Measures Descriptive and operating characteristics of 5 general and 2 disease-specific clinical criteria for identifying patients with a survival prognosis of 6 months or less, and 3 sets of combination criteria (broad, intermediate, and narrow inclusion) aimed at providing low, medium, and high thresholds for hospice eligibility based on National Hospice Organization guidelines.

Results Seventy-five percent of the sample survived more than 6 months after hospital discharge; 44% expressed a preference for palliative care. Broad inclusion criteria identified 923 patients eligible for hospice care, of whom 70% survived longer than 6 months. Intermediate inclusion criteria identified 300 patients, of whom 65% survived longer than 6 months. Narrow inclusion criteria identified 19 patients, of whom 53% survived longer than 6 months. Sensitivities and specificities of the combination criteria were 41.7% and 66.7% (broad inclusion), 16.2% and 90.1% (intermediate inclusion), and 1.4% and 99.5% (narrow inclusion), respectively.

Conclusions These data indicate that for seriously ill hospitalized patients with advanced chronic obstructive pulmonary disease, congestive heart failure, or end-stage liver disease, recommended clinical prediction criteria are not effective in identifying a population with a survival prognosis of 6 months or less.

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clearly dying of their disease. This observation has important implications for the treatment of patients with such diseases, especially with regard to their eligibility for hospice care.

Hospice programs in the United States provide specialized medical and support services for the management of terminal illness, mostly in patients' homes. The Medicare hospice benefit covers comprehensive services, including home care, short-term inpatient care, and medication costs, and is paid at a daily capitation rate of approximately \$100.7 Hospice care is also a covered benefit under most private insurance plans, managed care organizations, and state Medicaid programs.8 Hospice care has received widespread approval^{9,10} and is increasing in popularity; in the last 5 years, annual growth in the number of patients receiving hospice care nationwide has averaged 16%.8 The few studies comparing hospice with other care at the end of life suggest that (1) patients11 and families are satisfied with hospice care, (2) patients have fewer regrets than nonhospice patients, and (3) patients receiving hospice care are more likely to die in a way that is consistent with their wishes. 12,13

Despite its advantages, however, hospice care serves a small portion of the dying population for only a short period of time. About 20% of patients who die in the United States receive hospice care. Most patients enrolled in hospice are dying of cancer, although the proportion of hospice admissions for other diseases has increased steadily in recent years. 8

Under Medicare regulations, a beneficiary is eligible for hospice care coverage only if both the patient's attending physician and the medical director of the hospice certify that "the individual's prognosis is for a life expectancy of 6 months or less if the terminal illness runs its normal course." Surprisingly, the precise meaning of this definition has never been explicated and remains unclear. For example, the phrase "a life expectancy of 6 months or less if the terminal illness runs its normal course" could be interpreted to

mean that among patients with similar prognosis, more than half would be dead within 6 months. Alternatively, the phrase could be interpreted to require a much higher degree of prognostic accuracy (eg, 80% or 90% of patients would be dead within 6 months).

Aggregate Medicare survival data suggest that actual practice tends to reflect the latter, narrower interpretation.⁶ Only 15% of patients receiving Medicare hospice benefits survive longer than 6 months. The median survival of Medicare patients enrolled in hospice is under 40 days.¹⁷ Government regulators, too, may expect a high level of accuracy in predicting 6-month survival-not only in terms of aggregate patient data, but also at the level of individual patients. Fraud and abuse auditors acting for the Department of Health and Human Services Office of the Inspector General have begun investigating hospices and requiring repayment to Medicare for some patients who survived for more than 6 months.18 The Institute of Medicine's Committee on Care at the End of Life voiced its concern that regulators "may not understand the uncertainty inherent in projecting survival,"19 and that the Medicare prognosis provision "implies a degree of precision that does not exist."20 As the National Hospice Organization (NHO) has pointed out, "the Office of the Inspector General's intense scrutiny has had a chilling effect on appropriate referrals of terminally ill beneficiaries."21 The effect has been especially pronounced in patients dying of chronic conditions whose courses are difficult to predict.²⁰

