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For the SUPPORT Investigators

Being classified as "terminally ill" conveys a special status for certain public policies. Terminally ill individuals are eligible for hospice care funded by Medicare and also qualify to effectuate their living wills.[1] Under several current proposals, terminally ill individuals would also be permitted to have physician assistance in suicide.[2] The cases currently before the United States

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        1.   42 USCA § 1395d(4); Miesel A. *The Right to Die*; 2nd ed. (John Wiley & Sons Inc., NY) 1989.
        2.   *See* Compassion in Dying v. Washington, 79 F.3d 790 (9th Cir. 1996), *en banc*, *cert. granted*, Washington v. Glucksberg, 65 U.S.L.W. 3254 (U.S. Oct. 1, 1996) (No. 96-

Supreme Court require that a patient be terminally ill in order to have a Constitutional right to have a physician assist in suicide.[3] This article delineates three potential strategies for defining "terminally ill" and the empirical problems with each for purposes of policy development and interpretation. The evidence provided in this article shows that each of these strategies is so problematic that it seems untenable to have physician-assisted suicide restricted to those classified as "terminally ill."

In order for the categorization of "terminally ill" to be useful in policy, the following criteria apply:

1. A clear definition of "terminal illness" so that almost all individuals may be classified correctly;
2. A reasonable survival period of persons who are categorized as "terminally ill" (in order to make, effect, and be affected by decisions or to receive benefits);
3. A period of "terminal illness" recognizable for most lethal chronic diseases;
4. Competence of persons within the category, at least for part of their time as "terminally ill."

Surprisingly, public policy has not been forced to clarify this category. The Medicare hospice benefit, for example, is limited to persons whose physicians attest that the patient has "a terminal illness with a life expectancy of six months or less."[4] Neither statute nor regulation, however, delineates exactly how to translate the life expectancy requirement. One might infer that a "life expectancy of six months or less" means that any patient with less than a fifty-fifty chance of surviving for that time period would be eligible. The program, however, has not been implemented to reflect this interpretation. Only 15% of patients receiving hospice care under Medicare are alive for six months or more, and the median survival in hospice is about thirty-six days.[5] Hospice patients generally have much worse than a 50-50 chance to live six months. In fact, inspectors acting for Medicare have investigated certain hospices which were admitting unusual numbers of long-term survivors (more than six months) and have required repayment to Medicare for the care of these

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110); Quill v. Vacco, 80 F.3d 716 (2d Cir. 1996), *cert. granted*, Vacco v. Quill, 65 U.S.L.W. 3254 (U.S. Oct. 1, 1996) (No. 95-1858); C.S. Campbell et al., *Conflicts of Conscience: Hospice and Assisted Suicide*, HASTINGS CENTER REPORT 36-43 (May/June 1996); *A Model State Act to Authorize and Regulate Physician-Assisted Suicide*, 33 HARVARD JOURNAL ON LEGISLATION 1 (Winter 1996).

3. *Compassion in Dying*, 79 F.3d 790; *Quill*, 80 F.3d 716.

4. Xact Medicare Services, *Medicare Part B Reference Manual*, Revision 020, August 23, 1996.

5. N.A. Christakis & J.J. Escarce, *Survival of Medicare Patients After Enrollment in Hospice Programs*, 335 N. ENG. J. MED. 172-78 (1996).

patients.[6] A group sponsored by the National Hospice Organization has responded by drafting criteria for enrollment in hospice.[7] However, the group is unable to define successful compliance with the "less than six months survival" rule. Thus, it is difficult to determine whether the group has chosen the correct thresholds of disease severity. Should no one with better than a 10% chance to survive six months be enrolled? Or should the cutoff be set at a 50% chance?

Current proposals for legalizing physician-assisted suicide restrict eligibility to the "terminally ill." None of the proposals note or resolve the problems with defining that category. The discussion that follows sets forth three approaches for defining the term "terminally ill" and illuminates various problems with each based on an analysis of a large database collected from seriously ill hospitalized patients.

I. THE SUPPORT STUDY AND ITS PROGNOSTIC MODEL

SUPPORT is the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments, a five-hospital study of treatments and decision-making for seriously-ill patients.[8] SUPPORT enrolled 4301 patients between the years 1989 and 1991 and another 4,804 between the years 1992 and 1994. Every patient entering the five study hospitals during the four years of enrollment was evaluated for inclusion and was enrolled if the patient had one of nine serious illnesses at a stage worse than a defined threshold of severity. These illnesses, selected on the basis of high expected mortality rates and treatment dominantly in hospitals, included: acute respiratory failure or multiple organ system failure with sepsis; chronic obstructive lung disease; congestive heart failure; cirrhosis; coma; lung cancer; colon cancer; and multiple organ system failure with malignancy. The severity thresholds were established to select patients who were likely to survive more than 48 hours, but who otherwise represented advanced stages of the various diseases. Using these criteria, about 3% of the admissions to these hospitals were enrolled and accounted for 19% of the in-hospital deaths.[9] The overall population had 47% mortality

6. J. Lynn, *Caring at the End of Life*, 335 N. ENG. J. MED. 201-02 (1996).

7. National Hospice Organization, *Hospice Fact Sheet*, October 10, 1995.

8. SUPPORT, J CLIN EPI 43(suppl):1S-123S (D.J. Murphy & L.E. Cluff eds., 1990); The SUPPORT Investigators. *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)*, 274 JAMA 1591-1598 (1995).

9. W.A. Knaus et al., *The SUPPORT prognostic model: objective estimates of survival for seriously ill hospitalized adults*, ANN. INTERN. MED. 121,191-203 (1995).

within six months.[10] The exact enrollment criteria for each disease have been published.[11]

A model was developed for these patients which combined an array of laboratory measurements, vital signs, and diagnoses in a mathematical formula which estimates the patient's prognosis for survival to each day for the ensuing six months.[12] The model's estimates were very close to the actual survival of a new group of patients (good calibration) and to the estimates made by physicians. The nature of this kind of model and how to assess its performance has been summarized.[13] The data from SUPPORT provide the largest available source of empirical data on prognosis that are available for defining terminal illness in hospitalized patients with various diseases.

II. APPROACHES TO DEFINING "TERMINALLY ILL"

Three basic approaches are possible for defining the "terminally ill:" subjective judgment, statistical prognosis, or clinical condition. The first approach turns the determination over to someone, with some sort of process required, but without objective criteria. For example, the usual approach regarding living wills has been to delegate the determination of whether an individual is terminally ill to a physician, perhaps with some consultation required.[14] Other possibilities abound, including allowing the patient to make the determination, creating a committee for review, requiring judicial review, requiring consensus between the attending physician and named family members, etc. The subjective judgment approach is advantageous because it allows the individual making the judgment to consider many factors that are difficult to measure, such as patient preferences, weariness, readiness to die, spiritual preparation, suffering, and so forth.

