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Evaluation of the Prognostic Criteria for Medicare Hospice Eligibility

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Evaluation of the Prognostic Criteria for Medicare Hospice Eligibility

by

D. Helen Moore

A dissertation submitted in partial fulfillment
of the requirements for the degree of
Doctor of Philosophy
School of Aging Studies
College of Arts and Sciences
University of South Florida

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dementia, heart, stroke

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Dedicated

in Honor of

Mur

Dorothy Helen Moore Martin, of Georgetown, Kentucky

LOVELIEST of trees, the cherry now
Is hung with bloom along the bough,
And stands about the woodland ride
Wearing white for Eastertide.

Now, of my threescore years and ten,
Twenty will not come again,
And take from seventy springs a score,
It only leaves me fifty more.

And since to look at things in bloom
Fifty springs are little room,
About the woodlands I will go
To see the cherry hung with snow.

A. E. Housman, from *A Shropshire Lad*, 1896.
Acknowledgements

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Evaluation of the Prognostic Criteria for Medicare Hospice Eligibility

Abstract

This work evaluates Medicare Hospice Benefit (MHB) eligibility standards that are referenced throughout this work as either “Medicare prognostic criteria,” or “Local Medical Review Policies.” Following the Chapter 1 overview of prognosis in end-stage disease, association between the Medicare clinical predictors and survival outcomes in dementing, cardiovascular and cerebrovascular illnesses are described in Chapter 2. Chapter 3 examines the prognostic belief systems of multidisciplinary hospice personnel. Chapter 4 seeks to improve the predictive performance of the Medicare prognostic criteria for dementia. The fifth and final chapter critiques the Medicare prognostic criteria from conceptual, methodological, and applied perspectives and suggests related research and policy directions. The Chapter 2 sample comprised 453 medical records of terminally ill persons; Chapter 4 sample, 187 medical records. Thirty-seven hospice personnel comprised the respondent sample in the Chapter 3 study.

Chapter 2 assesses the scientific validity of federally sanctioned Medicare “severe illness/end-stage illness” demarcations in three non-cancer disease categories. Calculation of measures of predictive validity revealed striking and consistent imbalances of false negative and false positive errors across the three diagnostic categories studied, suggesting inequitable distribution of the costs and benefits of regulatory reform among public health payers, consumers and providers.

Chapter 3 qualitatively examines the belief systems of experienced hospice personnel regarding physical and non-physical time-to-death influences in end-stage
disease. Non-physical survival influences were believed by these expert informants to have more survival impact in non-cancer as opposed to cancer end-stage diseases, and at remote as compared to imminent death proximities. Chapter 3 highlights the enormous complexity of time-to-death influences as well as the importance of non-physical influences on duration of survival in end-stage disease.

Chapter 4 demonstrates that dropping one of the three prognostic criteria for dementia (the medical complications criteria) may improve predictive validity. This finding demonstrates that, in dementing illnesses at least, functional debility may better identify 6-month survival prognosis and thus hospice eligibility, than the composite Medicare prognostic criteria. The merit of parsimony in objective definitions of terminality is implied.

Chapter 5 critiques the Medicare prognostic criteria, and suggests policy alternatives that are both prognostically- and non-prognostically-based. Peripheral findings of this work and suggestions for future end-of-life research conclude the dissertation.
Chapter One

Introduction

This work uses a variety of methods to address systemic U.S. health care policy issues that concern individuals with life-threatening, non-cancer diseases. Specifically evaluated are three sets of disease severity indicators applied in non-cancer diagnostic categories to define Medicare Hospice Benefit eligibility. Administratively known as “Local Medical Review Policies” (LMRPs) and more generically as “Medicare prognostic criteria,” these clinical standards have an effect on admission, re-certification and discharge determinations for the nearly 1 in 4 Americans who die each year in hospice care settings (1). To this investigator’s best knowledge, this dissertation work comprises the single most comprehensive evaluation of the Medicare prognostic criteria to date. Results confirm previously reported findings on the predictive deficits of the Medicare prognostic criteria, and provide new details on the outcomes of these criteria in simulations of regulatory usages. The work further reveals the complex and often contradictory range of factors that can influence the timing of death. Further, it suggests that the Medicare prognostic criterion for dementia currently applied across the U.S to approve or deny hospice admission can be improved through simple modification.

The dissertation findings may be of interest to the many parties and entities that stand to be affected by the Medicare prognostic criteria, before, during and after the actual provision of hospice care. Such parties include present and potential consumers of palliative, hospice care services (patients and their families), referring physicians,
organizational providers of hospice care, those who can articulate policy concerns and, optimistically, those with the power to effectuate regulatory and reimbursement change.

Several factors have motivated this 4-year investigation. First, in 1999-2000, heart disease, stroke and dementia, the diagnostic foci of this study, respectively represented the first, third and eighth all-age death causes in the United States (2). Furthermore, cardiac and dementing diseases are among the top five non-cancer causes of death in hospice patients (1). Nearly 54 percent of all Medicare hospice patients served in 2002 were diagnosed with cancer upon admission, 46 percent with life-threatening diseases of non-cancer origin (1). Of all enrollees that year, 10 percent were diagnosed with heart disease, seven percent with dementia (2). The second, and perhaps most important motivating factor for research relates to the unprecedented reductions in hospice median lengths of stay that have paralleled Medicare prognostic policy instigation. As reiterated within the body of the work, the Medicare prognostic criteria may have influenced patient selection processes in favor of observably over less observably critically and terminally ill individuals, to the disadvantage of Medicare-eligible patients with certain non-cancer diagnoses. Although it is unlikely that such a causal link can be empirically established, the evidence that suggests such a link is highly suggestive (1). Third, in the present era of health care cost containment, the Medicare/Medicaid program consumes an annual budget of over 2 billion dollars (3). As death in America is increasingly defined by chronic, non-cancer illnesses (4) and as the population that seeks palliative end-of-life treatment grows (1), it is important to evaluate the costs and benefits of health care policy innovation.
The Medicare Hospice Benefit

The Medicare Hospice Benefit (MHB) provides medical, psychological, social and spiritual interventions to dying patients and uniquely includes the patient’s family caregiver in the unit of care. Palliative care in hospice settings has been Medicare Part A reimbursable since 1982. Third-party reimbursement for hospice is uniquely comprehensive and nearly all-inclusive, covering home care, acute care, respite care, prescription drugs, allied therapies, and psychosocial and spiritual interventions (5). Legal requirements of eligibility for this public service are: (1.) a terminal diagnosis, i.e., a life-threatening disease for which no cure is anticipated; (2.) a limited survival prognosis, i.e. six-months or less survival assuming normal disease course, and (3.) benefit election, i.e. patient/family choice of palliative, non-curative options over regular Medicare Part A benefits (6). Currently, there are two initial 90-day benefit periods in Medicare hospice followed by an unlimited number of 6-day periods. A physician must re-certify that a patient has six months or less to live before each benefit period (1).

Cancer was and is the most common diagnosis in hospice, but the proportion of cancer patients in Medicare hospice decreased from 75 percent in 1992 to 58 percent in 2000 (7). Under MHB statutory provisions, care can be provided for up to 210 days or sometimes longer. The majority of Medicare hospice beneficiaries receive the bulk of their care in their homes from family caregivers (1). Other beneficiaries receive hospice health care services in nursing homes, hospitals or other inpatient facilities. Seven out of ten hospice patients are dependent in basic self-care skills such as bathing, dressing or eating; about 70 percent are doubly incontinent; four out of five have mobility
limitations; and half use oxygen (7). Without a doubt, the hospice-eligible population comprises one of the most impaired and vulnerable groups in America.

The Dilemma of Prognostic Accuracy

Terminally ill persons, given physicians’ certification of 6-month or less survival prognosis, represent potential MHB-eligibles. From historical (8), contemporary (9) and scientific perspectives (10), however, accurate terminal status determination is notoriously inaccurate and may remain ever so, particularly in non-cancer diseases and at more remote, 6-month proximities from death. Interestingly, it has been shown that survival in hospice care settings varies substantially according to diagnosis (11). In one landmark study, relatively longer durations of survival in non-cancer categories were observed among hospice patients with dementia and pulmonary diseases (12).

Prediction of length of life remaining is one of the most complex and daunting tasks in medicine, hinging on consideration of a complex, interrelated and dynamically shifting array of contextual, patient- and disease-specific factors. Reliable prognostication will remain undefined, and the thresholds of terminality ambiguous, until the determinants of death are more comprehensively understood. As an introduction to prognostic issues, the possible range of such factors is briefly reviewed.

Clinical Factors that Affect Prognostic Accuracy

Age, race and sex, factors linked to the timing of mortality by a large and diverse literature (13), are notably absent from Medicare prognostic formulations. Although this omission may reflect the need to avoid discrimination-based protest in national health
care policy, it is also likely that age, race and sex play a role in life expectancy at birth
that are not significantly related to short term survival after hospice admission. Many
other patient-specific factors are similarly unaccounted for by the Medicare criteria, such
as the occurrence of idiosyncratic patient responses to certain hospice treatments that are
ambiguously palliative (diuretics, vasodilators and ACE inhibitors) (14), and the extreme
functional heterogeneity that characterizes older adult populations (15). Furthermore,
although the Medicare prognostic criteria do incorporate measures of general physical
debility (presence of pressure sores, 10% weight loss) and severe infection
(pneumonia/septicemia/recurrent fever/urinary tract infections), they do not account for
dual diagnoses, co-morbidities and intercurrent illnesses, the composite survival effect of
which remains unknown. This is a particular concern given that the acknowledged cause
of death in older adult populations is multifactorial (16).

Prototypical death trajectories provide a good example of the biologic confounds
of terminal prognosis. A short period of unmistakable deterioration typifies cancer
diseases; periodic exacerbation of long-term disabled status defines end-of-life
circumstances in non-cancer, chronic organ systems failures. In most cancer diagnoses,
fatal decline progresses rapidly and predictably downward (17); non-cancer fatal
trajectories are comparatively erratic (18). For example, end-stage dementia and
cerebrovascular illnesses are prototypically marked by variable and unpredictable
“plateaus of stability,” the durations of which are difficult to predict. Impaired
consciousness on hospice admission is a reported risk factor for stroke mortality (19).
The pattern of decline in congestive heart failure stands in sharp contrast to decline seen
in dementia, a condition in which death occurs due to overwhelming physiologic failure.
Typically a cardiac patient appears no more ill during the weeks that immediately precede death than in previous phases of illness (9), a factor that obviously confounds prognosis. As referenced above, patients severely ill with congestive heart failure may survive for many years if offered symptom control treatments that include vasodilators (14).

Non-Clinical Factors that Affect Prognostic Accuracy

A positive association between ease and accuracy of survival prediction and patient nearness to death is a prognostic fundamental. This is so because, in cancer and non-cancer illnesses alike, death’s imminent approach (days, hours) is clearly marked by a cascade of organ system failures (20). Prognosis of time to death from temporal perspectives that are “intermediate” (2-3 months) or “remote” (6-month) is much less straightforward, however, perhaps due in part to the influence of psychosocial and contextual factors that, according to the Chapter 3 informants, strongly influence end-stage survival duration in non-cancer diseases and at more remote death proximities. As one example of psychosocial effects on health outcomes, severely impaired stroke patients with little hope for recovery tend to experience shorter survival than those with more hopeful attitudes (21). Finally, mortality in advanced chronic and severely debilitating illnesses may be determined by factors as basic as the quality of custodial care rendered or as esoteric as patient-perceived quality of life (Chapter 3).
Approaches to End-of-life Prognostication

Beyond traditional physician clinical judgments, several models have been developed to prognosticate survival, including the Acute Physiological and Chronic Health Evaluation (APACHE) (22-24) and the SUPPORT model (25-27). These tools represent a modest advancement over clinical judgment (25), but are less appropriate for use with individual patients than for research conducted with large population-based samples. They were developed for use with acutely ill hospitalized patients and constructed based on studies of patients that received standard medical therapy in traditional medical settings. For these reasons, and because 6-month survival outcome measures were generally not employed, such models do not provide viable options for hospice-based survival estimates.