The comparatively predictable final course of cancer—with its 1- to 2-month phase of progressive decline at the end of life—is well suited to the hospice model of care.³ But for individuals dying of diseases other than cancer, access has been limited, in part because they rarely manifest a discrete phase of inexorable decline at the end of life.⁵ Nonetheless, many have suggested that hospice care be expanded to manage the care of persons dying of chronic diseases such as COPD, CHF, amyotro-

phic lateral sclerosis, and Alzheimer disease. 22-26

In an effort to clarify eligibility for hospice care among patients with CHF, COPD, and other serious illnesses, the NHO has drafted guidelines for determining prognosis in selected noncancer diseases.23 The guidelines were created by an expert panel after an extensive review of the medical literature concerning short-term mortality in noncancer diseases. They were intended as a starting point for determining patient eligibility under the Medicare hospice benefit, with the caveat that their accuracy would need to be validated by future research. Despite this, they have already been widely accepted and used. In fact, the Health Care Financing Administration has distributed NHO's guidelines to its fiscal intermediaries as a tool to assist in the claims process.27 These offices have, in turn, used the guidelines in developing the conditions under which Medicare coverage for hospice care is approved or denied.27

In this study, we applied a variety of potential criteria for determining prognosis, including those based on NHO guidelines, to an existing database²⁸ to evaluate their accuracy in predicting death within 6 months among seriously ill patients with advanced chronic disease.

METHODS Study Population

This analysis used data from the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT).28 From June 1989 to June 1991 (phase 1) and from January 1992 to January 1994 (phase 2), SUPPORT enrolled patients, 18 years or older, who met specific criteria for 1 of 9 serious illnesses (nontraumatic coma, acute respiratory failure, multiorgan system failure with sepsis or malignancy, COPD, CHF, cirrhosis, metastatic colon cancer, or inoperable nonsmall cell lung cancer) and who were admitted to 1 of 5 medical centers (Beth Israel Hospital, Boston, Mass; Metro Health Medical Center, Cleveland, Ohio; Duke University Medical Cen-

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ter, Durham, NC; St Joseph's Hospital, Marshfield, Wis; and the University of California Los Angeles Medical Center). Inclusion criteria were designed to result in a group of patients with an aggregate mortality rate of 50% within 6 months. Patients were excluded if they died or were discharged within 48 hours of study enrollment, were admitted with a scheduled discharge within 72 hours, did not speak English, or had acquired immunodeficiency syndrome, multiple trauma, or pregnancy.

In this analysis we focused on patients with COPD, CHF, or ESLD. Inclusion criteria for COPD were clinical diagnosis of COPD, chronic bronchitis, chronic obstructive lung disease, or emphysema with breathlessness, respiratory failure, or mental status change as the main reason for hospital admission, and hypercapnia and hypoxemia ($PO_2 \leq 60 \text{ mm Hg}$ and $PCO_2 \geq 50 \text{ mm Hg}$ if the patient was receiving room air, or $PCO_2 \geq 50 \text{ mm Hg}$ alone if the patient was receiving supplemental oxygen) documented at admission. Patients in status asthmaticus were excluded.

Inclusion criteria for CHF were clinical diagnosis of CHF or cardiomyopathy with an exacerbation of symptoms as the primary reason for hospital admission and 1 of the following: (1) a history of severe CHF at baseline (New York Heart Association class III or IV) manifested by a history of dyspnea at rest or with minimal exertion related to primary cardiac failure, and medications before admission that included at least 2 drug classes (diuretics, vasodilators, or adrenocortical extract inhibitors); (2) a history of class III or IV CHF at admission, dyspnea at rest, and systolic blood pressure of 100 mg Hg or less, or a history of hypotension that precluded the use of these diuretics, vasodilators, or adrenocortical extract inhibitors: or (3) documentation of severe CHF with an ejection fraction of 20% or less. Patients with CHF were excluded from the study if they had any of the following: severe COPD, shock, primary acute renal failure, decreased systemic vascular resistance, restrictive cardiac disease, circulatory overload, CHF primarily due to valvular heart disease, cardiac surgery, or thoracotomy during current hospitalization.