From a public policy perspective, however, a subjective approach virtually guarantees substantial variation in application, a large number of contested cases, and an inability to hold anyone accountable since there are no articulated standards. There is no uniform understanding of the meanings of words used to represent quantifiable categories.[15]

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10. The SUPPORT Investigators, *A Controlled Trial.*

11. Knaus et al., *supra* note 9.

12. *Id.*

13. *Id.*; J. Lynn et al., *Accurate Prognostications of Death: Opportunities and Challenges for Clinicians*, WEST J. MED. 163, 250-257 (1995).

14. Miesel, *supra* note 1.

15. G.P. Bryant & G.R. Norman, *Expressions of Probability: Words and Numbers*, N. ENG. J. MED. 302, 411 (1980); A. Kong et al., *How Medical Professionals Evaluate*

The other two approaches limit the contribution of individual judgment and instead define the population either by a statistical prognosis or by showing that the patient has crossed an identifiable threshold in the course of an illness.

The statistical prognosis approach requires that public policy (e.g., in defining the population eligible for physician-assisted suicide) adopt a definition that requires that a terminally ill person has "less than x% chance to live y time." The statistical prognosis approach could be more complex, for example, by stating that the patient's survival must also be less than (x+a)% at some later time (y+b).

The fact that a statistical prognosis must include both a rate of survival and a time frame is almost as self-evident as it is widely ignored. The Medicare hospice benefit, notably, manages to give a date but not a rate. One does not know what rate of six-month survival should make a patient eligible and what should be seen as including too many or too few patients. If physician-assisted suicide is to be limited to persons defined as "terminally ill," then a statistical definition must state both the maximum expected survival rate and the time frame (or a statistical equivalent, such as mean expected survival time), as well as some statement of the data and analyses required and the rules for handling inadequately known prognoses.

A second data-driven approach is to define an observable clinical threshold of illness for each fatal disease. A patient with an illness expected to be fatal will be classified as "terminal" if the patient's health becomes worse than a stated threshold. For example, a person with severe lung disease might be designated as "terminal" when the blood concentration of oxygen at rest deteriorates to a certain point. However, such delineation would have to account for substantially different survival spans for various patients (with differing reserves, concurrent illness, etc.) and for different illnesses. Applying these criteria, for example, "terminally ill" might include all patients with pancreatic cancer and pain, for whom survival is usually a few months, and also all patients living "bed-to-chair" with congestive heart failure, for whom survival is usually more than a year.

The two objective approaches overlap substantially: the thresholds would be roughly congruent with the desired statistical prognosis. However, the statistical approach requires a sizable investment in research to generate the statistical model,

Expressions of Probability, 315 N. ENG. J. MED. 740-44 (1986); M.A. Nakao & S. Axelrod, *Numbers are Better Than Words: Verbal Specifications of Frequency Have no Place in Medicine*, 74 AM. J. MED. 1061-65 (1983).

which can then adjust for an array of predictor variables, including other diseases and overall physiological reserve. There will be many ambiguous cases, nevertheless, and patient eligibility under the selected criterion will not correspond to any discernible clinical event. On the other hand, use of a clinical threshold yields more efficient administration, since this approach turns on noting that the patient has had something happen, such as a hospitalization, a critically worsening laboratory value, the discovery of spread of disease, and so forth. This approach, however, does not reflect the complex interaction of multiple factors in shaping lifespan, such as deficiencies in physiologic reserve and the presence of complicating illnesses. Thus, there will be much more variation in the expected survival time of the population labeled as "terminally ill" under this approach.

The interrelationships of the two kinds of objective approaches are illuminated in Figure 1. The prognostic approach uses certain characteristics to predict survival time and divides the population into three parts (right side of figure 1): those known to have prognoses below a specified probability of surviving, those known to have prognoses above a specified probability of surviving, and those whose prognoses are uncertain with regard to the limit.

An additional factor not considered in this article is the necessary confidence one must have in the prognosis, e.g. $\geq 75\%$ certainty that the prognosis is above or below the threshold.

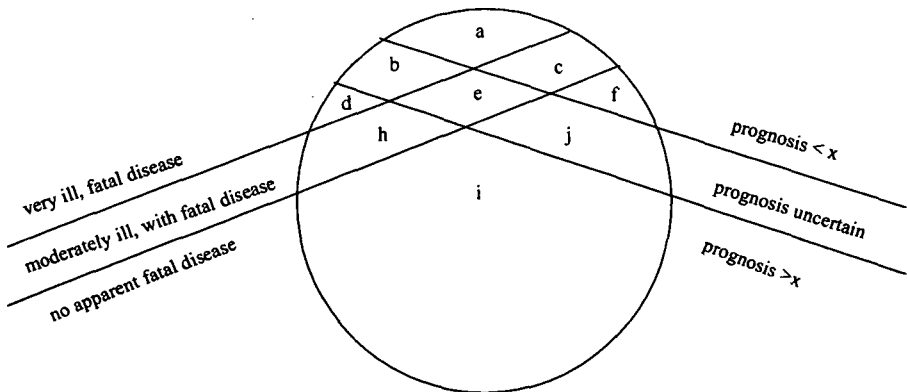Intersection of Prognostic and Threshold-Centered Approaches

Figure 1. Diagrammatic partitioning of the population using two approaches to objective definitions of "terminally ill:" by statistical prognosis and by clinical threshold.

The threshold criterion approach builds upon clinical evidence of disease severity and also divides the population into three parts: those individuals with illnesses which fall below some critical threshold; those individuals with illnesses which meet some less serious threshold, though are still expected to die of that illness; and those individuals who do not meet either threshold (i.e. the individuals are not sick, or only moderately so, or do not have a known fatal condition). Table 1 gives an example of the kind of condition which could be found in each partition of the population, using a prognosis of <20% to live six months in the right column and a set of thresholds similar to SUPPORT enrollment criteria on the left.[16] It is not clear which of these partitions would denote the "terminally ill" for any particular policy purpose, nor is it obvious which usage would best serve the population.

TABLE 1: Descriptions and examples of patients in each cell in Figure 1, using an óbjective prognosis of less than 20% to survive six months for the prognostic criterion.

	Description	Patient Example
a	near death and very ill	in shock from sepsis complicating metastatic cancer
b	very ill with fatal disease, statistical prognosis uncertain	bedbound with congestive heart failure
c	very bad prognosis, but not yet very ill	early pancreatic cancer
d	very ill, eventually fatal, but known to have longer life expectancy	Tay-Sachs infant, Huntington's disease, severe Parkinson's
e	moderately ill, eventually fatal but uncertain prognosis	Alzheimer's dementia with malnutrition
f	no illness, but bad prognosis	severe congenital lipoprotein abnormality
g	moderately ill, fatal illness, prognosis better than 20% for six months	early metastatic breast cancer
h	not ill, but uncertain prognosis	asymptomatic person with extremely high blood pressure
i	not ill, no reason for limited prognosis	healthy person

III. SUBJECTIVE APPROACHES TO DECIDING "TERMINAL ILLNESS"

One method of distinguishing the terminally ill from the sick or even the merely mortal is to apply individual judgment. Although the patient or a committee could render a judgment,

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16. Knaus, *supra* note 9.

actual or proposed statutes and regulations suggest that physicians make these determinations. How well can physicians be expected to do?