Regression-based studies of hospice mortality pointers are equivocal due to small sample sizes and failure to account for co-morbid and patient heterogeneity confounds (28-32). A third approach to end-of-life prognosis compares the severity of patient symptoms to pre-selected clinical points thought to possess prognostic significance (33). This final “threshold-based” or “staging theory” method was first developed in response to the need for improved cancer prognosis (34). This is the Centers for Medicare and Medicare Services (CMS) chosen approach as embodied by the Medicare prognostic criteria. Of note is the fact that the Medicare criteria are far more restrictive than are the eligibility parameters federally specified in the founding Medicare Hospice Benefit statutes (6).
Medicare Prognostic Criteria Origin

Criteria for evaluating the timeliness of hospice enrollment for patients with end-stage, non-malignant diseases were first proposed in 1993 (35) by a hospice physician and for selected non-malignant diagnoses, clinical guidelines were formally developed and published by the National Hospice and Palliative Care Organization (NHPCO) in 1995. The Medicare prognostic criteria were appropriated nearly verbatim from a second edition of the NHPCO monograph entitled “Guidelines for Determining Prognosis in Non-cancer Diseases,” commonly referenced as the “NHPCO Guidelines” (36). Terminality parameters as set forth in the Guidelines represent composites of previously published mortality pointers that are organized according to degenerative organ systems processes. The authors of the Guidelines clearly represent their work as a starting point for ongoing end-of-life prognostic research, with the caveat that the Guidelines should be adapted based on further research.

Medicare Prognostic Criteria Controversy

The appropriateness of the Medicare prognostic criteria, administratively known as “Local Medical Review Policies (LMRPs),” can and has been contested on several grounds (37). First, mounting quantitative evidence shows little association between the LMRPs and short-term survival outcomes in hospice populations (38). Second, although Medicare hospice was founded upon holistic, physical, psychosocial and spiritual treatment principles, the LMRP criteria exclude non-physical markers of disease progression. Third, although the consequences of regulatory reform have yet to be fully understood, the LMRPs appear to be disadvantageous to persons less obviously and
imminently terminally ill, as evidenced by a 20 percent decline in the national average length of hospice stay from 1992 to 1998 (39). In 2001, the most recent year for which comprehensive data are available, median length of stay was 21.5 days; 34 percent of hospice patients died within 7 days or less from admission, while only 6 percent died in 180 days or over (1). The decline in the mean number of per-beneficiary hospice days was most conspicuously apparent among non-cancer populations. Hospice lengths of stay for this group declined by 38 percent while cancer stays declined by 14 percent from 1992 through 1998 (39). Inordinately short lengths of hospice stay primarily disadvantage patients and providers (40); for example, short stays preclude patients from receiving the full value of hospice services (41), a benefit aimed in part at enhancing the quality of life during the dying process and providing support for the primary patient caregiver. From the organizational perspective, short-term stays typically entail acute and much more expensive care, a reality that disrupts the economic feasibility of hospice care provision. In the special case of delayed referrals, Medicare beneficiaries may be admitted “at the brink of death” or not at all. Many hospices have reported that patients are increasingly referred to them within days of death (42), a circumstance that undercuts the statutory Medicare Hospice Benefit mandate.

Conclusion

This work is an in-depth examination of the Medicare prognostic criteria for cardiac disease, dementia and stroke. It was undertaken to attain an increased understanding of the criteria from medical, applied and policy perspectives. In its sanction of prognostically-based the Local Medical Review Policies, Medicare
administrators sought to introduce consistent payment standards for legitimate hospice enrollment. The physician-researchers who authored the “Guidelines” assumed the use of their clinical parameters in concert with practitioner judgment and ongoing patient involvement (43). Although the disarticulation between these separate goals may not be readily apparent, the consequences of regulatory reform require careful analyses.
Chapter Two: Evaluation of the Local Medical Review Policies for Medicare Hospice Eligibility in Advanced Dementia, Stroke and Heart Disease

Abstract

Background

Medicare fiscal intermediaries judge the eligibility of patients for the Medicare Hospice Benefit (MHB) using “Local Medical Review Policies” or LMRPs. Because access to quality end-of-life care in the U.S is influenced by such policies, it is important to evaluate their validity and regulatory impact.

Methods

To evaluate the predictive validity and classificatory errors of the LMRP criteria, a retrospective case-control study was undertaken at a single, large, Medicare-certified hospice in Florida comparing 207 Medicare beneficiaries with primary diagnoses of heart disease, dementia, or acute or chronic stroke who experienced long-term survival post MHB enrollment (>180 days) with 246 patients matched on primary diagnosis and admission site of care (residence or nursing home) who experienced short-term survival (≤180 days).

Results

Only the dementia criteria were significantly associated with short-term duration of survival (OR = 2.97, 95% CI = 1.52 to 5.82, p < .005); the heart disease (OR = 1.65, 95% CI = 0.92 to 2.97; p = 0.08) and acute stroke criteria (OR = 3.60, 95% CI = 0.35 to 3.60, 95% CI = 0.35 to
were not. The percentage of patients who did not meet LMRP criteria but died within 6 months ranged from 55.8% for dementia to 75.4% for acute stroke. The percentage of patients who met LMRP criteria but survived more than 6 months ranged from 8.6% for acute stroke to 21% for dementia and heart disease.

**Conclusions**

Local Medical Review Policies for the MHB misclassify large numbers of hospice patients based on verified durations of survival.

**Introduction**

Accurate prediction of duration of survival is important for informed decision-making in the care of gravely ill patients. One example is the need to judge a patient’s terminal status for Medicare Hospice Benefit (MHB) eligibility, legally defined as a terminal diagnosis and six-month life expectancy, assuming normal disease course (1). End-of-life prognostication remains a precarious science (27-29, 32, 44-46), particularly in diagnostic categories other than cancer (10, 12, 46). Despite this, prognostically-based policies have been enacted as claims review tools for MHB reimbursement.

In 1998, the Centers for Medicare and Medicaid Services (CMS) adopted clinical protocols for prediction of six-month mortality in selected non-cancer, chronic diseases. These were disseminated to the five regional CMS-intermediary agencies, which enacted them into regulatory policies over a three-year period (1998-2001). Administrative records auditors use these protocols, termed “Local Medical Review Policies”(LMRPs) (47), to screen for long-surviving (>six months) MHB recipients who may have been inaccurately certified for hospice enrollment. Through such claims review processes,
legitimacy of physician certifications of terminal status have been approved or challenged, patient eligibility for Medicare hospice confirmed or denied, and organizational payment claims reimbursed or denied.

Previous studies of the LMRP criteria have focused on their validity for identification of short-term MHB enrollees. Schonwetter et al. (48) examined 104 chronically ill hospice patients who survived less than 6 months following admission and found that only 35% fulfilled the LMRP criteria. Fox et al. (38) studied 923 hospital patients who survived less than 6 months; of these only 277 (30%) were correctly identified as short-term survivors using simulated LMRP versions. Neither Schonwetter nor Fox investigated patients who fulfilled the criteria but experienced long-term (> 6 months) durations of survival. Luchins et al. (49) prospectively identified a short-surviving subgroup of hospice patients with dementia through applications of FAST stage 7C criteria (50-52), key components of the LMRP criteria for dementia. These investigators concluded that the FAST criteria might not be feasible for survival prognosis, given that dementia symptoms do not invariably progress ordinally, conclusions supported in a replication of study results (53).

To the investigator’s knowledge, this evaluation is the first to comprehensively evaluate measures of predictive validity, including errors of classification for the heart disease, dementia and stroke (Table 1) and general (Table 2) sets of LMRP criteria.
Table 1. Prognostic criteria for Medicare Hospice Benefit eligibility* by diagnostic category

<table>
<thead>
<tr>
<th>Diagnostic category</th>
<th>Required criteria</th>
<th>Optional criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dementia</td>
<td>(1.) FAST Stage 7 or higher AND impaired function (can’t ambulate, dress or bathe without help assistance + incontinent urine and stool + no meaningful communication) AND (2.) one of six medical complications (aspiration pneumonia; upper urinary tract infection; multiple decubitus, stage 3-4; septicemia; fever recurrent with antibiotics; 10% weight loss in 6 months)</td>
<td></td>
</tr>
<tr>
<td>Heart disease</td>
<td>(1.) optimally treated with two medications (diuretics, vaso-dilators, usually ACE inhibitors) ejection fraction ( \leq 20% ) arrhythmia</td>
<td>history of cardiac arrest or syncope</td>
</tr>
</tbody>
</table>
rest and on exertion (NYHA IV) brain embolism
resuscitation HIV disease

**Acute stroke**
- coma >3 days OR coma upper urinary tract infection
- with myoclonus OR dysphagia decubitus, stage 3-4
- that prevents sufficient septicemia
- nutrition fever with antibiotics
- 10% weight loss in 6 months.

**Chronic stroke**
1. FAST Stage 7 or higher aspiration pneumonia
   AND impaired function (can’t upper urinary tract assistance
   ambulate, dress or bathe w/o upper urinary tract assistance
   + incontinent urine infection
   and stool + no meaningful decubitus, stage 3-4
   communication) OR (2.) septicemia
   Karnofsky ≤ 40 OR poor fever w/antibiotics
   nutritional status 10% weight loss in 6 months.

*Palmetto Regional Home Health and Hospice Intermediary, formerly known as Palmetto Government Benefit Administrators, Local Medical Review Policies, 1/29/1998*
Table 2. *NHPCO general guidelines for determining prognosis

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.

   A. A “life limiting condition” may be due to a specific diagnosis, a combination of diseases, or there may be no specific diagnosis defined.

II. The patient and/or family have elected treatment goals directed toward relief of symptoms rather than cure of the underlying disease.

III. 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 disease-specific criteria, as documented by serial physician assessment, laboratory, radiologic or other studies.

      2. Multiple Emergency Department visits or inpatient hospitalizations over the prior six 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.

   a. Functional decline should be recent, to distinguish patients who are terminal from those with reduced baseline functional status due to chronic illness. Clinical judgment is required for patients with a terminal condition and impaired status due to a different non-terminal disease, e.g., a patient chronically paraplegic form spinal cord injury who is recently diagnosed with cancer.

   b. Diminished functional status may be documented by *either*:

   1. Karnofsky Performance Status of less than or equal to 50%

   2. Dependence in at least three of the following six Activities of Daily Living (ADL’s).

      i. Bathing

      ii. Dressing
iii. Feeding

iv. Transfers

v. Continence of urine and stool

vi. Ability to ambulate independently to bathroom

B. Documented recent impaired nutritional status related to the terminal process.

1. Unintentional, progressive weight loss of greater than 10% over the prior six months.

2. Serum albumin less than 2.5 gm/dl may be a helpful prognostic indicator, but should not be used in isolation from other factors in I-III above.

Methods

The original, 1998 versions of three of the sets of LMRP criteria implemented by the CMS administrator for the Southeastern region of the United States (54) were evaluated. These are very similar to the corresponding sets of LMRP criteria enacted by the other four national Medicare intermediary agencies (54-57). The study was conducted at a single, freestanding, not-for-profit hospice located in West Central Florida with an average 1998 daily census of approximately 1,200 patients. The 1998 case mix profile at this site (45% non-cancer/55% cancer) closely paralleled national hospice case-mix profiles in that year (43% non-cancer/57% cancer) (39).

An 18-month study enrollment interval (1/1/97-6/30/98) was selected that largely preceded the national period for staggered LMRP implementation (1/29/98 -10/1/00). This was done in order to give the policies a fair test based on assessment of physician-referred individuals who would have been admitted to Medicare hospice if the policies did not exist. Because the rarity of long-term durations of survival at the study hospice rendered a cohort design infeasible, a case-control design was adopted. Long-surviving (>180 days) MHB recipients admitted within the specified enrollment interval (cases) were compared to a random sample of short-surviving (≤180 days) recipients bearing identical primary ICD-9 codes (controls). Long-term durations of survival were verified based on nearly four years of follow-up through March 31, 2001, the end date of study observation.