Inclusion criteria for ESLD were chart documentation of cirrhosis and at least 2 of the following: a serum albumin level of 30 g/L or less, a serum bilirubin level of 51 µmol/L (3.0 mg/dL) or more, uncontrolled ascites, hepatic encephalopathy, cachexia, or a massive gastrointestinal tract bleed defined as transfusion of 2 or more units of blood in 24 hours and either hematemesis or gross blood on endoscopic visualization or nasogastric tube aspiration.

Data Collection

All patients admitted to the 5 hospitals were screened daily by trained research nurses and those meeting disease and severity criteria were enrolled. Protocols for enrollment and data collection were approved by the institutional review boards at all participating hospitals. Chart reviews provided information about each patient's disease history as well as clinical characteristics used to calculate survival estimates according to the multivariate SUPPORT prognostic model, as described elsewhere. 29 In addition, charts provided information about whether patients were transferred to hospice care or prescribed home care services on discharge from the index hospitalization or on any later discharge from a SUPPORT hospital during the 6-month study follow-up, as well as whether patients were readmitted to a SUPPORT hospital within 2 months of the first discharge. For COPD patients, charts were also reviewed for documentation of clinical evidence for cor pulmonale. For CHF patients, left ventricular ejection fraction (if assessed within the prior 6 months and documented), and supraventricular or ventricular arrhythmias (before study entry or during any hospitalization) were noted. For ESLD patients, chart documentation of cachexia (including wasting, malnourishment, emaciation) was recorded.

During the first week after study entry, informed consent was obtained for interviews with both patients and surrogate decision makers. Interviews included questions about the patient's functional status 2 weeks prior to study entry, weight change in the last 2 months, and preferences about palliative care. Functional status was measured by a modified version of the Katz Index of Activities of Daily Living Scale.³⁰ The Activities of Daily Living Scale ranged from 1 to 7 points and measured impairment in bathing, dressing, eating, continence, transferring, toileting, and walking, with a higher score indicating worse function. Preference for palliative care was assessed by the question, "If you had to make a choice at this time, would you prefer a course of treatment that focuses on extending life as much as possible, even if it means having more pain and discomfort, or would you want a course of treatment that focuses on relieving pain and discomfort as much as possible, even if that means not living as long?"

Prognostic Criteria

Variables tested in this analysis were chosen to approximate the prognostic criteria listed in the NHO's *Medical Guidelines for Determining Prognosis in Selected Noncancer Diseases*. ²³ The NHO criteria were operationalized using the SUPPORT data as summarized in TABLE 1. Information was available relevant to each proposed domain. In the instances that data from SUPPORT were insufficient, a proxy measure in the same domain was substituted. Proxy measures were selected to err on the side of broader inclusion.

For each patient case, 7 variables were analyzed. Of these, 5 were general clinical criteria that applied to all patients regardless of their disease category: readmission within 2 months, home care after discharge, activities of daily living dependency of 3 or more, weight loss of 2.3 kg (5 lb) or more within 2 months, albumin level of less than 25 g/L. In addition, 2 disease-specific clinical criteria were applied to each case: cor pulmonale and PO₂ of 55 mm Hg or less while receiving oxygen in patients with COPD; ejection fraction of 20% or less and arrhythmia in pa-

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tients with CHF; and cachexia and creatinine level of 153 umol/L (2.0 mg/dL) or more in patients with ESLD.

Current NHO guidelines do not specify the number or combination of the recommended clinical criteria to be used to predict 6-month mortality; rather, clinical judgment is suggested. This analysis used 3 sets of combination criteria, termed broad inclusion, intermediate inclusion, and narrow inclusion, aimed at providing a low, medium, and high threshold for selecting patients for hospice care eligibility based on the NHO recommendations. All 3 sets of criteria required that either the patient or the surrogate express a preference for palliative care, as consent was always a prerequisite for hospice enrollment. In addition to preference for palliative care, the different combination criteria required varying numbers of the 7 possible clinical criteria relevant to the disease. Broad inclusion required at least 1, intermediate inclusion required at least 3, and narrow inclusion required the presence of 5 of 7 possible clinical criteria.