Although information about physician performance is available from many sources, the following statement is a previously unpublished insight from SUPPORT: Physicians often do not acknowledge impending death until late in the dying process when it is very certain. In hospitals, a patient whose heart stops will immediately receive resuscitation efforts unless a physician writes a "do not resuscitate" ("DNR") order precluding such attempts. Since all dying persons are potential candidates for resuscitation and because it is usually considered more harmful than beneficial to try to resuscitate a person dying from a known fatal disease, the timing of and rate at which DNR orders are written can be used as a proxy measure for the rate at which impending death is noted and plans acknowledging that eventuality can be made. Figure 2 shows the rate of DNR orders by days before actual death for the support population in the hospital on those days, and for some examples by disease.
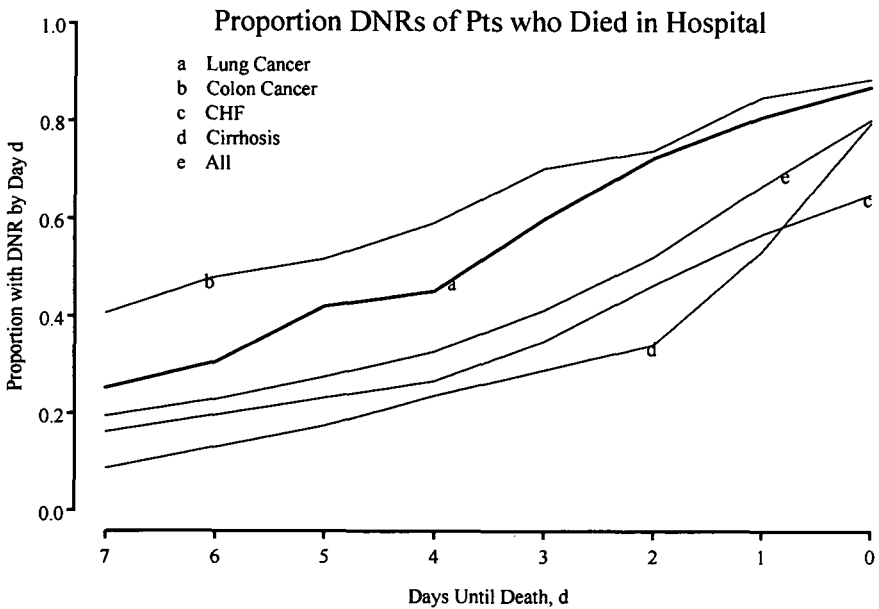

Figure 2. Proportion of the support population, overall and by disease, which had a DNR order, by day before death.

Figure 2 shows that DNR is generally applied late in the course of illness, usually in the last few days. For example, less than half of cancer patients have a DNR order one week before death. Although impending death is more predictable in cancer

patients, physicians are not managing these patients as if they were dying until death is clearly imminent.

Additionally, physicians' practices ordinarily vary substantially from region to region and from physician to physician.[17] This variation may be immaterial to many issues but is troubling to the issue of whether physicians should be permitted to provide lethal drugs for patients the physicians deem to be terminally ill. If terminal illness is not recognized until late within SUPPORT patients' last two weeks, and if there is substantial variation among physicians, those patients included within the category of "terminally ill" would often have little time in that status and would be included as "terminally ill" only in some regions or with some physicians.

IV. A STATISTICAL CRITERION FOR TERMINAL ILLNESS

Some categories reflect clear and natural divides, such as the categories of male and female. Often categories, however, are unavoidably arbitrary such as the categories of tall and short. Terminal illness as a statistical construct creates an arbitrary divide along a continuum that starts with optimal health, continues though various degrees of illness, and ends with states imminently incompatible with life. In order to understand the merits and difficulties with a statistical definition, it is necessary to review the actual survival curve for persons with less than a 50% chance to live six months according to the SUPPORT prognostic model. A 50% criterion represents the most inclusive statistical specification of a prognosis of "six months" as the definition of terminal illness.

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17. J.E. WENNBERG, THE DARTMOUTH ATLAS OF HEALTH CARE IN THE UNITED STATES (1996).

Observed Survival in Patients with
Predicted 6m Survival <= 0.5

a ARF/MOSF w/Sepsis
b All
c CHF
d Lung Cancer
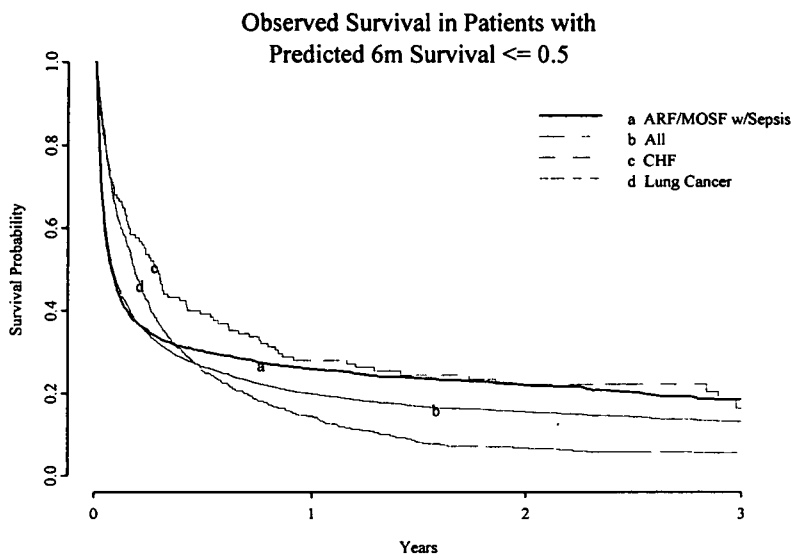
Survival Probability

Years

Figure 3. Actual survival of patients with SUPPORT model prognoses on their third study day of 50% or less chance to live six months, by disease.

The prognostic curve reflects a population whose members generally die quickly. Despite having the same range of prognoses, using one of the best models available, the mortality rates of the various illnesses differ over time, with half as many people being alive with lung cancer in a coma as with CHF at six months. Except for colon and lung cancer, each illness has a substantial "tail" of long term survivors: more than one-fifth of some patient groups are alive after two years.

If a definition of terminal illness were chosen that used a statistical prognosis of 50% survival at six months or less, questions of inclusion would be raised for patients with estimates near that divide. To illustrate the survival scenario for those whose six-month prognosis is near 50%, Figure 4 replicates Figure 3 above, but for those patients whose prognosis lies between 40% and 60% for six month survival.