All deceased, discharged and surviving MHB recipients admitted to the study site during the enrollment interval with primary ICD-9 codes for cardiac, pulmonary, cerebrovascular and dementing diseases (n = 1,123) were identified. Eleven patients
discharged prior to 181 days of hospice care were dropped because it was not possible to
determine whether they died before or after 180 days. The remaining medical records
were dichotomized into control (≤180 days) or case (>180 days) survival categories.
Cases were matched on primary ICD-9 code and admission site of care (residence or
nursing home) to one or more randomly selected controls. The majority of pulmonary
cases (n = 63) were missing lab values for hypoxemia and hypercapnia, data essential for
assessment of criteria fulfillment, because these diagnostic tests were not required
previous to policy initiation. Therefore, this ICD-9 category was dropped from the
analysis. The final sample (n = 453) consisted of 207 long-surviving cases and 246
short-surviving controls.

Two nurse abstractors with clinical and research backgrounds abstracted data
from archived medical records. Demographic and duration of survival data were
electronically abstracted from the study site administrative database and/or from the
Social Security Death Index (SSDI). Local newspaper obituary files were searched if the
date of death could not be SSDI verified.

The LMRP criteria were formatted into assessment instruments for pilot testing
on a randomly selected sample of medical records (n = 40). Following the pilot study,
hard-copy prototype instruments were revised and operationalized into a Microsoft
Access 2000™ application to provide disease-specific data entry screens with checks for
completion and errors.

Abstraction was restricted to a specific set of forms (transfer records, clinical
summary checklists, interdisciplinary team admission assessments and plan of care
narratives) completed or available at the time of initial MHB enrollment. Abstractors
were cautioned against review of re-certification or other data recorded after the initial intake. For patients experiencing more than one enrollment (n = 8) during the observation period, only initial intake data were abstracted. Karnofsky scores (58-59), an optional measure of global disablement relevant to the LMRP for stroke, are narratively recorded in study site records and were missing for 5.1% of the total sample.

To reduce potential observational bias, the abstractors were cross-trained in uniform LMRP interpretation, subject to inter-rater reliability tests and blinded to case/control survival outcome. During the training period, conferral between abstractors, investigator and hospice and non-hospice physicians was permitted. During chart review proper, assistance with clinical interpretation was limited to individual abstractor consultation with the hospice Medical Director. For every case and control record in the sample, each LMRP criterion was assessed according to a “fulfilled/failed to fulfill” standard. Along with the appropriate set of disease-specific criteria, the National Hospice and Palliative Care Organization’s (NHPCO) “general guidelines” (Table 2) were concurrently applied to every sample record. Assessment of fulfillment status was carried out on a disease-by-disease basis.

Inter-rater reliability was computed using the simple kappa coefficient following independent and simultaneous abstractor assessments of criteria fulfillment in the 11th through 20th record in each diagnostic grouping. The strength of the association between fulfillment of the overall prognostic criteria and short-term duration of survival was assessed by simple logistic regression. Within each diagnostic grouping, patients were classified into 2 x 2 tables to calculate measures of predictive validity. Because there were more short-term survivors in the cohort than those selected for study, positive and
negative predictive values and false positive and negative rates were adjusted for the sampling fraction of controls. This was done by multiplying the number of controls selected who met and did not meet criteria by the total number of short-term survivors divided by the number of controls who were randomly selected. Statistical Applications Software (SAS)™ 8.2 (SAS Institute, Inc., Cary, NC) was used for all analyses.

Results

Demographic and clinical characteristics of the sample are displayed in Table 3. The mean (±SD) patient age was 85.5 ±8.2 years; 60.3% received hospice care in nursing homes (heart disease 45.2%; stroke 51.9%; dementia 79.7%) as opposed to residential care settings.

Individuals selected and non-selected as controls from among the original cohort of short-term survivors did not differ significantly with respect to age, sex, functional status or site of care for any of the diagnostic categories. Cases and controls within each diagnostic category did not differ significantly on age, gender or site of care (Table 4).

Assessors completely agreed on fulfillment of dementia and stroke criteria (kappa = 1.0). The kappa for fulfillment of the heart disease criteria was 0.6, indicating moderate agreement.
Table 3. Characteristics of the sample by diagnosis at hospice admission

|                               | Acute & Chronic |  | Total |  |
|--------------------------------|-----------------|-------------------------------|-----------------|
|                                | Heart (n=210)   | Stroke (n=56)                | Dementia (n=187)| Sample (n=453) |
| Mean (±SD)                     |                 |                               |                 |                |
| Age                            | 85.0(±8.7)      | 84.9(±9.2)                    | 86.3(±7.3)      | 85.5(±8.2)     |
| Karnofsky score                | 30.3(±10.4)     | 23.3(±8.8)                    | 25.6(±8.1)      | 27.5(±9.7)     |
| Percentage                     |                 |                               |                 |                |
| Female                         | 54.8            | 76.0                          | 79.1            | 67.5           |
| Institutional site of care     | 45.2            | 51.9                          | 79.7            | 60.3           |
| Weight loss 10% or more in     |                 |                               |                 |                |
| 6-months                       | 52.2            | 45.7                          | 78.1            | 61.9           |
| Incontinence of urine and stool| 34.3            | 94.0                          | 98.3            | 68.1           |
| Dyspnea                        | 64.3            | 24.1                          | 23.5            | 42.4           |
| Karnofsky ≤30                  | 65.2            | 88.2                          | 87.6            | 77.2           |
| Bedridden                      | 32.9            | 74.1                          | 53.0            | 46.2           |
Table 4. Case/control comparison of the sample at hospice admission

<table>
<thead>
<tr>
<th></th>
<th>Heart n=210</th>
<th></th>
<th>Stroke n=56</th>
<th></th>
<th>Dementia n=187</th>
<th></th>
<th>Total Sample n=453</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Case</td>
<td>Control</td>
<td>Case</td>
<td>Control</td>
<td>Case</td>
<td>Control</td>
<td>Case</td>
<td>Control</td>
</tr>
<tr>
<td>Age [mean(±SD)]</td>
<td>n=93</td>
<td>n=117</td>
<td>n=23</td>
<td>n=33</td>
<td>n=91</td>
<td>n=96</td>
<td>n=207</td>
<td>n=246</td>
</tr>
<tr>
<td></td>
<td>84.7(±9.9)</td>
<td>85.1(±7.6)</td>
<td>84.8(±9.1)</td>
<td>85.1(±9.2)</td>
<td>86.2(±8.0)</td>
<td>86.5(±6.6)</td>
<td>85.4(±9.0)</td>
<td>85.67(±7.5)</td>
</tr>
<tr>
<td>% female</td>
<td>57.0</td>
<td>52.0</td>
<td>61.0</td>
<td>85.0</td>
<td>84.0</td>
<td>76.0</td>
<td>69.0</td>
<td>66.0</td>
</tr>
<tr>
<td>% nursing home site of care</td>
<td>41.9</td>
<td>47.9</td>
<td>52.2</td>
<td>48.5</td>
<td>73.6</td>
<td>85.4</td>
<td>57.0</td>
<td>62.6</td>
</tr>
</tbody>
</table>
Using short-term survival (≤6 months) as the outcome variable, odds ratios for fulfillment of the Medicare LMRP prognostic criteria are displayed in Table 5. Only in patients with dementia was the association between fulfillment of prognostic criteria and short-term (≤6 months) survival statistically significant (OR = 2.97, 95% CI = 1.52 to 5.82, p<0.05). The association in heart disease approached, but did not attain statistical significance (OR = 1.65, 95% CI = 0.92 to 2.97; p = 0.08). The association in acute stroke was not significant (OR = 3.60, 95% CI = 0.35 to 34.71, p = 0.17). The odds ratio between the prognostic criteria for chronic stroke and short-term survival could not be calculated, because all chronic stroke patients met the criteria irrespective of duration of survival. One hundred percent of the sample met the NHPCO general guidelines tested. Therefore, odds ratios and measures of predictive validity were not calculated for these criteria.

Across the three sets of disease-specific LMRP criteria tested, overall rates of classification error were high and false negative error rates were consistently much higher than corresponding false positive error rates. False negative rates ranged from 56% in dementia to 70% in heart disease and 75% in acute stroke (Table 4). In contrast, false positive errors ranged from 9% in acute stroke to 20-21% in heart disease and dementia.

Discussion

Hospice is one of the fastest growing Medicare services (39). Increasing admission of patients with non-cancer diagnosis in part motivated the Centers for Medicare and Medicaid Services (CMS) to institute Local Medical Review Policies (LMRP) for non-cancer claims review (60). We investigated the association of the
Table 5. Odds ratios and measures of predictive validity by LMRP diagnostic category.

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>% Met criteria</th>
<th>Odds ratios 95% confidence interval</th>
<th>P-value</th>
<th>*Sensitivity †Specificity ‡PPV §NPV rate rate</th>
<th>ÔFalse positive rate</th>
<th>#False negative rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dementia n=187</td>
<td>64.2</td>
<td>2.97(1.52 – 5.82) .005</td>
<td>76.04</td>
<td>48.35</td>
<td>78.98</td>
<td>44.16</td>
</tr>
<tr>
<td>Heart n=210</td>
<td>55.7</td>
<td>1.65(.92 - 2.97) .075</td>
<td>61.21</td>
<td>51.06</td>
<td>79.60</td>
<td>29.67</td>
</tr>
<tr>
<td>Acute stroke n=29</td>
<td>79.3</td>
<td>3.60(**.35 – 34.71) ††.168</td>
<td>85.71</td>
<td>37.50</td>
<td>91.69</td>
<td>24.58</td>
</tr>
<tr>
<td>Chronic stroke n=27</td>
<td>100.00</td>
<td>Zero cells, chi square not a valid test</td>
<td>Zero cells, unable to calculate measures of predictive validity</td>
<td>Zero cells, unable to calculate measures of predictive validity</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Sensitivity - probability that short-term survivors meet the criteria.
†Specificity - probability that long-term survivors do not meet the criteria.
‡Positive predictive value (PPV) - probability that those who meet the criteria survive 6 months or less.
§Negative predictive value (NPV) - probability that those who do not meet the criteria survive longer than 6 months.
ÔFalse positive rate - percent of those meeting criteria who were long-term survivors.
#False negative rate - percent of those not meeting the criteria who were short term survivors.
**Cornfield limits not accurate; exact limits used.
††Fischer exact results used due to small sample size.
criteria specified in these policies with actual survival and classification error frequencies. With the exception of dementia, the LMRP criteria were not significantly associated with short vs. long term duration of survival. These findings raise substantial concerns about the use of LMRP criteria as the gold standard upon which the approval or denial of Medicare Hospice Benefit (MHB) reimbursement claims are based.

The LMRPs represent modified versions of disease-specific sets of severity indicators that were first published in The Medical Guidelines for Determining Prognosis in Selected Non-cancer Diseases (36). The “Guidelines“ were constructed based on expert opinion combined with previously existing data on clinical markers associated with short-term (≤6-month) survival, and were developed by the National Hospice and Palliative Care Organization (NHPCO), the nation’s largest hospice membership group.. Although the two instruments similarly profile the physical signs of terminal status, they are not similar in content, structure, and intended usage (31,32). The NHPCO Guidelines define conditions of hospice referral by providing general and disease-specific protocols, but do not attempt to codify the formulation of end-of-life prognoses. The Medicare policies specify the number and combinations of required criteria and are applied as screening tools in official chart audit processes to protect Medicare against improper use and payments. The LMRP criteria notably narrow and restrict MHB eligibility as defined in the founding MHB Federal statutes (6).

Sets of criteria to reliably distinguish the terminal phases (six months or less of life expectancy) of advanced and progressive diseases would serve important clinical, practical and humanitarian goals in hospice and in many other health care settings (33). However, the LMRP criteria investigated appear to have limited scientific merit. With
the exception of dementia, neither this study nor those of others (37,38,49,53) have shown these criteria to be significantly associated with short-term (≤6-month) duration of survival outcomes. Although predictive models may improve survival estimation for groups of patients (48,23, 61, 62), wide variability exists in actual survival durations of individual patients (9,38).