In tabulating physiologic measurements (PO2, albumin, creatinine), we used the most normal value if more than

1 were available. For the interview data (preference for palliative care, use of home care, activities of daily living dependency, weight loss), surrogate responses were calibrated to patients' responses and substituted if the patient was not interviewed but the surrogate was. In this analysis, patient information was missing and surrogate responses were substituted in 30.1% of cases for these scores, while neither patient nor surrogate data were available in 17.6% of cases. Patients with no interview data did not differ significantly from patients with interview data in respect to disease severity, predicted prognosis, or actual survival.

Data Analysis

The relevant clinical criteria and the 3 different combinations of criteria were applied to patients in each disease category. For comparison, we also examined 6-month prognostic estimates of 50% or less and 10% or less by the SUPPORT model,²⁹ as well as actual referrals to hospice care. These analyses were applied only to the subset of patients who survived the enrollment hospitalization, as they were considered the

most likely candidates for hospice referral and, therefore, the group for whom prognostic criteria would be relevant in clinical practice.

Descriptive statistics were used to characterize patients for each criterion regarding survival days after discharge from the index hospitalization. The number of survival days was determined by the National Death Index, updated to December 31, 1994. If a patient were still alive on this date, his/her survival time was censored. The interquartiles of survival days for patients who met each criterion were estimated using the Kaplan-Meier estimator. To further elucidate the clinical usefulness of various methods for identifying patients with a prognosis of 6 months or less, we calculated sensitivity, specificity, and positive and negative likelihood ratios (LRs). In addition, we calculated the area under the receiver operating characteristic (ROC) curve for the NHO guideline-based criteria.

RESULTS

SUPPORT enrolled 9105 patients, of whom 2954 were categorized with 1 of the targeted advanced chronic dis-

Table 1. Operationalization of National Hospice Organization (NHO) General Guidelines for Determining Prognosis

NHO Guidelines Criteria Used in This Study

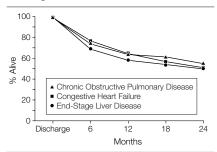
The patient should meet all of the following criteria:

- I. The patient's condition is life limiting, and the patient and/or family have been informed of this determination.
- II. The patient and/or family have elected treatment goals directed toward relief of symptoms, rather than curing the underlying disease.
- The patient has either of the following:
 - A. Documented clinical progression of disease, which may include: 1. Progression of the primary disease process as listed in the disease-specific criteria, as documented by serial physician assessment, laboratory, radiologic, or other studies
 - 2. Multiple emergency department visits or inpatient hospitilizations over the prior 6 months.
 - 3. For homebound patients receiving home health services, nursing assessment may be documented.
 - 4. For patients who do not qualify under 1, 2, or 3, a recent decline in functional status may be documented. Functional decline should be recent. . . . Clinical judgment is required for patients with impaired status due to a different non-terminal disease. . Diminished functional status may be documented by either a Karnofsky performance status of <50%, or dependence in at least 3 of 6 activities of daily living (bathing, dressing, feeding, transfers, continence of urine or stool, ability to ambulate independently to bathroom).
 - B. Documented recent impaired nutritional status related to the terminal process:
 - 1. Unintentional, progressive weight loss of >10% over the prior
 - Serum albumin <25 g/L may be a helpful prognostic indicator, but should not be used in isolation from other factors above.

- I. All Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT) patients were hospitalized with a serious life-limiting illness. The degree to which they understood this was not systematically assessed.
- The analogous measure used in this analysis was termed preference for palliative care.
- III. A. 1. Disease-specific criteria were selected from factors named in NHO guidelines for chronic obstructive pulmonary disease and congestive heart failure, excluding those that matched SUPPORT inclusion criteria. For chronic obstructive pulmonary disease we used evidence of cor pulmonale and hypoxemia ≤55% on supplemental oxygen. For congestive heart failure we used ejection fraction ≤20% and supraventricular or ventricular arrhythmia. The NHO guidelines do not specify criteria for end-stage liver disease, but to parallel the other analyses we chose documented cachexia and creatinine ≥153 µmol/L (2.0 mg/dL).
 - 2. SUPPORT did not collect data on the 6 months prior to enrollment, Instead, we examined patients who were readmitted to a SUPPORT hospital within 2 months of the first discharge.
 - 3. Although home care nursing assessments were not available, we were able to determine whether patients were prescribed home care services after discharge.
 - 4. SUPPORT did not collect data on how recently a decline in functional status occurred. We used Katz index ≥3 (indicating dependence in at least 3 of 7 activities of daily living) 2 weeks prior as reported on patient or surrogate interviews.
 - We used weight loss >2.3 kg (5 lb) in the preceding 2 months.
 - 2. Albumin measurement was available for 605 patients

eases as their first diagnosis: 1016 with COPD, 1404 with CHF, and 534 with ESLD. Among all 3 groups of patients