Observed Survival in Patients with
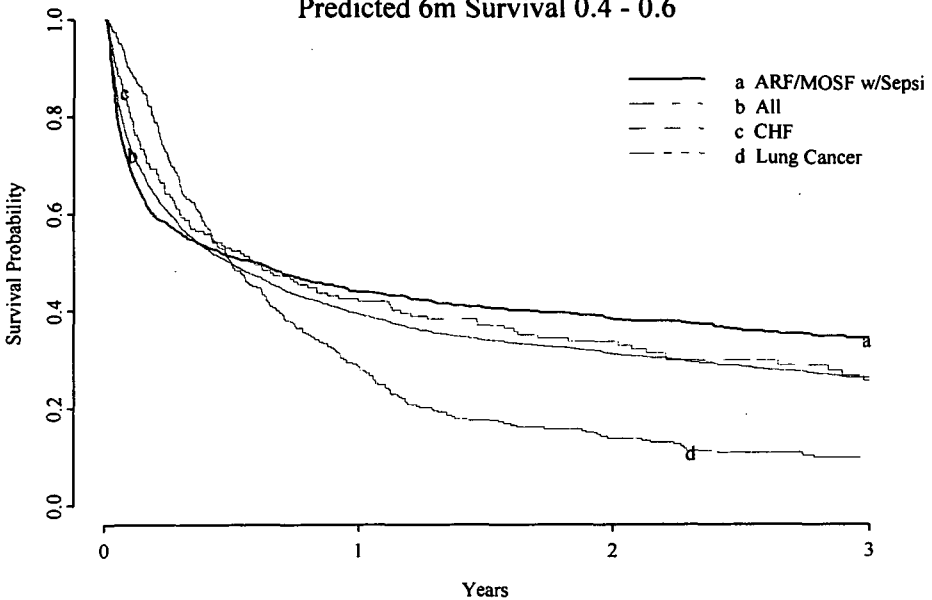Predicted 6m Survival 0.4 - 0.6

Figure 4. Actual survival of patients with SUPPORT model prognoses on their third study day of 40-60% chance to live six months, by disease.

In the population near the divide, obviously more "area lies under the curve," a representation of the amount of time that persons like this are still alive (if not dead by suicide). The size of the "tail" of long term survival in Figure 4 is approximately double that of Figure 3, with nearly two-fifths of patients with congestive heart failure still alive after two or three years.

Such large "tails" should be troubling to those trying to craft a definition of terminal illness suitable for allowing easier suicide. If the reason for creating a category of "terminally ill" is to include only persons with little life left to live, then the substantial rate of potential survivors refutes that aim. Policymakers might, therefore, choose to use a much more restrictive criterion, such as a <20% chance to live for six months. A set of curves for that group is given in Figure 5.

Observed Survival in Patients with
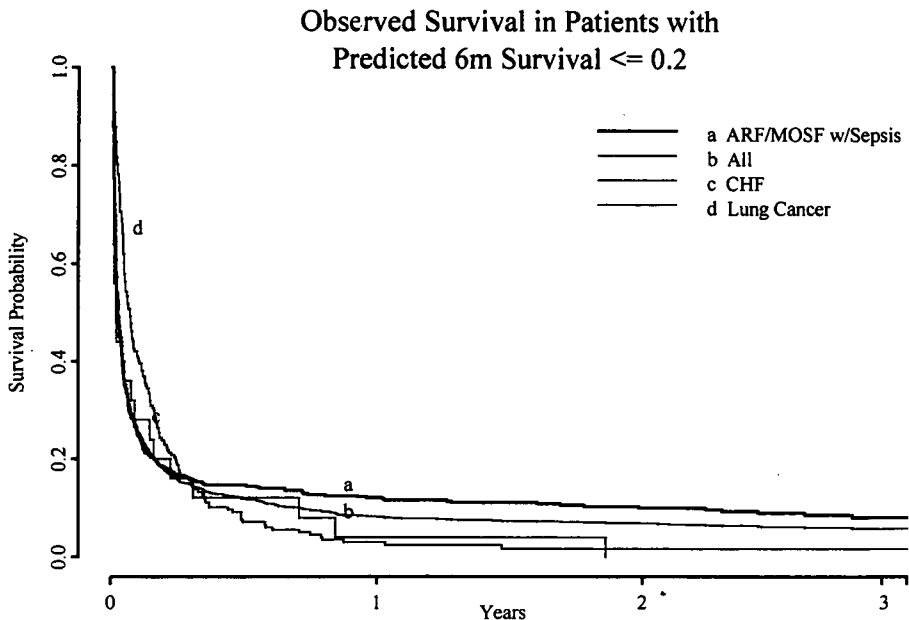Predicted 6m Survival <= 0.2

Figure 5. Actual survival of patients with SUPPORT model prognoses on their third study day of 20% or less to live six months, by disease.

Most individuals with prognoses this poor die within a few weeks. For many of these individuals, death is so close that there would not be any time to consider and effectuate a choice to die much differently. With prognoses this serious, few survive one year, though there are always some individuals who live for several years.

This set of figures is not intended to provide arguments for or against any one possible criterion. Instead, these figures show that every criterion has very serious problems and complexities, even in a population for whom good models for predicting survival is available. The number of long-term survivors increases when more inclusive criteria are applied while the number of very early deaths increases when more restrictive criteria are used. No statistical criterion seems to capture only the population which was really intended.

An additional point of concern is the interplay between serious illness and competence. As people became sicker, they were less likely to be competent. SUPPORT had two indicators of whether or not a patient was competent (Table 2). First, the Glasgow coma score assessed on the third day of the study provided a measure of serious neurological impairment (inability to move one's eyes, to move one's body purposefully, or to respond to ver-

bal stimuli). Patients whose scores were abnormal on this scale were unlikely at that time to be competent to make any decisions or to process information. However, patients with a normal Glasgow coma score might still be incompetent since higher order functions (e.g., thinking, paying attention) are not measured on this scale. Furthermore, patients with abnormal Glasgow coma scores might improve at some later time although then their prognoses would also improve. A second indicator of competence was the ability to be interviewed for the study. Some non-interviewable patients, especially those whose communication problems arose from being intubated for ventilator support, had periods of greater ability to communicate or might have been able to attend to some short presentation and respond "yes" or "no." Similarly, some patients may have been interviewable only in part of the four days allowed, days 2 through 5 of the study. The rate of being too sick to be interviewed, nevertheless, gives an estimate of the rate of incompetence.

TABLE 2: The rate of apparent incompetence for decision-making for patients with various ranges of prognoses,* as measured by two indices of mental functioning.

Prognosis	N	Abnormal Glasgow Coma Score %	Too Sick for Interview %
0-9%	864	69	50
10-19%	526	57	62
20-29%	607	53	59
30-39%	710	38	51
40-49%	975	34	54
50-59%	1208	28	49
60-69%	1487	19	39
70-79%	1636	12	29
80-89%	1010	6	22
90-100%	81	0	20

* for surviving six months, by the SUPPORT prognostic model

A high likelihood of dying correlates closely with being disabled for decision-making purposes. The diseases that very sick, dying individuals have and the treatments these individuals undergo are likely to cause disorientation, sedation, drowsiness, and the inability to attend to issues. Delirium is also commonplace and often unrecognized.[18] If physician-assisted suicide is to be restricted to those individuals who are capable of requesting it at the time of the act, then those drafting policy will have to

18.   J. Francis et al., *A Prospective Study of Delirium in Hospitalized Elderly*, 263 JAMA 1097-1101 (1990); S.K. Inouye et al., *A Predictive Index for Functional Decline in Hospitalized Elderly Medical Patients*, 8 J. GEN. INTERN. MED. 645-52 (1993).

accept that a small number of individuals defined as "terminally ill" according to a "tight" criterion (e.g., <20% probability of surviving 6 months) will be competent. If policy is to include a broader range of prognoses so as to have more persons with contemporaneous competence, then it must include persons with more uncertain and longer prognoses. Alternatively, policymakers could drop the requirement of contemporaneous competence and allow some forms of advance direction. That provision, however, is not part of any current court case or legislative proposal, most likely because it raises serious possibilities for abuse.