As is apparent from these findings, application of the LMRP criteria can yield considerable misclassification. A consistent pattern of relatively low rates of false positive error was observed in conjunction with much higher corresponding rates of false negative error. In this policy context, the practical consequence of high false negative errors is erroneous classification as MHB-ineligible of individuals who would survive less than six months. The consequence of false positive errors is erroneous classification as MHB-eligible of individuals who survive longer than six months. Relative to the costs and benefits of regulatory innovation, false negative errors most disadvantage patients, families and providers; false positive errors most disadvantage payers of publically-funded health care services.

A conspicuous annual reduction in hospice median lengths of stay has paralleled national LMRP implementation. From 1992 to 1998, the national average length of stay in hospice declined 20 percent, from 74 to 59 days (39). The decline in the median number of hospice days used per beneficiary was particularly striking among patients with diagnoses other than cancer; length of stay among this patient group declined by 38 percent, while cancer patients’ stays declined by 14 percent (39). In 2002, the most recent year for which data are available, median length of stay in US Medicare hospice programs was 26 days (1). Decreasing length of stay trends may suggest altered post-
LMRP decision-making behaviors on the part of referring physicians and hospice providers, who may favor hospice certification and enrollment of patients whose condition is most reflective of LMRP criteria.

Sixty percent of the sample received hospice care in nursing homes, a proportion substantially higher than the 36 percent of MHB recipients who resided in nursing homes on a national basis in 2000 (39). This discrepancy is largely explained by two study design features. First, only patients with non-cancer diagnoses were selected, and second, long-term survivors were over-sampled. Patients with non-cancer diagnoses are disproportionately represented among nursing home populations (39). Of all patients treated at the study site in 2000, approximately 38 percent resided in nursing home settings at admission, similar to the above referenced national percentage.

We elected to study hospice populations, rather than those rather than terminally ill, community-based individuals who might show a different association between fulfillment of Local Medical Review Policies and life expectancy. Given the regulatory simulation objective of the study, this may not pose a limitation. We utilized a hospice sample for two additional reasons. First, we sought to hold constant any selection processes that might predispose certain groups to opt for palliative care in lieu of traditional end-of-life health care services. Second, it has been noted that patient quality of life may improve or stabilize in hospice care settings and that prognosis may become less well defined (41).

Potential reporting bias presents another area of concern. Given that a large proportion of sample patients suffered cognitive impairment, much of the clinical source data were based on surrogate rather than self-report. Further, certain of the LMRP
criteria, e.g., nutritional status, require at patients or surrogates recall patient patterns of weight loss that occurred over the 6 months that precede hospice admission. Reliance on surrogate report is an accepted practice in investigations that rely on secondary sources, however, and was unavoidable in this study. In addition, there is no reason to expect that the quality of data for cases and controls would differ, so any bias introduced is unlikely to be differential.

The kappa for fulfillment for heart disease criteria was only moderate (6), which may have led to a weaker association between the criteria fulfillment and case/control status for this disease group.

Finally, the findings represent the survival outcomes of patients at a single large, Florida hospice. Replication in hospices with different organizational structures and in nationally representative samples is required.
Chapter Three

Time-to-Death Factors in Far Advanced Disease: The Belief Systems of Experienced, Multidisciplinary Hospice Personnel

Abstract

Prognostic beliefs of experienced, multi-disciplinary hospice personnel on long-term (6-month), physical and non-physical prognostic influences in far advanced diseases were identified through content analysis of focus group data. Belief was consistent across disciplinary boundaries (nurses, social workers, chaplains, home health aids and physicians) that duration of survival in end-stage disease is primarily influenced by physical factors. Consensus of belief additionally existed that non-physical factors additionally influence longevity in terminal illness, but more so in non-cancer relative to cancer diseases and at remote (months) versus more imminent (days, weeks) death proximities. Beyond diagnosis, progression and severity of disease, quality of life, stress level, social support, caregiver traits and the milieu of care were identified as particularly important patient time-to-death influences. Although hospice experts explain time to death primarily physically, they additionally report the effects of a complex and dynamically shifting array of patient-specific and contextual factors. Prognosis in advanced diseases may best be informed by physical and non-physical factors.
Introduction

Development of reliable formulations for long-term (6-month) time-to-death estimation remains a highly desirable but elusive medical goal (9), particularly in non-cancer diseases (32). Attempts to codify the more traditional and subjective approach to this dilemma, namely physician clinical judgment, have met with limited success (10). The few indices that attempt to stratify general patients into risk groups for long-term mortality have a number of limitations. Most apply to hospitalized patients (25, 61) and all require complex calculations and data not routinely available to health care personnel in applied clinical settings. Only a few include functional status measures despite its association with mortality in older hospitalized patients (63).

The prognostic formulations in use today typically exclude non-physical factors, despite the widespread acceptance of their health effects. The goal of this descriptive, exploratory study was a increased understanding of physical and non-physical factors that may influence prognostic accuracy in end-stage disease. The study was undertaken as a preliminary step in a broader research agenda that evaluates the performance of so called “Medicare prognostic criteria” for the establishment of hospice eligibility.

Methods

Research Protocol

Five discipline-specific focus group sessions of 90-minutes each were conducted with experienced, multi-disciplinary staff with direct patient-care responsibilities at a single large, non-profit hospice located in Florida. Through a pilot testing and revision process, a three-part interview protocol (introductory and closing statements, sets of
queries, and instructions for a pen-and-paper exercise) was developed to ensure adherence to the principles of qualitative research (66). Focus group discussion was restricted to time-to-death factors believed to influence the survival duration of newly admitted Medicare hospice beneficiaries, or those initially certified by two physicians to be within a 6 months or less proximity to death.

The Sample

Hospice personnel from dissimilar health care disciplines (registered nurses, social workers, chaplains, home health aides and physicians) with a minimum two years of direct patient care experience were recruited for voluntary study participation. Of the 37 total respondents, 23 (61.16%) were female and 100% were Caucasian (Table 6). Individual focus group size ranged from 4 physicians to 11 registered nurses. Mean number of years of hospice experience ranged from a low of 4.5 years (social workers) to a high of 9.4 years (physicians) with a 6.9 years mean level of experience for the total sample.
Table 6. Focus group composition, hospice personnel

<table>
<thead>
<tr>
<th>Discipline</th>
<th>Number of participants</th>
<th>Male/Female</th>
<th>Mean years hospice experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurses</td>
<td>11</td>
<td>0/11</td>
<td>6.8</td>
</tr>
<tr>
<td>Social Workers</td>
<td>11</td>
<td>3/8</td>
<td>4.5</td>
</tr>
<tr>
<td>Home Health Aides</td>
<td>6</td>
<td>3/3</td>
<td>9.0</td>
</tr>
<tr>
<td>Chaplains</td>
<td>5</td>
<td>4/1</td>
<td>4.6</td>
</tr>
<tr>
<td>Physicians</td>
<td>4</td>
<td>4/0</td>
<td>9.4</td>
</tr>
<tr>
<td>Total</td>
<td>37</td>
<td>14/23</td>
<td>6.9</td>
</tr>
</tbody>
</table>

*Focus Group Interviews*

Two co-moderators and a trained and experienced moderator facilitated each focus group session. A co-moderator who read a scripted statement on research goals introduced each session. The other co-moderator then in turn phased all queries (physical; psycho-social; spiritual; environmental; caregiver) exactly as scripted: “What _______ factors do you consider most influential in determining time-to-death among patients newly admitted (terminally diagnosed and assigned a 6-month or less survival prognosis) to hospice care?” A concluding written exercise was also introduced as scripted: “List your opinions on the top three physical or non-physical factors that most strongly influence time to death in newly-admitted hospice patients.” All focus group discussions were audiotaped, transcribed verbatim and later checked for accuracy against co-moderator hand-written notes.
Data Analysis

A three-person moderator/co-moderator team applied consensus-based analysis to cross-disciplinary focus group data (65). Each analyst individually applied coding and categorization (66) to each of the five transcripts; transcript notations were then compared in a moderator/co-moderator group process to identify recurrent, cross-disciplinary themes of discourse. To provide for test-retest reliability, the process of analysis was documented and archived. A full transcript of the raw data is stored on computer disk.

Results

Analysis revealed cross-disciplinary consensus on a more powerfully influential role of non-physical mortality factors in non-cancer relative to cancer diseases, and at remote (months) versus imminent (days, weeks) death proximities. Care has been taken herein to present findings within a framework of existent medical evidence and to include all study data, including that which may appear contradictory or paradoxical. Verbatim transcript excerpts are displayed in Tables 7-12.
Table 7. Hospice-related time-to-death beliefs hospice personnel
(Commentator discipline is signified by RN=nurse; SW=psychosocial professional; C=chaplain; CNA=certified nurse assistant; and P=physician)

<table>
<thead>
<tr>
<th>Hospice survival benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>“I think with hospice care you finally get your caregiver, change in the environment, psychosocial support, spiritual support. Just as important, the patient gets his medications on a regular basis, maybe for the first time. Someone is showing him how to use them, and the patient lives longer than expected. Hospice actually provides a spectacular service that allows people to be really comfortable, maybe for the first time.” P</td>
</tr>
<tr>
<td>“I think hospice people have the capacity to come in when the family is obviously upset because of the process and the reality of the events. ...And hospice, because of lack of turnover, confidence of staff, the support staff gives each other, is pretty much able to maintain a concerned, matter of fact attitude.” P</td>
</tr>
<tr>
<td>“It could be an indication that this person may go sooner if they are particularly lonely. But at the same time, when we get these folks with hospice we see them rebound because they have people who are tending to their needs, caring for them. SW</td>
</tr>
<tr>
<td>“It depends on the diagnosis. It seems like our cardiac people, real elderly cardiac people, actually thrive when hospice care arrives. The COPD people, the people who are left at home alone.” And the dementia people, they just go on and on.” RN</td>
</tr>
</tbody>
</table>
Table 8. General time-to-death beliefs of hospice personnel
(Commentator discipline is signified by RN=nurse; SW=psychosocial professional; C=chaplain; CNA=certified nurse assistant; and P=physician)

**Survival outcomes tend to be patient-specific**

“Because everybody is unique, it (decline) goes on at a different rate.”

SW

“That is always the problem with setting up guidelines. It is so iffy. It is relative to the individual at the time.”

C

“...it (prognosis) is a nonlinear process. It is the attempt to use actuarial data to apply to a single patient with a number of imponderables and variables.”

P

**Survival influences are dynamic**

“...All of this stuff can change, the caregiver issues, the environment, the psychosocial aspects and the spiritual. So two weeks from when you did that (made the prognosis) the net balance may have changed.”

P

“Any intervention will change the prediction. Any change in the environment. There are lots of ways of changing it.”

P

“My point is that during six months period, the estimate of survival you made initially may be so affected by these other changes that it is meaningless.”

P

**Survival influences vary by diagnosis**

“They may last nine months, they may last that year, in poor shape, granted, but their will may be a little stronger than their illness at that time, if you are talking about a cardiac or a COPD versus a cancer. We have two different kinds of patients we are talking about.”

SW

“I’m not sure what the reason is, but patients with non-neoplastic diagnoses like chronic lungers seem to do better after they come through the front door of hospice than when they don’t. It seems like just on the same regimen (as cancer patients) they do better.”

P
Table 9. Patient-specific time-to-death beliefs of hospice personnel
(Commentator discipline is signified by RN=nurse; SW=psychosocial professional; C=chaplain; CNA=certified nurse assistant; and P=physician)

“Will to live”

“We have all seen people who should have been dead months ago…Their will to live is keeping them here, their body is not…Their sheer determination to keep going for whatever reason is keeping them here.”

SW

“We hear a lot of them say on admission, ‘Well, I have to live until – ‘I will see that baby,’ ‘I promised her I would walk her down the aisle. I have to be there…’ And come hell or high water, they usually are.”

RN

“Will to die”

“…When they realize that they are just going to get weaker and weaker, they just say ‘I’m not going to do this, I am just going to die.”

SW

Depression hastens death. I think it’s a sense of ‘If this is all there is, I don’t want to be here’.”