Figure 1. Estimated Survival of SUPPORT Patients With Chronic Disease After Hospital Discharge



SUPPORT indicates the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments.

with advanced chronic disease, 347 (12%) died during their enrollment hospitalization, including 116 COPD patients (11%), 92 CHF patients (7%), and 139 ESLD patients (26%). Of the 2607 patients who survived to leave the hospital and would therefore be potential hospice care candidates, 54 (2%) were discharged to a hospice program. FIGURE 1 depicts survival after discharge for patients in each disease category.

TABLE 2 summarizes survival after discharge for patients meeting various prognostic criteria for hospice enrollment, stratified by disease. The combined data for all 3 diseases are summarized here. Of the 2607 patients who

survived to leave the hospital and were included in this study, 655 (25%) were dead within 6 months of discharge. The estimated median survival time for the study population was 804 days (interquartile range, 181 to . . . [not able to calculate accurately]). A large minority of patients expressed a preference for palliative care (44%). Those who did express such a preference had an increased probability of dying within 6 months. Each of the 5 general criteria and the 2 disease-specific criteria we tested also identified a subset of patients with a similar or slightly increased risk of dying within 6 months.

Simulating the NHO criteria as described for broad inclusion (preference

Table 2. Survival After Hospital Discharge Among Patients With Chronic Disease Meeting Prognostic Criteria for Hospice Enrollment, by Disease Category*

	Chronic Obstructive Pulmonary Disease			Congestive Heart Failure			End-Stage Liver Disease		
Prognostic Criteria	No. of Subjects	Alive at 6 mo, %	Median (Interquartile Range) Survival, d	No. of Subjects	Alive at 6 mo, %	Median (Interquartile Range) Survival, d	No. of Subjects	Alive at 6 mo, %	Median (Interquartile Range) Survival, d
SUPPORT inclusion Survived to discharge	900	74	896 (178-NA)	1312	77	760 (208-NA)	395	69	720 (111-NA)
Patient preference Palliative care	302	70	849 (138-NA)	524	75	654 (187-NA)	134	63	425 (74-NA)
General clinical criteria Readmission within 2 mo	194	61	442 (90-NA)	311	68	600 (105-1664)	135	55	279 (62-NA)
Use of home care services	336	72	790 (168-NA)	417	76	579 (190-1664)	85	59	316 (95-NA)
Dependent in ≥3 activities of daily living	109	58	307 (65-1573)	124	69	391 (95-1312)	58	53	431 (64-NA)
Weight loss ≥2.3 kg (5 lb) within 2 mo	274	68	748 (120-NA)	525	79	804 (238-NA)	158	68	700 (96-NA)
Albumin <25 g/L	39	59	663 (43-NA)	30	63	281 (52-NA)	208	67	802 (94-NA)
Disease-specific clinical criteria Evidence of cor pulmonale	225	81	1058 (337-NA)						
Hypoxemia ≤55 mm Hg while receiving oxygen	81	77	1105 (219-NA)						
Ejection fraction ≤20%				553	73	680 (164-NA)			
Documented arrhythmia				503	75	579 (190-1664)			
Documented cachexia							75	69	963 (131-NA)
Creatinine ≥153 µmol/L (2.0 mg/dL)							29	45	78 (11-NA)
Combination criteria† Broad inclusion	323	68	796 (118-1901)	473	75	618 (175-NA)	127	61	346 (67-NA)
Intermediate inclusion	78	67	765 (116-NA)	170	69	411 (102-1233)	52	48	164 (47-1165)
Narrow inclusion	2	50	NA	12	58	186 (59-330)	5	40	132 (75-963)
Predicted survival, 6-mo prognosis‡ ≤50%	117	56	284 (50-1190)	97	53	206 (52-1041)	99	52	241 (29-NA)
≤10%	8	25	39 (30-520)	8	38	82 (36-311)	11	55	273 (10-NA)

^{*}SUPPORT indicates Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments; NA, data unavailable because they cannot be determined; ellipses, data not applicable.