V. THE LIMITS OF PHYSICIANS' ABILITY TO RECOGNIZE IMPENDING DEATH

It is commonly believed that physicians know, or at least have the potential to know, who is dying and when they are dying. SUPPORT offers an interesting insight into the actual limits of this ability, indicating that physicians' prognostications and a "state of the art" statistical model substantially differ. Table 3 compares physicians' prognostications in SUPPORT to actual survival for populations stratified by the prognostic model.

TABLE 3: Actual patient survival at six months, in populations with physician estimates of <.2 and <.5 survival for six months

Disease	MD Prognosis < 0.2 for 6 months			MD Prognosis < 0.5 for 6 months		
	N	mean prog estimate	% surviving	N	mean prog estimate	% surviving
ARF/MOSF	693	.08	.22	1096	.27	.30
COPD	80	.10	.19	178	.32	.36
CHF	79	.06	.43	192	.33	.53
cirrhosis	76	.08	.21	155	.26	.29
coma	290	.06	.12	344	.19	.16
colon Ca	109	.08	.21	160	.25	.27
lung Ca	271	.08	.14	387	.28	.17
MOSFmalig	286	.07	.10	380	.21	.15

ARF/MOSF	= acute respiratory failure and multiple organ system failure with sepsis, which are presented together.
COPD	= chronic obstructive pulmonary disease (emphysema and chronic bronchitis)
CHF	= congestive heart failure
Ca	= cancer
MOSFmalig	= multiple organ system failure with malignancy

Table 3 shows that physicians often erred in their estimations of likely prognosis, especially when the physicians predicted low probabilities of survival. Among patients with congestive heart failure whose physicians estimated a chance of survival of less than 20%, actual survival was more than double that upper limit and was seven times the rate expected by the physicians. In con-

trast, the rates of survival in most other categories are only about twice the physician's prediction.

The SUPPORT population is a "best case" scenario since the patients had been hospitalized, were well-diagnosed, had survived at least forty-eight hours (so the situation was well-understood), and were treated by highly skilled physicians. Cases examined in less well-equipped settings, with less secure diagnoses, in a more dynamic clinical setting (such as in an emergency room or with more sudden change in health) would probably yield less ability to prognosticate impending death. Furthermore, the illnesses in SUPPORT were well-studied while prognostic models have not been developed for many diseases and combinations of diseases, especially the multiple coincident frailties of old age.

Many of the SUPPORT patients, nevertheless, came upon death with surprisingly optimistic prognoses. Figure 6 presents the prognoses of patients who actually died in the hospital or within a few days of discharge by giving the median prognoses from the SUPPORT model for six month survival on each day before death. As medians, these prognoses illustrate the experience of the "patient in the middle." To remind us of the variation, the vertical lines attached to the graph show the range from the twenty-fifth percentile to the seventy-fifth percentile of model estimates of survival.

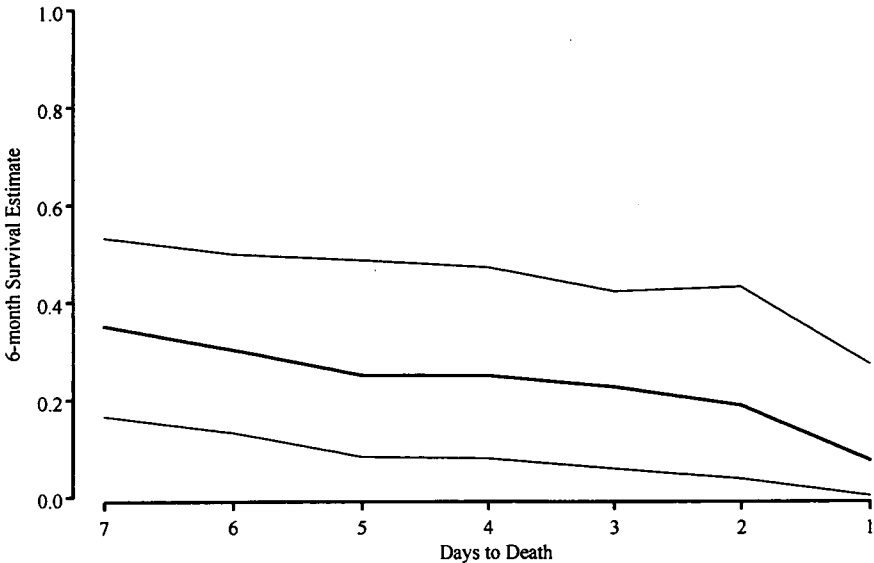6-month Model Estimates, All Diseases, with Quartiles

Figure 6. Median predicted survival in SUPPORT, by day before death, with interquartile range

On the day before the patient's death, the median patient in SUPPORT was approximately to have about a 17% chance to live two months and approximately a 7% chance to live six months. One week earlier, those rates were 35% for six months and 51% for two months. While a prognosis of 50% for two months is a very serious prognosis, it is not clear that society desires to categorize individuals who still have a "fifty-fifty" chance to live two months as "terminally ill" and certainly not as "imminently dying." Yet, half of the patients in SUPPORT had prognoses better than this within a week of their deaths. Again, this poses a policy dilemma. If the prognosis criterion is drawn tightly, most people who actually die are excluded. If one allows a broader range of prognoses, then many will actually survive for substantial periods of time. Analyses not illustrated here showed that the physicians' estimates and the statistical models gave quite similar prognoses, and that prognoses for six-month survival decline less than 20% in comparison with estimates for two months.