C

Self-defined Quality of life

“I think in certain situations hospice extends life and in certain situations, it makes the quality of life much better. Maybe in all situations it makes the quality of death better.”

P

“Part of the quality of life issue is normalcy. When normalcy declines, people lose those things through which they once defined themselves.”

SW

“I think choice equals quality of life and quality of life equals choice. When a decrease of choice happens, a decrease in the quality of life happens.”

SW
Table 10. Physical time-to-death beliefs of hospice personnel (Commentator discipline is signified by RN=nurse; SW=psychosocial professional; C=chaplain; CNA=certified nurse assistant; and P=physician)

“…If they are telling me “Gee, I was out walking around the block last week and now I can barely get out of bed, I’m not eating, I’m not drinking.” They are really telling me that they know what is going on.” RN

“Within each disease category there are factors which measure the disease, which are important. It basically translates into time in bed and vital signs. And if the weight loss is ten pounds per month, they can’t live very long.” P

“Pain control, far and above for most patients, is the most important thing. Get the pain under control, and then the other things come into play. No matter how much somebody loves you, if you have bone cancer and are screaming in pain, nothing will do.” C

“From a medical standpoint, when people’s pain is out of control, very rarely will they be able to “let go” until they, either through medication or psychosocial intervention can become relaxed and then they can go.” SW

“I don’t think there is any doubt that (with skillful control of pain) it (death) may come sooner, but I don’t think that is the issue…” P
Table 11. Spiritual time-to-death beliefs of hospice personnel
(Commentator discipline is signified by RN=nurse; SW=psychosocial professional; C=chaplain; CNA=certified nurse assistant; and P=physician)

**Spiritual beliefs**

“They are resolved about whatever is next. They may be resolved about the spiritual beliefs they have or they may be resolved that this is it, there is nothing else. So the question is, are they resolved, or are they in fear, unresolved?” **SW**

“I had one patient who lived so long because of his uncomfortableness with what was going to happen in the hereafter. If we can get to a place where whatever we believe in, whether it is heaven, paradise or reincarnation, and we can accept that belief spiritually, then it is easier to let go of this life.” **C**

“If they are atheistic, they are not going anywhere for awhile… I have only two who were really true atheist and the patient hung on and hung on. Because there is nothing to go to and they have something here, and there is nothing anywhere else.” **RN**

“...
Table 12. Caregiver time-to-death beliefs of hospice personnel
(Commentator discipline is signified by RN=nurse; SW=psychosocial professional;
C=chaplain; CNA=certified nurse assistant; and P=physician)

“...she is elderly, has had lots of health problems. When she greeted me at the door with a
walker, then I knew I had a problem. The man just had a hip operation so he is having a
hard time getting out of the bed.” CNA

“You go in and you say to this little caregiver, ‘Why are these Monday’s meds
(medications) when it is Wednesday?’ and she will say, ‘Oh, I forgot’.” CNA

“She never had a child. She never had to give any care. She didn’t care if her husband
was taking a bath or not. She didn’t care if he ate or not.” CNA

“I think when a caregiver is stressed, it goes right back to the patient. If you are giving
the patient stress, it is going to shorten their lives.” CNA

“Anxiety level of the caregiver. The minute I went into the house she grabbed me. She
said ‘I can’t take care of him.’ ‘I don’t want him to die’.” CNA

“One of the things is the attitude of the caregiver toward the patient. Are they providing
care because they want to, because they have to, out of duty, are they hostile about doing
it?” P

“Culture. Culture often dictates the type of care and the extent of care that will be given
by the family…A lot of…from their own spirituality in terms of such things as DNRs,
living wills, feeding tubes, withholding nutrition and these types of things…. Maybe the
point is that they are weak and that they need food so we are going to make sure that they
eat… Maybe narcotics are bad…. It is drugs, no I don’t want to give them that. That is
our culture.” C
Paper and pencil responses have been thematically categorized in Table 13. The majority of written responses concern management of death anxiety and late-life developmental tasks through coping mechanisms that are religious, spiritual and/or philosophical in nature. The only physical survival effects listed by these respondents were diagnosis and overall level of disease severity.

Table 13. Time-to-death factors recorded by multi-disciplinary hospice personnel in a written exercise

<table>
<thead>
<tr>
<th>Physical factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-cancer diagnoses</td>
</tr>
<tr>
<td>Physical debility</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>General non-physical factors</th>
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<tbody>
<tr>
<td>Patient psycho/social/spiritual posture.</td>
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<tr>
<td>Psycho/social/spiritual environment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient cognitions, attitudes, mood state factors</th>
</tr>
</thead>
</table>

**Will**
- Patient’s will to live.
- Will to die.
- Patient’s will to die
- “Will” (strong desire to control what is wanted).
- Will to live or die.
- Patient’s will/attitude towards illness/dying.

**Acceptance**
- Acceptance of death - will to die.
- Verbalization of acceptance and peacefulness to die
- Acceptance of diagnosis.
- Patients attitude.
- Patient’s attitude toward dying.
- Patient expects to die in certain time frame - 6 months.
**Quality of Life**
Decreed quality of life - having choices.
Loss of control.
Loss of choice and will.
Quality of life.
Loss of perceived control.
Loss of control and choices.

**Depression**
Lack of hope and meaning at that point of prognosis.
Loss of hope.
Hopelessness.
Loss of meaning.
Lack of goals to continue living.
Loss of desire to fight illness any longer
Depression - both that of patient and caregiver including lack of meaning, lack of support, sense of isolation

**Social support factors**

**Social support**
Emotional ties.
Lack of support system - being alone.
“Family” support and attitude.
Family/caregiver dynamics.
Support system.
Lack of supportive care environment.
Limited support systems.
Loss of support.
Lack of interpersonal relationships.
Relationships of people involved in care.
Emotional climate surrounding patient.
Lack of caregivers.
Lack of support.

**Closure in interpersonal and practical affairs**
Resolution of end-of-life issues.
No “unfinished business.”
Completion of unsettled issues.
Bothersome issues have been resolved.
Unfinished business.
Patient reports he/she is “ready to go,” all goals/tasks have been completed.
Loved ones will be cared for.
Patient feels confident that ones left behind will be O.K. at the time of death.
Financial.
Permission to die
Primary caregiver has accepted patient’s terminal diagnosis.
Family caregiver tells patient “it”s O.K. to go, I’ll be O.K.”
Family permission to leave (die).
Patient and family acceptance of end of life.

Spiritual factors

Reconciliation, forgiveness
Patient’s issues re: forgiveness of self and others.
Reconciliation with God, family - or others - forgiveness, independence.
Reconciliation of life issues (includes patient’s discussion with deceased persons)

Peace, acceptance through spiritual/religious belief system

Inner peace
Whether patient has made peace with his dying - psychosocial/spiritual acceptance
Belief system surrounding death - spiritual preparedness.
Spiritual belief vs. Non-belief.
Belief that they are going to a better place.
Belief system.
Patients belief system or lack of same.
Open discussion with family members regarding belief in future life.
Willingness to discuss their religious - spiritual issues.
Patients with strong faith or those with none seem more able to face the unknown.
Patient is O.K. with dying - feels has had a good life, believes in some kind of after life
Patient reports he/she is at peace has lived a good life, will go to a better place.
Spiritual.

Spiritual comfort
Patients view and meaning of death.
Patient and caregiver find peace in near death experiences.
Visualizing the calling “to go” from other deceased.

Physical Time-to-Death Beliefs of Hospice Personnel

Respondents perceived time-to-death judgments to be much more precarious in non-cancer than cancer diseases, a belief epidemiologically verified (12). Furthermore, imminently impending death (death within days) was considered relatively easy to
predict through reliance on clinical signs of organ system shutdown, but the range of
time-to-death markers at long-term (6-month) proximities were characterized more than
once as “imponderable.” These respondents linked prognostic accuracy with clinical
knowledge of patients obtained within that patient’s own care milieu, a belief supported
by the traditions of clinical medical practice. Although physical factors were deemed the
primary time-to-death determinants in advanced diseases, dissimilar hospice survival
curves were observed to occur in patients with similar diagnostic and physiological
profiles. Physical control of pain through pharmacological methods was paradoxically
referenced as both supporting prolonged survival and facilitating life/death transitions.

Patient-specific Time-to-Death Beliefs of Hospice Personnel

Patient Attitudes, Cognitions and Behaviors

Patient verbal expressions and/ or behavioral manifestations of “will to live” or “will
to die” attitudes were described as weak but consequential survival influences in non-
cancer but not cancer diseases. Patients’ “will to survive” intents were most often
discussed in previously reported end-of-life contexts (67), such as patient desire to live to
experience upcoming visits, holidays or ceremonial occasions of deep personal
significance and/or patient resolve to attain pre-death closure practical, psychological,
spiritual and/or interpersonal affairs (68). The reality of such effects on survival is
supported by (69-70) “dip-peak” death patterns that are known to cross-culturally bracket
events of broad social importance.
Quality of Life

Improved quality of life (QOL) has been identified as a chief benefit of palliative over traditional end-of-life care (71). Quality of life patient-appraised as unsatisfactory was associated by these respondents with previously described late-life syndromes that include “weariness with life,” “loss of the will to live,” and late life clinical depression (72-75). Quality of life more positively appraised by patients was believed to be a powerful motivator for a continued personal struggle for survival (76).

Stress

The tremendous challenges and burdens inherent in conditions of advanced old age, severe illnesses, and limited survival prognoses were discussed by research participants, burdens described as encompassing limited function, chronic pain, alteration of personally significant life roles, conflictual or unresolved or relationship issues the reality of impending loss of the Self and others, and the developmental tasks of life completion and closure. “Death or existential anxiety” thus described is in accord with the psychoanalytic belief systems of Erikson (77), who maintained that the central late life developmental challenge concerns the maintenance of psychological equilibrium or “integrity versus despair.” Individual management of stressful late life challenges through religiously- or spiritually-oriented channels was linked by these respondents with improved well-being (78) and improved mental and physical health. Further, these informants linked religious preoccupations of a less positive nature, those for example that might be focused on after-life retribution, with heightened patient anxiety. Late life anxiety
thus intensified was paradoxically described as both a life-prolonging and death-hastening agent.

According to respondent beliefs as analyzed herein, the survival effects of patient religious beliefs vary according to death proximity. For example, at more remote 6-month proximities, self-comforting religious or spiritual ideations and/or behaviors were described as important contributors to positively appraised patient QOL, health maintenance and prolonged survival. At more imminent death proximities, however, similar thoughts and actions were more commonly linked with facilitated and hastened life/death transitions. In sum, these data suggest that hospice personnel perceive end-stage health status and longevity to be subject to modification through cognitive/behavioral channels.

While these findings are not clear-cut, they are consonant with similarly mixed literature reports. For example, Jarvis and Northcott found associations of religion with survival (79), whereas Christakis (40) did not. The general association between religious and spiritual behaviors and improved health and well-being is well known (80-84). The negative health consequences of stress are also established (85-86), and intriguingly, prayer has been associated with improved health outcomes (87).

Contextual Time-to-Death Beliefs of Hospice Personnel

Social Relationships

Supportive social relationships were described as quality of life essentials, their absence an ominous mortality risk factor. This was held to be true even given contrary
patient social habits or preferences. Related research shows that social isolation places patients at increased mortality risk (88-90); cardiac patients appear to be differentially disadvantaged by this factor (91).

**Caregiver Factors**

Focus group members believed that caregiver-specific traits, including certain disordered mood states (depressed, extremely anxious) and care delivery styles described as sub-optimal (hostile, withholding, inept) have an effect on patient time to death in hospice settings. The association most frequently referenced linked impaired caregiver physical or cognitive function with negative patient survival outcomes. Because over 50 percent of MHB beneficiaries are aged 75 years and over (1), their care at home is, according to these respondents, largely provided by spouses who are themselves elderly, and oftentimes significantly hindered by cognitive or physical health problems. Crippling arthritis, heart conditions, back problems that impede lifting and hearing impairments were among the caregiver problems discussed by focus group members. A related study on caregiving noted a rapidly increasing extent of ill health as the age of the “carer” increases; in this study over three quarters of the careers over the age of 75 years reported some previous ill health. Finally, an absent or neglectful caregiver was universally held by focus group members to place patients at premature death risk.