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[†]Broad, intermediate, and narrow inclusion criteria required both preference for palliative care and at least 1 for broad, 3 for intermediate, and 5 for narrow of the 7 clinical criteria relevant to each disease.

‡Estimated by the SUPPORT multivariate model.

for palliative care and 1 or more relevant clinical criteria), 923 patients were identified, of whom 70% survived more than 6 months after discharge. Using the intermediate inclusion criteria (preference for palliative care and ≥ 3 clinical criteria), 300 patients were identified and 65% survived more than 6 months. Using the narrow inclusion criteria (preference for palliative care and ≥5 clinical criteria), 19 patients were identified and 53% survived more than 6 months. The corresponding median survival was 654 days (interquartile range, 129 to . . . [not able to calculate accurately]) for broad inclusion, 418 days (interquartile range, 89-1763) for intermediate inclusion, and 183 days (interquartile range, 65-474) for narrow inclusion.

Using the SUPPORT prognostic model to estimate 6-month survival after discharge, we identified 313 patients whose prognosis was 50% or less and 27 patients whose prognosis was 10% or less. Of those with a prognosis of 50% or less, the actual 6-month survival rate was 54% and the median survival was 236 days (interquartile range, 46 to . . . [not able to calculate accurately]). For those with a prognosis of 10% or less, 41% were still alive at 6 months, and the median survival was 67 days (interquartile range, 18-666).

TABLE 3 shows the characteristics of the 54 patients whose medical records documented a discharge to hospice care. Compared with other patients in the study, those referred to hospice care were slightly older and more often white, but similar with respect to sex. In the hospice group, a higher proportion of patients had COPD or ESLD, while a lower proportion had CHF. Patients discharged to hospice programs were not significantly more likely to meet the broad, intermediate, or narrow inclusion criteria. The SUPPORT prognostic model predicted significantly lower 6-month survival rates for the hospice care group. Actual median survival among patients referred to hospice was 23 days (6-145), in contrast to 842 days (200 to . . . [not able to calculate accurately]) for other patients. The propor-

Table 3. Characteristics of Patients Discharged to Hospice Compared With Other Patients*

	0 1		
Characteristic	Discharged to Hospice (n = 54)	Other Patients (n = 2553)	P Value
Demographic variables	70 (64 70)	67 (56 76)	000
Age, median (interquartile range), y	72 (64-78)	67 (56-76)	.002
Male	56	58	.68
White	93	79	.02
Diagnostic group Chronic obstructive pulmonary disease	55	34 7	
Congestive heart failure	15	51	.001
End-stage liver disease	30	15	
Combination criteria† Broad inclusion	80	85	.27
Intermediate inclusion	56	54	.88
Narrow inclusion	35	23	.05
Predicted survival, 6-mo prognosis‡ ≤50%	47	11	.001
≤10%	11	1	.001
Actual survival Alive at 6 mo	22	76	.001
Survival, median (interquartile range), d	23 (6-145)	842 (200-NA)	.001

^{*}Values are percentages unless otherwise indicated.

Table 4. Operating Characteristics of Prognostic Criteria for Predicting Death Within 6 Months After Hospital Discharge Among Patients With Chronic Disease

ecificity, %†	Ratio‡	Likelihood Ratio§
66.7	1.25	.874
90.1	1.63	.931
99.5	2.68	.991
91.4	2.57	.867
99.4	4.33	.981
99.4	10.43	.942
	90.1 99.5 91.4 99.4	66.7 1.25 90.1 1.63 99.5 2.68 91.4 2.57 99.4 4.33

^{*}Sensitivity indicates the probability that a patient who died within 6 months met the criterion. †Specificity indicates the probability that a patient who survived more than 6 months did not meet the criterion.

iate model.

tion of patients in hospice who outlived their 6-month prognosis was 22%.