The dilemma for policymakers is compounded by the observation that different diseases have quite different courses near death, and some of them are much more unpredictable than others. Figures 7a-7d indicates the median prognoses for two-

month survival on each day before death for each disease in the SUPPORT study.
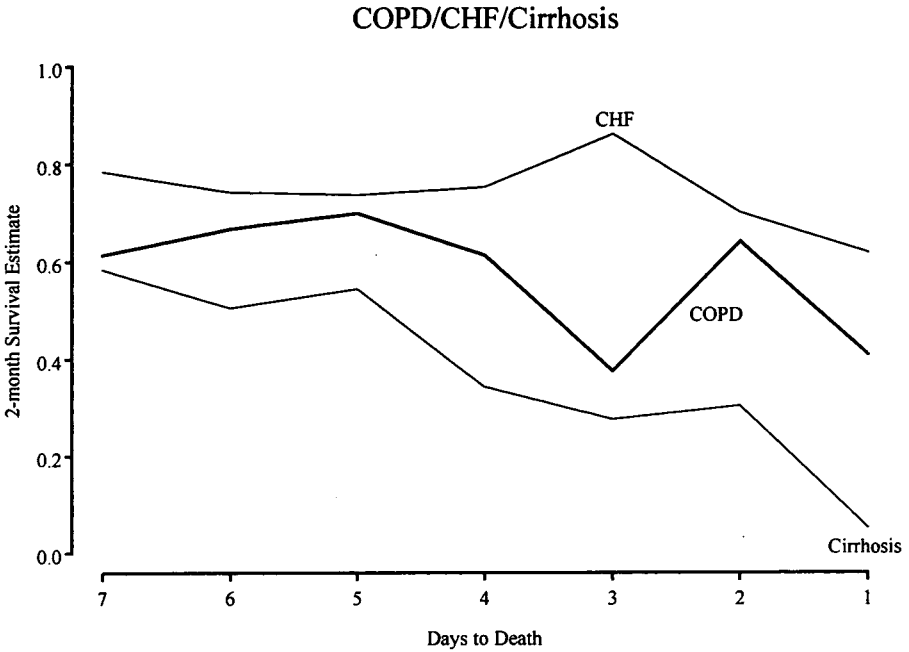
COPD/CHF/Cirrhosis

Figure 7a (Panels a-d). Median predicted survival in SUPPORT, by day before death, for each SUPPORT diagnosis: Panel a: Chronic obstructive pulmonary disease; congestive heart failure; Cirrhosis
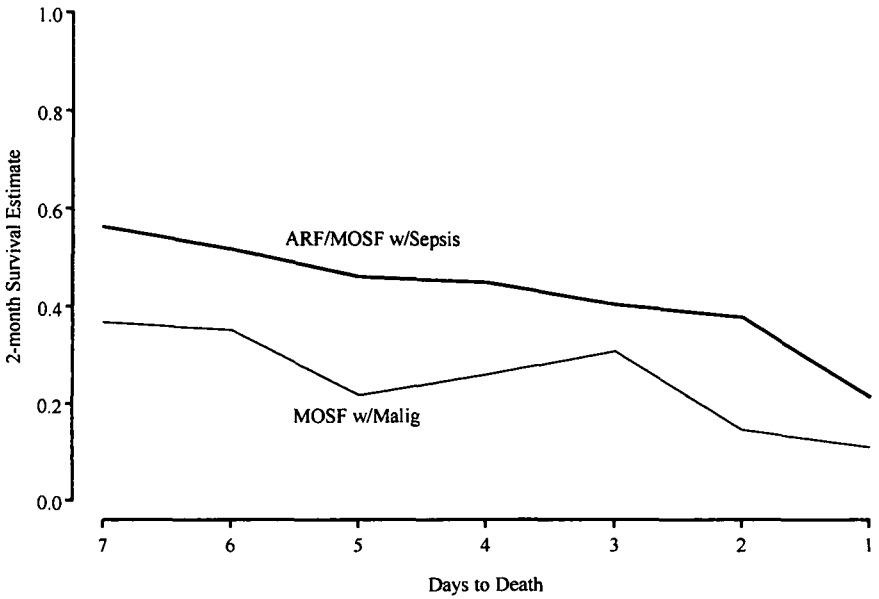
ARF/MOSF

Figure 7b. Panel b: Acute renal failure with multiple organ system failure and sepsis; Multiple organ system failure with malignancy
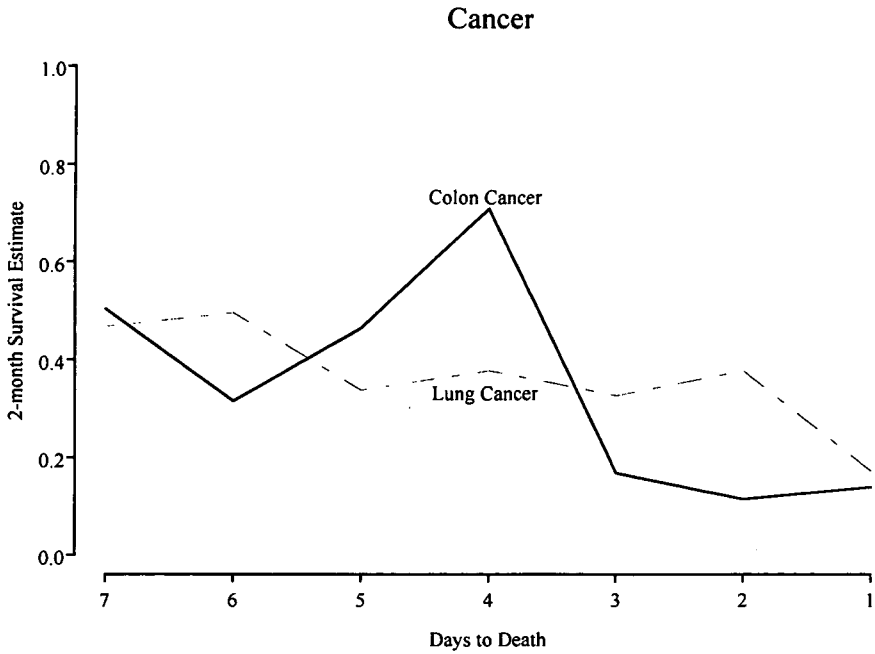
Cancer

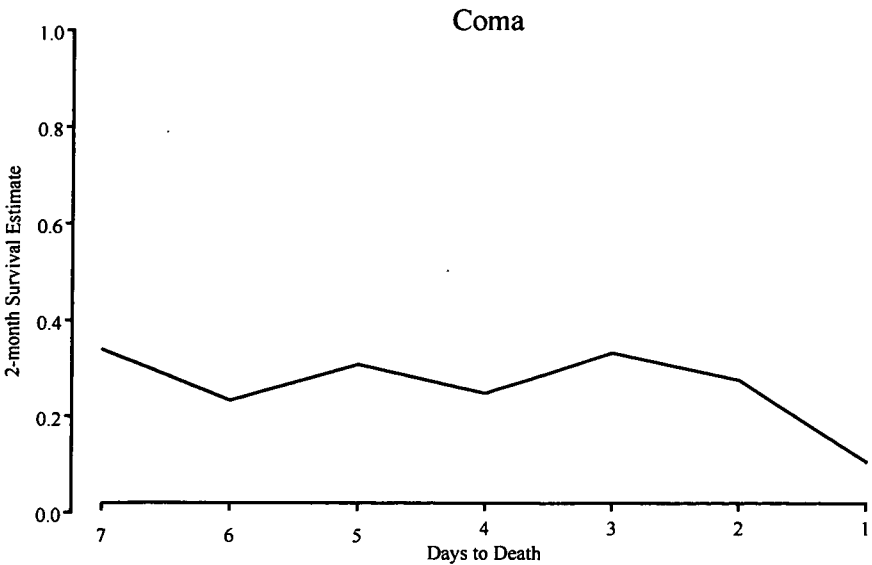Figure 7c. Panel c: Cancer

Coma

Figure 7d. Panel d: Coma

Death resulting from congestive heart failure was much less predictable than the others, and only coma was consistently grim. The short-term prognosis in congestive heart failure was

so unpredictable that even on the day before death, the median patient had a prognosis of better than 50-50 to live two months. Most patients with congestive heart failure severe enough to be in the SUPPORT study were living a "bed to chair" existence with periodic exacerbations of severe shortness of breath often requiring hospital care. Most deaths, however, deemed sudden, are probably precipitated by uncoordinated electrical activity in the heart, called cardiac arrhythmias. There is an ongoing high risk of this activity in seriously damaged hearts, but anticipating an occurrence is more like predicting when and where lightening will strike than predicting whether it will rain. It is very hard to predict precisely when a particular person will be "hit." A patient with this kind of disease lives with the ongoing risk of death on any day but usually has little warning about when death will actually occur. This is very different from dying from lung cancer, where the patient is usually sickest on the day of death, with signs of decline that had become increasingly obvious over several weeks.