Although caregiving has been intensively studied over the past decade, surprisingly little is known about the association of explicit caregiver variables and survival outcomes. Higher stress levels among caregiver populations has been established (92), however, as have lower levels of life satisfaction (93), greater incidence
of depression (94) and poorer health (95) in comparison to non-caregivers. According to these respondents, because hospice care is usually provided in the patient’s home, or those of relatives or friends, the caregiver’s physical and psychological abilities are key patient quality of life and survival factors.

**Milieu of Care**

Focus group members strongly endorsed a hospice versus conventional care survival advantage. On the one hand, proving a hospice survival effect is methodologically problematic and remains to be empirically established. On the other, hospice patient and caregiver satisfaction levels exceed those reported in conventional medical settings (96-97). Effective management of physical and psychological distress is fundamental to the hospice model of care.

**Discussion**

Accurate prediction of the course of end-stage disease becomes increasingly urgent in terminal conditions. Patients and families need reliable survival estimates to facilitate end-of-life planning; physicians must rely on prognosis for appropriately timed hospice referrals. Despite the humanitarian and administrative relevance of this topic, little is known about “long-term mortality predictors,” or time-to-death factors operative within 6-month as opposed to a days or weeks timeframe. Hospice care settings are ideal for the study of both long-term and more immediate time-to-death factors.

In the focus group discussions, non-physical, patient-specific, cognitive/behavioral factors (will to live, quality of life, stress and anxiety) and contextual factors (social support, caregiver, environmental) were believed to be
important time-to-death influences, but much more cogently so in non-cancer as compared to cancer diseases.

Focus group members were convinced, irrespective of disciplinary background, that hospice care interventions benefit quality of life and late life survival, and particularly so for patients with non-cancer diseases. If or why this might be so is unknown, but rationales may be found in “burden of illness” theories. The burden of illness in dementia, heart disease, stroke and other chronic, life-threatening conditions is particularly high for both patients and caregivers. This is because the consequences of chronic illnesses are persistent and recurring over many years’ duration and significantly limit individual ability to perform routine activities of daily living. Thus, in addition to medical services, people with chronic conditions often experience “weariness with life,” and may require intervention that are social, psychological and/or rehabilitative in nature. Furthermore, increased burden of illness factors have been associated with higher incidence of clinical depression (94), and psychosocial factors are known to modify the association between disability and depression in older adults (98). At the risk of oversimplification, hospice may sufficiently improve the quality of life to tilt the balance toward protracted individual struggle for survival. As previously referenced according to hospice experts, any “will to live” survival effect may be essentially null in cancer diseases, but significantly important to the prolongation of non-cancer survival. Stress is known to alter biomarkers (91), and as previously referenced; hospice may confer superior advantages that support effective stress management.

The health effects of many of the time-to-death factors qualitatively identified are empirically established, but prognostic usefulness by and large remains unfounded.
Based on these analyses, it may be concluded that prognosis from months-long perspectives is considerably more complex than reflected in codified tools such as the “Medicare Prognostic criteria” that screen for 6-month survival, requiring attention to influences other than physical disease severity. The relative lack of evidence showing a role for non-physical, patient-specific and contextual factors in remote prognosis of death leaves the contribution of such factors largely unknown. The value of the focus group findings may therefore lie less in prognostic implication, but may point to the need for psychosocial interventions aimed at improving patient and caregiver well-being and health status and in medical settings. The value of training in life completion and closure issues for both patients and caregivers is suggested, as are the development of techniques specifically targeted at the management of death anxiety and late-life stress. Maximization of interpersonal connectedness and social support in healthcare settings is strongly suggested as therapeutic. Such interventions and others, including increased awareness of and treatment for late-life anxious and depressive disorders are likely to be beneficial regardless of their implications for duration of survival.

Limitations of the Research

Staff or patient demographics that may be unique may limit generalizability of the findings. Hospice volunteers were unfortunately omitted from the respondent pool even though they contribute 13% of all clinical hours to hospice patients and families (1). The study design did not allow for differentiation of terms commonly used by respondents such as “loss of the will to live” “will to die,” “readiness to die,” and “acceptance of death.” For example, it was not possible from these analyses to deduce whether the
described “will to die” attitudes of terminally ill individuals are expressions of mental disorder or of rational self-determination.

Further Research on Prognosis

An accuracy comparison of various methods for time-to-death estimation might prove instructive, including clinical judgments of physicians, team-based consensus of multidisciplinary hospice teams, and formulaic approaches as represented by the Medicare prognostic criteria. Disease-specific, serial measures of reserve capacity over the trajectory of fatal decline would also be instructive and might include immune function, neuroendocrinology and/or cardiovascular activity and other stress response variables. Disease-specific comparisons of psychosocial and spiritual, patient and caregiver issues over the course of fatal decline would also offer insight.
Chapter 4: Can the Predictive Performance of the Dementia Criterion for Medicare Hospice Eligibility Be Improved?

Abstract

Certain Medicare prognostic criteria validly predict short-term survival (≤6-month) among Medicare hospice beneficiaries with dementia. Methodological difficulties exist in these nationally applied screening instruments that include high rates of false negative errors that restrict patient inclusiveness. Tests of the original Medicare dementia criteria individually and in all possible combinations revealed that the self-care skills criterion, when applied in isolation, yields improved prognostic performance over the original three criteria, including a better balance of false negative/false positive error rates. Functional impairment measures may offer improved prognosis in dementia because of their integrative rather than single organ- or body-system focus. Clinicians and healthcare planners should be aware of the potential usefulness of functional dependence as a prognostic indicator in end-stage dementia.

Introduction

Families and clinicians face difficult decisions in dementia care, particularly the initiation of palliative or hospice care in lieu of curative treatments. Hospice care may be an attractive health care option for family caregivers because an atypically comprehensive array of medical and psychosocial services is available for the care of
severely impaired and largely bedbound (99-101) demented patients. In addition to obvious service advantages offered, the growing proportion of patients with dementia among hospice populations can be demographically explained. Currently dementia is the fourth leading cause of death among older Americans (2). Whereas in 1995, 2% of all patients admitted to Medicare hospice were diagnosed with dementia; this proportion had climbed to 7 percent in 2001 (1).

Health care professionals who treat demented individuals strongly endorse palliative goals in end-stage dementia care (102-104). However, because Medicare-hospice eligibility requires physician-certified 6 months or less life expectancy, prognostic difficulty in dementia (105-106) poses significant barriers to hospice access (42). Furthermore, due to recent Centers for Medicare and Medicaid Services (CMS) regulatory innovation, patients with far-advanced multi-infarct dementias and those of the Alzheimer’s type must now fulfill disease specific, clinically oriented “Medicare prognostic criteria for dementia” for hospice eligibility in addition to broader certification requirements (Table 14).
Table 14. Medicare prognostic criteria for dementia

(Patient must criteria I, II and III)

I. FUNCTIONAL ASSESSMENT STAGING

Patient meets *one* FAST Stage 7 or beyond:

A. 6 words – Speech ability limited to approx. half dozen words or fewer, in the course of an average day or in the course of an interview

B. 1 word – Speech ability limited to the use of a single intelligible word in an average day or in the course of an intensive interview

C. Unable to sit up

D. Unable to smile

E. Unable to hold head up

II. KATZ INDEX OF ACTIVITIES OF DAILY LIVING

Patient has *all of the 5* functional impairments listed:

A. Unable to ambulate without assistance

B. Unable to dress w/o assistance

C. Unable to bathe without assistance

D. Urinary and fecal incontinence, intermittent or constant

E. No meaningful verbal communication, stereotypical phrases only, or ability to speak is limited to six or fewer intelligible words
III. MEDICAL COMPLICATIONS OF TERMINAL ILLNESS

Patient has one of the medical complications listed within the past 12 months:

A. Aspiration pneumonia
B. Pyelonephritis or other upper urinary tract infection
C. Septicemia
D. Decubitus ulcers, multiple, stage 3-4
E. Fever, recurrent after antibiotics
F. Inability to maintain sufficient fluid and calorie intake with a 10% weight loss during the previous six months or serum albumin <2.5 gm/dl.

This investigation aimed to improve the predictive performance of the Medicare prognostic criteria for dementia through selective dropping and re-combination of the indices of which the policy is constructed. The specific objective was to reduce classificatory error rates and to achieve an improved false negative/false positive error rate balance. The three clinical indices (see “Methods” below) that make up the Medicare prognostic criteria for dementia were tested individually and in various combinations.
Methods

According to the LMRP criteria for dementia (Chapter 2, Table 1), patients should specifically fulfill all of the following three criteria to legitimize Medicare hospice certification:

1) “FAST (50-52)” - meets one level of the Functional Assessment Staging Scale, Stage 7C;
2) “KATZ (107)” - has five of five ADL impairments;
3) “MEDICAL” - has one of six medical complications.

Tests were conducted in which criteria were systematically dropped and re-examined in all possible combinations. Subsequent to each modification, risk estimates and measures of predictive validity were re-calculated.

The strength of the association between fulfillment of each set of criteria and the outcome variable (≤6-months survival) was assessed by simple logistic regression, yielding odds ratios (OR) and 95% confidence intervals. The sample was classified into 2 x 2 tables to calculate measures of predictive validity. A previously described sampling fraction was applied (Chapter 2) and Statistical Applications Software (SAS)™ 8.2 (SAS Institute, Inc., Cary, NC) was used for all analyses.

The study was conducted at a Medicare-certified Florida hospice selected based on the availability of access to a large sample of medical records (n=187) of dementia patients admitted during a specified 18-month interval (1/1/97-6/30/98). Selection of the sample has been previously described (Chapter Two).
Results

Demographic and clinical characteristics of the sample (n=187) are shown in Table 15. The sample was overwhelmingly Caucasian (96%), very old (mean age 86.3), and largely female (80.0%). The majority of sample patients received hospice care in nursing home settings (80.0%) as compared to home-based or other residential settings. The mean sample Karnofsky score (58), a global measure of disablement and dependency upon others to conduct daily life activities, was 25.6 (±8.1). A score of 26 indicates “severely disabled status, with the possible need for hospital admission (58).”
Table 15. Characteristics of patients with dementia on first admission to hospice care

<table>
<thead>
<tr>
<th></th>
<th>Dementia (n=187)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean (±SD)</strong></td>
<td></td>
</tr>
<tr>
<td>Age</td>
<td>86.3(±7.3)</td>
</tr>
<tr>
<td>Karnofsky score</td>
<td>25.6(±8.1)</td>
</tr>
<tr>
<td><strong>Percent (%)</strong></td>
<td></td>
</tr>
<tr>
<td>Caucasian</td>
<td>96.0</td>
</tr>
<tr>
<td>Female</td>
<td>80.0</td>
</tr>
<tr>
<td>Nursing home-based</td>
<td>80.0</td>
</tr>
<tr>
<td>Bedbound</td>
<td>52.9</td>
</tr>
<tr>
<td>History of ER visits</td>
<td>13.9</td>
</tr>
<tr>
<td>Weight loss</td>
<td>78.1</td>
</tr>
<tr>
<td>Edema</td>
<td>4.8</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>23.5</td>
</tr>
<tr>
<td>Altered speech</td>
<td>66.3</td>
</tr>
<tr>
<td>Decubitus, multiple, stage 3-4</td>
<td>30.0</td>
</tr>
<tr>
<td>Incontinent urine and stool</td>
<td>98.3</td>
</tr>
<tr>
<td>Agitation</td>
<td>20.3</td>
</tr>
<tr>
<td>Unresponsive</td>
<td>12.8</td>
</tr>
<tr>
<td>Pain</td>
<td>25.7</td>
</tr>
<tr>
<td>Anxiety</td>
<td>16.6</td>
</tr>
<tr>
<td>Depression</td>
<td>19.8</td>
</tr>
</tbody>
</table>
Predictive performance of differing combinations of the Medicare prognostic criteria

Table 16 compares odds ratios for 6 month or less survival, false positive, and false negative rates for 7 models encompassing all possible combinations of the criteria. When criterion III was dropped, leaving criteria I and II, the strength of association between the independent variable (criteria) and dependent variable (≤6-month survival) increased, as evidenced by a higher odds ratio. Furthermore, false positive and false negative error rates were lower, a better balance of false positive/false negative errors was achieved; and a larger proportion of sample patients fulfilled the reduced set of two criteria. Because all patients met criterion I, the use of the functional criterion (II) in isolation yielded identical findings.