TABLE 4 compares test characteristics for predicting death within 6 months of hospital discharge for broad, intermediate, and narrow inclusion criteria based on NHO guidelines; for the SUPPORT prognostic model; and for actual discharges to hospice. For all the criteria tested, the sensitivity was low. For example, if intermediate inclusion criteria were used to determine

hospice eligibility, only 16% of patients who were to die within 6 months would have qualified. Specificity, however, was high, such that most patients surviving more than 6 months would have been excluded.

Meeting the combination criteria we used to simulate NHO guidelines would increase a patient's chances of dying within 6 months so slightly as to be of limited usefulness clinically (positive LRs between 1.25 and 2.68). For example,

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[†]Broad, intermediate, and narrow inclusion criteria require both preference for palliative care and at least 1 for broad, 3 for intermediate, and 5 for narrow of the 7 clinical criteria relevant to each disease.

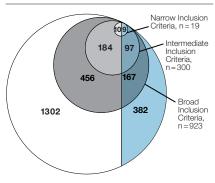
[‡]Estimated by the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments multivariate model.

Positive likelihood ratio indicates the likelihood that a patient who died within 6 months met the criterion, divided by the likelihood that a patient who survived more than 6 months met the criterion and reflects the degree to which the criterion increased a patient's pretest probability of dying within 6 months.

SNegative likelihood ratio indicates the likelihood that a patient who died within 6 months did not meet the criterion, divided by the likelihood that a patient who survived more than 6 months did not meet the criterion and reflects the degree to which not meeting the criterion decreased a patient's pretest probability of dying within 6 months.

||Estimated by the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments multivar-

Figure 2. Representation of Limited Ability of Prognostic Criteria to Predict Death Within 6 Months After Discharge Among Patients With Chronic Disease



Survived to Hospital Discharge, N=2607

Broad, intermediate, and narrow inclusion criteria required both preference for palliative care and at least 1 for broad, 3 for intermediate, and 5 for narrow of the 7 clinical criteria relevant to each disease. The left side of the figure represents the 1952 patients who were alive at 6 months and the right side of the figure that is highlighted in blue represents the 655 patients who were dead at 6 months. Values were estimated using the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments multivariate model.

any patient who was sick enough to be included in the current study would have a prior probability of 25% for dying within 6 months. Meeting the narrow inclusion criteria (positive LR, 2.68) would give a posterior probability of 47%. Changes of this magnitude are not sufficient to establish "a life expectancy of 6 months or less."

A 6-month prognosis of 50% or less or 10% or less according to the SUPPORT prognostic model would affect a patient's chances of dying within 6 months only somewhat more significantly (positive LRs, 2.57 and 4.33). Actual discharge to hospice care was the most powerful predictor of death within 6 months (positive LR, 10.43). In all cases, however, failure to meet the criteria would carry very little prognostic significance (negative LRs between 0.87 and 0.99).

Another method of assessing the value of a test across all possible cutoff points is the area under an ROC curve. The ROC area serves as a measure of diagnostic accuracy, specifically rank-order discrimination of a test. The possible values for this measure range from

0.5 to 1; the closer the area under the ROC curve is to 1, the more discriminating the test. For the NHO guideline—based combination criteria, the ROC area was 0.54 ± 0.01 , in which 0.5 would indicate a completely valueless test. The test achieved only 8% of the potentially available rank-order discrimination and can be seen, therefore, to be an extremely poor discriminator.

FIGURE 2 illustrates schematically the limited accuracy of the broad, intermediate, and narrow inclusion criteria in identifying patients with a prognosis of 6 months or less. The most restrictive criteria excluded almost all patients who survived longer than 6 months (falsepositive rate, 5.1%) but also excluded almost all patients in the target group (false-negative rate, 99%). The least restrictive criteria identified a group of patients whose risk of 6-month mortality was only slightly higher than that of the remaining SUPPORT patients, while still excluding most patients who were actually near death.

COMMENT

The prognostic criteria we used to simulate NHO guidelines were largely ineffective in predicting which seriously ill hospitalized patients with COPD, CHF, or ESLD have a prognosis of 6 months or less. Among patients meeting various combinations of criteria, 6-month survival ranged from 53% to 70%.