The additional implications for policy are abundant. First, physicians are not likely to categorize patients with substantial chances to survive as "terminally ill." Yet, since congestive heart failure is the most common cause of death in the United States, many individuals are going to arrive at death's door without ever having a thoroughly dismal prognosis.

Furthermore, if one were to set some benefit or entitlement at a statistical prognostic threshold at or below 50% to live two months, most patients with congestive heart failure would never qualify. In fact, just one week before their deaths, most patients who died in SUPPORT would not have qualified as terminally ill because their average two-month prognoses were too good. If the criteria were set at a lower prognosis, however, only a small fraction of very sick persons (many of whom would be too sick to be competent) would be included in the category.

Further exploration of differences among diseases is possible with an examination of the typical survival curve for patients with one of two diseases of different trajectories selected for the same bad prognosis (20%) at six months.

Survival of Patients with Coma or Cancer
And Equal 6m Survival Probability

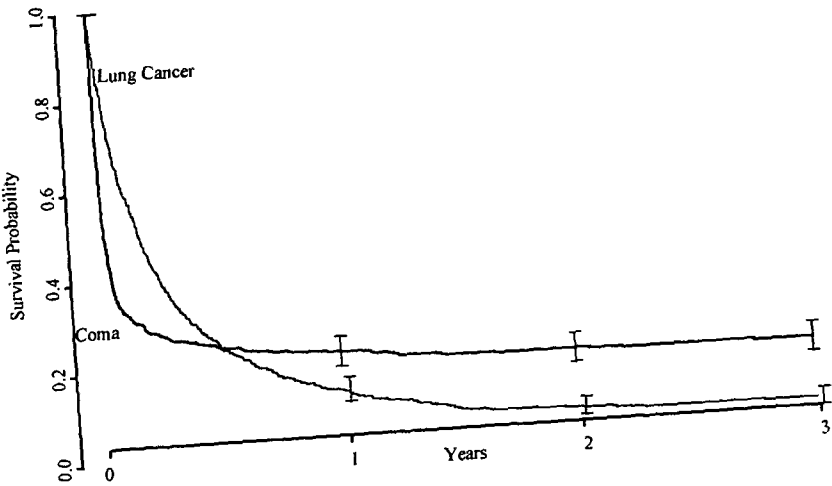All Coma Pts, Lung Cancer Pts with survival <=.495

Figure 8. Survival estimates for patients with coma or lung cancer, with each having 20% chance to survive six months

Virtually all deaths for patients in coma occur early, with survival rates reaching a plateau by six months. The prognosis with lung cancer, however, continues to decline to a point where there are almost no survivors by two years. The rate of dying early with lung cancer, on the other hand, is substantially lower. This observation creates the possibility that "terminally ill" could be interpreted to refer not only to a specific threshold but also to something about the course at various points in time.

To illustrate the variation in trajectory by disease, Table 4 presents the rates of early deaths (e.g., before one month) and late deaths (e.g., after twelve months), with the population stratified by prognosis for six-month survival.

TABLE 4: Proportion of SUPPORT patients by disease who
would be included in a "terminally ill" population as defined
by two thresholds, and the rates at which they die within
one and within twelve months.

Disease	N	< 50% survival (6 mo.)			< 20% survival (6 mo.)		
		N	% alive 1 mo.	% alive 12 mo.	N	% alive 1 mo.	% alive 12 mo.
ARF/MOSF	3515	1333	49	26	458	28	12
COPD	967	164	62	25	39	49	15
CHF	1387	125	70	28	25	32	4
Cirrhosis	508	186	47	23	70	20	13
Coma	596	478	25	13	252	13	6
Colon Ca	512	157	70	19	64	53	14
Lung Ca	908	657	68	13	197	44	3
MOSF/Ca	112	593	41	13	285	26	4

Although the patients have the same upper limit on prognosis,
they vary substantially in the proportion of very early deaths and
of longer term survivals. Cancer has higher short term survival
(one month) but very low one-year survivals. Congestive heart
failure has very few patients with a prognosis under 20% for six
month survival. Most patients who have such a poor prognosis
die very quickly, with few lasting a year. Considering the find-
ings in Figure 7 above, which shows that most congestive heart
failure patients die with a prognosis of at least 50% to live six
months, it seems likely that the few congestive heart failure
patients who have very bad prognoses (<20% for six month sur-
vival) are generally dying in a different way than are most con-
gestive heart failure patients. Most likely, these patients have
severe dysfunction affecting more than one organ system and are
effectively dying from severe progressive physiological dysfunc-
tion rather than from the arrhythmias that more commonly
cause death in congestive heart failure.

Changing from an operational definition of prognosis of 50%
six-month survival to 20% would have quite different effects on
the size of the population in each disease. With congestive heart
failure and COPD, it nearly eradicates what is otherwise a large
group of hospitalized, fatally ill patients. The effect is much
more modest for ARF/MOSF, however, demonstrating that dying
after at least a short period with a poor prognosis is more com-
monplace in these illnesses.

VI. PROGNOSTICATION BY DISEASE THRESHOLD

SUPPORT defined the categories for enrollment by using the
best evidence available to define a clinical threshold for each ill-
ness that could be expected to have no more than 50% survival in