Discussion

Although the use of prognostic criteria for 6-month survival in dementia has been Centers for Medicare and Medicaid Services-sanctioned since 1998, the predictive validity of Medicare screening tools remain empirically unresolved. On the one hand, one early study showed little association between this predictive formulation and short-term, 6-month survival (48), on the other, an independent research team reported that the FAST component of the Medicare prognostic criteria was significantly related to 6-month survival times of hospice patients (49, 53). A 2003 study (108) evaluated both the predictive validity of the original Medicare prognostic criteria for dementia and related but novel long-term survival predictors. No significant association was found between the Medicare dementia criterion and short-term survival; however, advanced
<table>
<thead>
<tr>
<th>Criteria included</th>
<th>Odd ratio (95% CI)</th>
<th>Odds ratio</th>
<th>False positive rate</th>
<th>False negative rate</th>
<th>% patients meeting criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>‡I, II and III</td>
<td>2.97 (1.52-5.82)</td>
<td>21.02</td>
<td>64.2</td>
<td>86.6</td>
<td></td>
</tr>
<tr>
<td>§I and II</td>
<td>5.12 (1.83-14.33)</td>
<td>24.38</td>
<td>59.4</td>
<td>37.78</td>
<td></td>
</tr>
<tr>
<td>ÔII and III</td>
<td>2.05 (1.13-3.71)</td>
<td>22.63</td>
<td>51.3</td>
<td>62.50</td>
<td></td>
</tr>
<tr>
<td>#I and III</td>
<td>1.45 (0.78-2.69)</td>
<td>19.04</td>
<td>100.0</td>
<td>50.00</td>
<td></td>
</tr>
<tr>
<td>**I</td>
<td></td>
<td></td>
<td>False positive rate</td>
<td>False negative rate</td>
<td>% patients meeting criteria</td>
</tr>
<tr>
<td>††II</td>
<td>5.12 (1.83-14.33)</td>
<td>24.38</td>
<td>86.6</td>
<td>24.38</td>
<td></td>
</tr>
<tr>
<td>‡‡III</td>
<td>1.45 (0.78-2.69)</td>
<td>25.78</td>
<td>67.9</td>
<td>66.44</td>
<td></td>
</tr>
</tbody>
</table>

Table 16. Assessment of the predictive validity of the Medicare Local Medical Review Policy for dementia; individual and composite indices

- False positive rate – percent of those meeting criteria who were long-term survivors
- False negative rate – percent of those not meeting the criteria who were short term survivors
- Original Medicare criteria (I, II, III inclusive)
- FAST + Katz
- Katz + Medical Complications
- FAST + Medical Complications
- **FAST**
- #KATZ
- + Medical Complications
age, and impaired nutritional and functional status were found to be independently associated with this outcome.

The findings reported here demonstrate a significant association between the Medicare prognostic criterion for dementia and survival duration of $\leq 6$ months. Furthermore, these findings demonstrate that improved predictive performance of this criterion may be achieved through dropping one of the criteria. A single Katz ADL criterion (107) used in lieu of the original Medicare composite criteria results in an improved risk estimate and a more acceptable balance between false negative and false positive error rates. Balanced error rates are important because these demonstrate equitable distribution of the costs and benefits of regulatory reform, in this case among Medicare payors, patients and providers. In sum, the use of a single functional, integrative measure of disease severity in lieu of more explicit and composite severity measures may yield prognostic improvements in the Medicare prognostic criteria, a finding of obvious policy relevance.

Dementia prognosis, particularly prognosis in the early stages of dementia (109-110), has been extensively studied and multiple factors have been identified as having a significant relationship with survival in this disease (111-116). The Medicare prognostic criteria are composites of specific clinical measures of internal physiologic function, such as laboratory values and vital signs, functional performance measures and signs of general physical debility that include a range of medical complications. As described by Stein and her group (117), measures of integrative function such as the Katz ADL index may support improved prognosis because they reflect the impact of illness on the whole person rather than single organ or body systems. Judging by study outcomes, measures
of integrative functioning add important information about the severity of end-stage dementia beyond that provided by internal physiologic measures. Of note is the fact that past and more current prognostic work strongly supports the relationship between functional status and mortality in general older adult populations (118), in hospitalized cohorts (119, 120) and in nursing home residents (121-124), who disproportionately tend to be patients with dementia. Alternately, findings may imply that time to death in end-stage dementia is less a feature of individual health status and more of generalized physiologic reserve capacity (125).

As previously referenced, the criteria that comprise FAST Stage 7 have been found associated with 6-month or less hospice survival (50-51). However, this criterion may not be suitable for end-of-life prognosis because dementia severity does not always progress in an ordinal fashion, as might be implied by the FAST structure (least severe to most severe indices). Furthermore, FAST severity indicators were developed exclusive of reference to the many non-Alzheimer’s dementia sub-types among hospice populations. In addition, as demonstrated by our finding of 100 percent FAST criteria fulfillment, FAST stage 7 indices may not sufficiently reflect the levels of disease severity that are most prevalent among hospice populations.

Co-morbidity, the third Medicare prognostic criterion for dementia, has been linked with increased dementia mortality (126, 127). Because of the severe motor impairment caused by dementia brain pathology, aspirations, decubitus ulcers, falls, incontinence and organ system infections are common occurrences among patient populations. Not surprisingly then, many patients with dementia die from secondary complications that most prominently feature pneumonia (128) rather than from the
assigned primary diagnosis (129). Given the body of prior research, the lack of association between the overall Medicare co-morbidity criterion and 6-month mortality reported here is surprising. It may be worthwhile to individually examine the predictive validity of the six conditions that comprise the co-morbidity index.

Single vs. multiple study site design should be noted as a possible study limitation. The positive association reported here between predictor and outcome variables may be nationally atypical, reflective of a unique study site census, organizational structure and/or administrative approaches. While such a circumstance does not negate study results, multi-site replication would resolve the issue of the predictive utility of these criteria across nationally diverse hospice samples and organizations.

Further Research

An objective set of prognostic criteria would be advantageous to increase the confidence of families and physicians that the hospice care option is appropriate for patients with dementia. Although correlation between LMRP functional status measures and patient prognosis has been demonstrated, closer examination of the data is required to define that point in time at which the discriminatory power of these measures diminishes. The question remains, are functional status measures useful for remote, 6-month prognoses, or merely as predictors of death within a few weeks or days timeframe? Further study of predictors of intermediate (2-3 months) versus long-term (6-months) mortality in dementia through survival analysis methods would be of value. Factors associated with “ultra-long” patient survival (1 year or more) in end-stage dementia
would also be of considerable interest. Cost/benefit analyses would also be highly instructive to compare traditional, acute care costs of dementia patients judged hospice ineligible against dementia patients judged eligible with similar levels of disease severity treated in Medicare hospice settings. Finally, research on serial measures of reserve capacity in end-stage dementia have led to fascinating insights (130) and if pursued might increase understanding of dementia time-to-death influences.

Conclusion

The composite Medicare prognostic criterion for dementia is a significant discriminator between \( \leq 6\text{-month}/>6\text{-month} \) survival in end-stage disease, suggesting prognostic utility. However, the occurrence of false negative errors associated with these criteria persists and may be reduced by dropping one criterion, thus increasing the practical value as a screening tool for appropriate hospice enrollment.
Chapter Five: Medicare Local Medical Review Policies (LMRPs):

Concepts and Consequences

Abstract

Due to concerns about United States medical costs, third-party and Medicare interest has increased in strategies to control health care usage. Local Medical Review Policies or “LMRPs” represent a nationally relevant example. Administrators apply these sets of clinical criteria, to justify Medicare claims payments or denials. LMRPs were nationally sanctioned and regionally implemented beginning in 1998, but remain controversial to this day on scientific (108, 37-38, Chapter 2) and social equitability grounds (131). The 1997 statement of a SUPPORT investigator proves prescient in an LMRP context, “Using statistical estimates of prognosis to designate a category of ‘terminally ill’ patients for public policy purposes is unavoidably arbitrary, will often be contested, and will have differential effects upon those dying of different diagnoses (9).”

Local Medical Review Policies: “Clinical Guidelines or Policies?”

The Centers of Medicare and Medicaid Services have represented the LMRPs as akin to “clinical guidelines” that health care practitioners and hospice providers may flexibly interpret. This characterization does not appear to be accurate, however, from technical and applied perspectives. First, according to standard medical terminology, clinical policies apply to collections of patients and are designed to reduce clinician
subjectivity and to increase the uniformity of medical decision-making. Clinical
guidelines are designed as clinical reference tools for use by clinicians as they formulate
medical decisions in regard to individual patient judgments (132,133). Second, flexibility
claims are not supported by the historical facts of LMRP policy evolution. The National
Hospice and Palliative Care Guidelines (36), the LMRP source document, suggest
general hospice eligibility given the presence of three clinical conditions. These are the
terminality and election requirements shown in Table 17, plus fulfillment of either the
general physical debility or the disease-specific criteria. The LMRPs in contrast specify
MHB eligibility if all four conditions shown in Table 17 are fulfilled. The Guidelines
when appropriated for policy usage were thus altered to become more stringent.
Moreover, a close examination of the disease-specific (as opposed to general) criteria
exposes a cross-diagnostic differential in inclusiveness. As may be observed in Table 18,
the numbers of criteria that must be fulfilled vary diagnostically (Table 18), denoting
differential eligibility restriction across disease-specific screening instruments studied.

LMRP Assumptive, Methodological, and Applied Limitations

The Local Medical Review Policies are based on related assumptions that may or
may not be valid: first, the existence of a discernable end of life phase in chronic, life
threatening illnesses; second, the validity of cancer-based methods for non-cancer
prognostication; and third, similar mortality curves as a function of similar non-cancer
diagnoses. The second assumption is particularly relevant because, despite the exclusive
LMRPs non-cancer focus, these criteria represent obvious extensions of cancer-based
“staging theory” for disease severity estimation. Cancer systems use tumor size and location (134), and more recently, performance status in lung cancer (135) to estimate Table 17. NHPCO “General Guidelines of Medicare hospice eligibility”

- The patient’s condition is life-limiting
- The patient and/or family have elected palliative treatment goals
- The patient shows symptoms of severe physical debility: Patient- or caregiver-reported decrements in patient health status over the months that precede MHB enrollment as documented by home health or hospice personnel. Qualifying symptoms may include multiple emergency room visits OR recent decline in functional status OR 10% unintentional weight loss over the prior six months.

OR

The patient shows signs of progression in disease severity
Clinical or objective data obtained through serial physician assessment, or laboratory, radiologic or other studies.

Table 18. Disease-specific comparison Local Medical Review Policies fulfillment requirements

<table>
<thead>
<tr>
<th>Disease</th>
<th>Required Criteria by Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heart</td>
<td>1(a &amp; b) and 2</td>
</tr>
<tr>
<td>Pulmonary</td>
<td>1(a &amp; b) and 2</td>
</tr>
<tr>
<td>Stroke</td>
<td>1 or 2 or 3</td>
</tr>
<tr>
<td>Dementia</td>
<td>1 or Fast Score 7c and 2</td>
</tr>
</tbody>
</table>

disease severity and time to death. The relationship between symptom severity and disease progression in non-cancer diseases may not be analogous, however (Chapter 3). Investigations including Chapter 2 of this work report little predictive relationship between the LMRP clinical indicators and 6-month mortality (108, 37-38).
Methodological Limitations

A second LMRP concern is their assumptive as opposed to empirical origin (Chapter 2). Furthermore, although the LMRPs comprise several different scales, the validity and reliability of each of which has been previously confirmed, the reliability of composite scale application has not been confirmed. When empirically assessed in the present investigation, the LMRPs appear to largely lack predictive validity.