Despite their limited ability to predict 6-month survival, all criteria reduced the eligible population dramatically. Even the most inclusive combination of criteria eliminated 65% of SUPPORT patients with advanced chronic disease, including 58% of patients who actually died within 6 months of discharge. The most restrictive combination eliminated 99% of patients who died within 6 months.

Thus, the combination criteria we analyzed all succeeded in excluding most patients who lived longer than 6 months, but in doing so they also excluded the vast majority of the target group they were supposed to identify—patients who were dead in 6 months or less. And even though patients meeting various crite-

ria were somewhat more likely to die sooner, invariably a large proportion (>53%) lived longer than 6 months.

Does this imply that suggested clinical guidelines for determining prognosis in noncancer diseases are seriously flawed? Not necessarily. The more likely implication of this study is that the goal of determining in advance—with a high degree of accuracy—which individual patients with COPD, CHF, or ESLD will die within 6 months is unrealistic.

This analysis further suggests that if a high degree of predictive accuracy is demanded by those who interpret the 6-month prognostic requirement for hospice enrollment, few patients who die of these types of chronic diseases will be eligible for hospice care. Setting the threshold high (eg, stipulating that only 20% of patients should outlive their 6-month prognosis) would eliminate hospice access for these patients almost entirely. None of the criteria tested in this study succeeded in identifying a population of patients who met this stringent standard—not even by eliminating more than 99% of seriously ill patients.

Certainly, the prognosis for patients with advanced COPD, CHF, or ESLD is poor overall-worse even than the prognosis of many terminal cancer patients. But while cancer patients are often in relatively good health until a period near the end when they experience steady decline, patients with advanced lung, heart, or liver disease tend to live for variable lengths of time in a continuous state of poor health punctuated by intermittent exacerbations. For these patients, the proximate cause of death is often a relatively sudden and unpredictable event such as a pulmonary infection, a cardiac arrhythmia, or a massive gastrointestinal tract hemorrhage, which are all events that have a low rate of occurrence but a substantial per incident mortality rate. Put another way, the sickest patients are not necessarily the ones who die first.

This randomness factor in death due to chronic disease also explains why the SUPPORT prognostic model, which is known to have a high predictive accuracy overall among the patient population included in the study, ²⁹ failed to

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identify a sizable population of COPD, CHF, or ESLD patients who died within 6 months. Even among the small subset of patients with the worst prognosis (only 1% had an estimated prognosis of ≤10% at 6 months), 41% survived more than 6 months.

Of all the groups examined in the study, the 55 patients discharged directly to hospice care had the shortest median survival (24 days), as well as the smallest chance of surviving more than 6 months (21%). One possible explanation for this finding is that clinicians were able to identify patients with worse prognoses based on factors other than those analyzed in this study. Another possibility is that patients referred to hospice care are less likely to receive life-prolonging treatment and therefore die sooner. The current study does not attempt to differentiate between these 2 alternatives.

Another limitation of this analysis is that we were not able to precisely simulate all components of the NHO criteria. For example, the NHO guidelines rely heavily on changes over time, a dimension that is not well captured in the SUPPORT data. Although it is unquestionably possible that death within 6 months could be more accurately predicted through further refinement of these criteria, it seems implausible that accuracy for individual patients would improve enough to alter the central findings of this study.

It is also important to note that SUPPORT was a study of hospitalized patients and may not be generalizable to broader populations of patients with advanced chronic disease.³¹ For instance, seriously ill patients who seek aggressive hospital care may be less likely to choose hospice for their future care. Also, the SUPPORT population was younger than the national average for dying, and younger age has been shown to correlate with the use of more aggressive care.^{32,33}

This analysis presents a preliminary effort to test prognostic criteria for hospice enrollment among patients with advanced lung, heart, or liver disease

using existing data. A prospective study is required to understand the effects of these criteria in actual clinical practice. However, such a prospective study should assure that the overall population of persons dying due to chronic diseases is assessed, and not just those now referred for hospice enrollment. Studying only those referred could be helpful in addressing the question of whether a small population with dire short-term prognoses can be identified but would not address the question of how to meet the needs of the much larger population of patients who are dying of advanced chronic disease but who do not meet current eligibility criteria for hospice care.

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