six months. SUPPORT, therefore, stands as an attempt to simulate one kind of definition of terminal illness. The actual criteria for enrollment are complex and have been published elsewhere.[19] The criteria generally require the most severe forms of each disease: congestive heart failure living from bed to chair, chronic obstructive lung disease with extremely serious levels of oxygenation in the blood, etc. The survival curve for the entire study is presented according to disease in Figure 9.
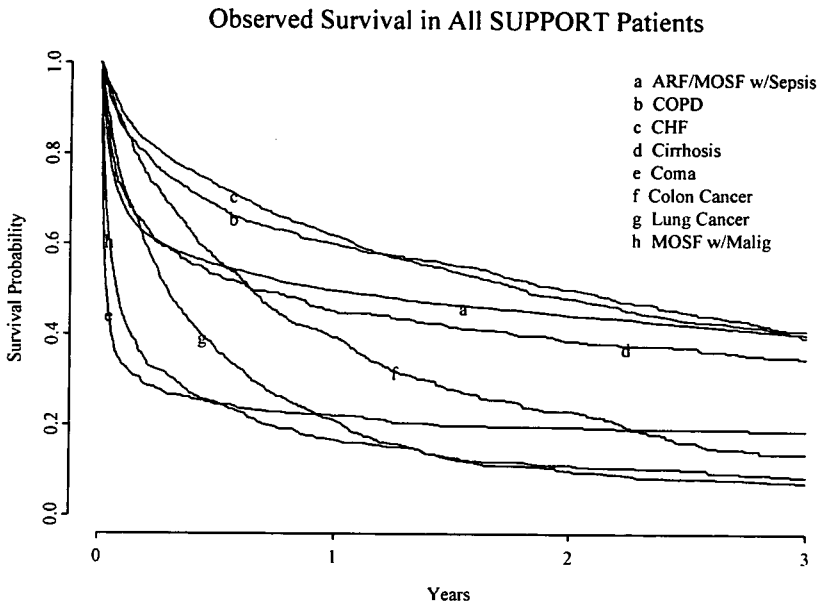
Observed Survival in All SUPPORT Patients

Figure 9. Proportion surviving over three years, by disease

Survival up to six months varied substantially among diseases, although the entire SUPPORT population had almost exactly 50% mortality. The "tail" of survival, furthermore, had very different shapes. In some diseases, such as coma, there was almost no additional mortality past 6 months. In other diseases, such as colon cancer, the initial rapid loss of life was not marked, but the subsequent decline was unremitting and substantial (colon cancer). In still other diseases, attrition was at a slower, steady, rate throughout the period of study.

The SUPPORT population is arrayed by the frequency of prognoses for each disease in Figure 10.

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19. J CLIN EPI 1990, 43(suppl):1S-123S.

Distribution of Prognoses by Disease Group

a   ARF/MOSF w/Sepsis
b   COPD
c   CHF
d   Cirrhosis
e   Coma
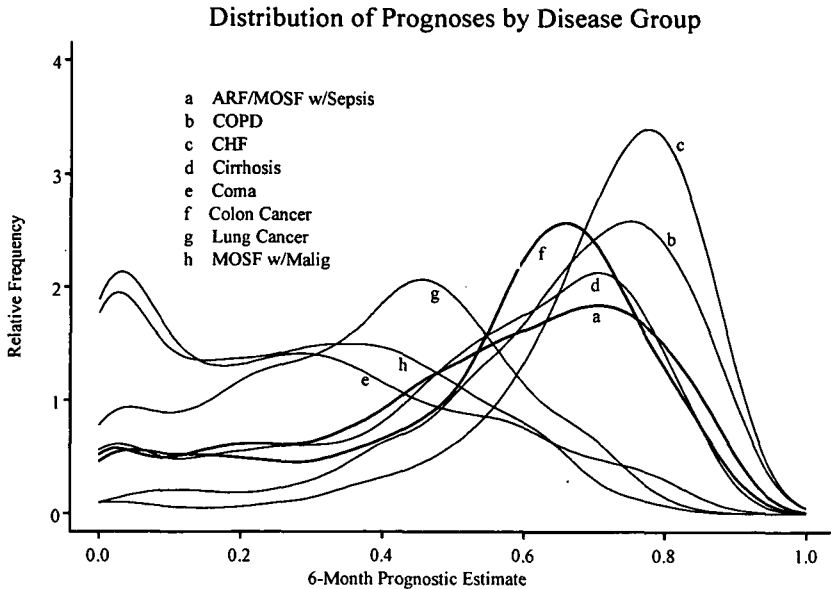f   Colon Cancer
g   Lung Cancer
h   MOSF w/Malig

Figure 10. Proportion of each SUPPORT population, by disease, which had each prognosis on the third study day, for survival to six months

Figure 10 demonstrates that even among a population chosen on the basis of serious illness and aiming for no more than 50% survival at six months with the best pre-existing data, different patterns of six-month survival remain for each disease. The ICU-treated categories (ARF/MOSF, MOSF with malignancy, and coma) and lung cancer comprise most of the patients with prognoses of less than 50% to live six months. Exceedingly few of the patients with COPD or CHF actually had prognoses known to be worse than "even chances" to survive six months.

VII. POLICY IMPLICATIONS

Deciding who should be counted "terminally ill" will pose such severe difficulties that it seems untenable as a criterion for permitting physician-assisted suicide. Allowing physicians (or anyone else) to decide who is terminally ill without standards or guidance will result in uneven application with unjustified variations across diseases, across physicians, and across regions. Efforts to gain entry into the category will engender substantial litigation.

Adopting a statistical threshold entails a myriad problems. Any such threshold is arbitrary and will incur a large number of ambiguous cases, both because many prognoses are unavoidably ambiguous and because the data are not available for many

groups of dying persons. Furthermore, a restrictive threshold will limit availability to a small proportion of those who die, many of whom will be incompetent. It will also exclude almost all of some commonplace causes of death. Conversely, a more inclusive threshold will entail allowing physician-assisted suicide for a substantial number of persons who are otherwise destined to survive for an extended period.

The last approach, determining a threshold of illness severity, avoids some of the ambiguity but entails including a great number of persons who live for a long time, most of whom are not now commonly considered "terminally ill."

Varying definitions of "terminally ill" could be implemented for different public policy purposes. An individual might be "terminally ill" for purposes of receiving hospice care, but not "terminally ill" for requesting physician-assisted suicide, or vice versa. The effects of this approach, however, seem unsettling in the policy arena. This approach, furthermore, does not avoid the fundamental problem of delineating a clear and practical category for each use.

The means of defining terminal illness described in this article are almost entirely novel ways of examining data about seriously ill individuals. Until recently, there has been no research of this sort and little motivation for it. This fact alone should give pause to those individuals who would regulate important public behavior on the basis of the category "terminally ill." There has been so little research attention to this subject that reliable data are generally unavailable for almost all important questions in this area. The problems and possibilities are just beginning to be recognized and described. Certainly this initial perception is sufficient to evoke concern as to whether any definition would prove to be workable.

The data indicate that none of the criteria suggested in the introduction as necessary for a practicable policy were met:

1. No strategy allows one to define the "terminally ill," with clear and consistent classification of almost all patients;

2. At most possible thresholds of illness for most fatal illnesses, the period of survival with "terminal illness" will often not be long enough to make and implement choices;

3. At most possible thresholds, "terminal illness" will not be recognizable for most causes of death.

4. Narrow definitions will include mostly incompetent persons who survive for short periods while broader definitions will include more competent persons who are likely to survive for prolonged periods.

Defining terminal illness in any particular way will exclude some who are now commonly considered terminally ill and will include others who are not now commonly considered terminally ill. Many people will have an uncertain status regardless of the definition selected. Patients labeled "terminally ill" may be too sick for the designation to be useful or too healthy for it to be appropriate. Most individuals will arrive at death with uncertain prognoses which still offer possibilities of substantial survivals.