Applied Limitations

Large-scale LMRP regulatory simulations such as this work call the objectivity, reliability and speed of application of these criteria into question. Reliability or consistency of results is a leading measure of an instrument’s quality. Only moderate inter-rater agreement (kappa=.06) was obtained between experienced and well-trained nurse assessors in applications of the heart disease LMRP. (In contrast, perfect agreement (1.0) was observed in the Kaplan correlation coefficients between these raters in audits of identical dementia and stroke LMPR medical records). A lesser rate of inter-rater reliability for the overall heart disease criteria tested (Chapter 2, Results section) indicates cross-diagnostic disparity in LMRP reliability. Sub-optimal reliability may result from the unavoidable subjectivity of certain LMRP criteria. For example, one of the LMRP heart disease criteria, “the patient has the inability to carry on physical activity without discomfort,” requires assessor reference to personal, internalized notions of pain and discomfort. Furthermore, in test applications, newly encountered clinical questions were often so perplexing that they could not be resolved without physician’s consultation. Similar IRR comparison among Medicare auditors in field settings would
test the hypothesis that acceptable IRR on LMRP fulfillment varies with the intensiveness of training and the availability of ongoing medical consultation.

Moreover, the pilot study conducted prior to commencement of Chapter 2 research demonstrated a 22- to 35- to 59-minute mean time variability among RNs who assessed LMRP fulfillment of identical patient records. Apparently, an average of about one-half hour is required for a careful and comprehensive LMRP assessment. A comparative study of time assessment among Medicare claims auditors in field settings would be instructive.

Test applications conducted here identified additional LMRP logistical issues:

- Required 6-month background data were not reliably obtainable in hospice records

- Required laboratory data included as LMRP core and optional criteria were not reliably obtainable in hospice records, since they were not required prior to LMRP implementation.

- Certain functional status indices (bathing, dressing) are inapplicable to mainly bed bound hospice patients; as evidenced by 100% fulfillment of certain such criteria (bathing, dressing) in this study. Such criteria were thus not useful discriminators of short-term from longer-term survival.

- The dichotomous LMRP format (fulfilled/failed to fulfill), does not allow for fine gradations of health status assessment. Expansion of disease severity grades would allow for more precise assessment.

LMRPs: Background, Costs and Benefits

The evolution of the Local Medical Review Policies into hospice eligibility standards was driven by two related regulatory concerns: skyrocketing hospice growth and inappropriate hospice utilization by non-terminally ill persons. Despite this, the
LMRPs are popularly framed as the regulatory sequel of fraud convictions obtained in Puerto Rican but not continental U.S. hospices (136). Wrongdoing in this highly publicized case involved hospice usage for essentially long-term, custodial as opposed to time-limited, palliative care.

However objectionable the issue of Medicare fraud, the occurrence of longer-term hospice stays is relatively rare, and should not be overstated. At the time of 1998 LMRP initialization, slightly less than 15% of all hospice patients could be classified as “long-term survivors,” i.e., patients whose hospice survival duration exceeded 6-months duration (12). In that year, the long-stay population was balanced by almost an identical number of “short-term survivors,” i.e., patients who survived in hospice for one week or less (12). In 2001, however, the prevalence of long-term stay in hospice had dropped to 6% (1); but short-term stays had skyrocketed to 28 percent (39). These unprecedented shifts in hospice utilization rates have been more recently confirmed by a 2003 Centers for Disease Control study (7).

The LMRPs may have profoundly affected hospice lengths of stay, dramatically altering the historical long-stay/short-stay equilibrium, and reducing the proportion of patients who survive in hospice for periods in excess of 6 months. As curbs to explosive hospice growth, the Local Medical Review Policies have additionally achieved the apparent goals of regulatory reform, but through channels less direct and perhaps not anticipated. On the one hand, the number of Medicare Hospice Benefit enrollees has continued to increase, more than doubling in the last decade, from 143,000 in 1992, to 360,000 in 1998 (39) to 885,000 in 2002, the most recent date for which data are currently available (1). On the other hand, in tandem with LMRP instigation, the 1974 to
1997 sharp annual growth rate in hospice provider organizations ceased in 1998, and remained level to 2003 (1). From 1999 to 2002, the numbers of organizational providers has essentially remained flat, at 1998 levels (1).

While it may never be possible to link initiation of the LMRPs and altered hospice utilization patterns, any resultant barriers to hospice access would be manifested by delayed patient referrals, biased certifications/re-certifications processes and inappropriate (premature) discharges. Precisely these trends are suggested by recent study results that show that patients discharged alive from hospice are more likely to be female, to have received hospice care for more than 60 days, and to have non-cancer diagnoses (7). “Brink of death” hospice admissions and/or discharges are contrary to 1982 federal mandates establishing hospice care as a feasible non-crisis/non-cure oriented health care option in the United States.

The origin of hospice short-stay/long stay imbalance remains speculative, but may most reasonably be explained by altered post-LRMP decision-making behaviors that are systemic. Fear of professional and/or economic sanction, and the known unreliability of prognostic estimates coupled with policies that imply otherwise, can help to explain how and why the LMRPs have become so pervasively influential throughout the hospice enterprise, before, during and after the actual delivery of hospice care (Table 20).

If such rationales were indeed valid, disparities in MHB eligibility might be observed across diagnoses. A multi-site hospice comparison of post-LMRP long-term/short-term survival trends by non-cancer diagnosis would shed light on this important question. The results of this study and one important other (36) do in fact show variability in numbers of patients who fulfill the criteria on a disease-specific basis.
Once again, the real-life consequence of a seemingly minor technicality in regulatory policy is hospice eligibility discrimination by diagnosis. This most worrisome LMRP consideration is clearly illustrated in Chapter 2, Table 4 that lists disparate rates of criteria fulfillment on a disease-specific basis. Additional hypothesized consequences of LMRP regulatory reform, some but not all testable, are listed in Table 19 and are graphically depicted in Table 20.

Policy-based Alternatives to the Prognostic Criteria for Medicare Hospice Eligibility

One alternative to present policy is a legal amendment to include 6 months or more Medicare hospice eligibility if the terminal illness runs its normal course. Given official recognition that a range of error naturally accrues to probability estimates, and that short-stay, long-stay rates in hospice are beneficially balanced, federally approved hospice utilization parameters could be more explicitly stated. For example, rather than current governmental scrutiny focused on individual long-term patient stays, organizational long-term stay utilization rates might be nationally monitored. Non-concordat utilization rates would instigate closer regulatory scrutiny of individual hospice organizations. Another idea is a program whereby hospices might receive pre-authorization from Medicare contractors for hospice care is cases in which prognosis is difficult.

Suggestions for Systems-wide Research in Terminal Illness

Health care systems research might include longitudinal outcome studies of patients who are questionably hospice eligible, and are therefore not admitted. Such
studies would examine length of survival, patterns of health care services utilization and trends of hospice readmission. A cost analysis of hospice ineligible admissions/eligible denials would also be of value. Additionally, a descriptive study of “ultra-long survivors,” i.e., patients who survive for one year or more post hospice admission, might prove administratively and clinically instructive.
Table 19. Potential outcomes of the Local Medical Review Policies for Medicare hospice benefit eligibility

<table>
<thead>
<tr>
<th>Patients</th>
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</thead>
<tbody>
<tr>
<td>• hospice eligibility discrimination by diagnosis</td>
</tr>
<tr>
<td>• absent, delayed or prematurely discontinued hospice care</td>
</tr>
<tr>
<td>• discontinuity in model of care and locale</td>
</tr>
<tr>
<td>• diminution of patient quality of life</td>
</tr>
<tr>
<td>• adverse health outcomes</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Family caregivers</th>
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<tbody>
<tr>
<td>• increased caregiver burden/stress</td>
</tr>
<tr>
<td>• adverse caregiver health outcomes</td>
</tr>
<tr>
<td>• discontinuation of informal care</td>
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<table>
<thead>
<tr>
<th>Physicians</th>
</tr>
</thead>
<tbody>
<tr>
<td>• jeopardized diagnostic/prognostic autonomy</td>
</tr>
<tr>
<td>• disrupted patient/physician clinical relationships</td>
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<thead>
<tr>
<th>Hospice Organizations</th>
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<tbody>
<tr>
<td>• resource shift from patient care to administrative compliance</td>
</tr>
<tr>
<td>• increased per-patient cost of care provision</td>
</tr>
<tr>
<td>• financial viability threatened</td>
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</tbody>
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<table>
<thead>
<tr>
<th>U.S. Health Care System</th>
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</thead>
<tbody>
<tr>
<td>• increased use of curative in lieu of palliative services</td>
</tr>
<tr>
<td>• increased resource allocation for end-of-life costs.</td>
</tr>
</tbody>
</table>
Table 20. Health-systems outcomes of the prognostic criteria for Medicare Hospice eligibility

### PRE-AND POST-ADMISSIONS OUTCOMES

- **1. Patients**
  - Admission discrimination by Dx.
- **2. Physicians**
  - Altered decision-making processes
  - Late or avoided Referrals to hospice
- **3. Providers**
  - Increased documentation/reduced patient care
  - Reduced lengths of stay = increased severity, increased per patient expense

### U.S. Health Care System

- National decline in hospice length of stay
- Increased use of acute care system

### REIMBURSEMENT & POST-DISCHARGE OUTCOMES

- **1. Patients**
  - Premature discharge
  - Barriers to quality end-of-life care
- **2. Physicians**
  - Compromised clinical authority and patient relations
- **3. Providers**
  - Financial threat to hospice viability
Conclusion

Existent LMRP studies examine the capacity of LMRP clinical criteria to accurately categorize short-stay/long-stay hospice survival outcomes. The potential for disparity in Medicare Hospice Benefit access where groups with non-cancer diseases disproportionately encounter eligibility barriers is a troubling implication. A more comprehensive understanding might be achieved through systems-wide study of the costs and benefits of prognostically-based Local Medical Review Policies.

The question remains “Is it possible to identify valid and useful predictors of 6-month survival? What rate of classificatory error may be considered unacceptably high? Is there a viable alternative to LMRP/Medicare prognostic criteria governance of the Medicare Hospice Benefit? According to Joanne Lynn, MD, a well-known SUPPORT team scholar, reliable, disease-specific demarcation of severe from terminal illness may not represent an achievable scientific goal (9). Based on the findings reported within, it appears that prognostic science does not currently provide a reliable foundation upon which to establish exclusions for public health care benefits.
Dissertation Conclusion

The tools of science, including quantitative, qualitative and analytical methods, have been applied to better understand the Medicare prognostic criteria, their validity, applied utility and patient, physician and provider impact. From the perspective of federal analysts, chart auditors need well-defined, time-efficient and nationally relevant standards to facilitate objective Medicare claims review. From a more global perspective, reliable markers of 6-month life expectancy would be undeniably valuable. A poorly designed policy, however, can result in mismanagement of thousands of patients and misallocation of millions of dollars (135). It is recognized that the limits of public health service are properly set by a society at any given time. However, if some deem the current bounds of public health care sub-optimal, substantive and articulated rationales for regulatory reform are required.
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About the Author

D. Helen Moore earned a BA in Social Work at Florida State University (1972) and an MA in Gerontology at the University of South Florida (1980). As a gerontologist serving for over 20 years in clinical, administrative and service planning roles, she has also authored a trade book on consumer-directed eldercare, 100 monthly aging issues columns for The St. Petersburg Times (1991-1998), 3 U.S. Administration on Aging monographs, numerous aging-related grant proposals and curricula. While an Aging Studies Doctoral Candidate at U.S. F, she was a research award recipient, 1997 co-president of the Aging Studies Student Association, adjunct instructor in the U. S.F. Department of Gerontology, and a clinical evaluator in Alzheimer’s clinical drug research. Research interests include Alzheimer’s disease, functional impairment, end-of-life and caregiver issues and health-systems studies.