Initial Assessment of a New Instrument to Measure Quality of Life at the End of Life

KAREN E. STEINHAUSER, Ph.D.,[1,2,4,7,8] HAYDEN B. BOSWORTH, Ph.D.,[2,4,7]
ELIZABETH C. CLIPP, Ph.D., M.S., R.N.,[3,5–8] MAYA McNEILLY, PhD.,[7,10]
NICHOLAS A. CHRISTAKIS, M.D., Ph.D., M.P.H.,[9] JOANNA PARKER, M.A.,[1]
and JAMES A. TULSKY, M.D.[1,2,4,7,8]

ABSTRACT

Purpose: We conducted this study to pilot a new multidimensional instrument to assess the quality of life at the end of life.

Methods: Items were derived from focus groups and a national survey identifying attributes of the quality of dying. Fifty-four items measured on a five-point Likert scale covered six domains. We administered the instrument to equal numbers of Veteran's Administration (VA) and university medical center outpatients with advanced serious illness. We assessed psychometric properties using factor analysis.

Results: Two hundred patients completed the instrument (response rate, 85%). Diagnoses included cancer (64%), congenital heart failure (CHF) (19.5%), end-stage renal disease (ESRD) (10%) and chronic obstructive pulmonary disease (COPD) (6.5%). Seventy-four percent were male, 64% were caucasian, and 34% African American. Item reduction and factor analysis yielded a final instrument with 24 items in 5 distinct domains (overall Cronbach $\alpha = 0.83$). The first factor (6 items; $\alpha = 0.84$) measured a sense of completion, particularly through contributions to others. The second factor (7 items; $\alpha = 0.77$) measured relations with the health care system. The third factor (6 items; $\alpha = 0.77$) measured preparation. The fourth factor (4 items; $\alpha = 0.77$) measured symptom severity, and the final factor (2 items; $\alpha = 0.60$) measured affective social support.

Conclusions: We have developed a new instrument to measure the quality of life at the end of life that assesses empirically derived domains that are of demonstrated importance to dying patients, is acceptable to a seriously ill population, and exhibits excellent psychometric properties. Some items related to completion and preparation represent particularly new contributions to quality-of-life measurement.

[1]Program on the Medical Encounter and Palliative Care, [2]Center for Health Services Research in Primary Care,
[3]Geriatric Research Education and Clinical Center, Durham VA Medical Center, Durham, North Carolina.
[4]Department of Medicine, [5]Division of Geriatrics, [6]School of Nursing, [7]Center for the Study of Aging and Human Development, [8]Institute on Care at the End of Life, Duke University, Durham, North Carolina.
[9]Department of Health Care Policy, Harvard Medical School, New Haven, Connecticut.
[10]Institute for Multiculturalism, Durham, North Carolina.

INTRODUCTION

As EFFORTS TO IMPROVE care of dying patients and their families intensify, improved measurement tools are needed to evaluate the quality and effectiveness of palliative care interventions. The Institute on Medicine, the American Medical Association, and the Robert Wood Johnson Foundation, among others, have identified outcomes assessment as a high priority within the effort to advance care of the dying.[1–3] In short, if we want to help patients die better, we have to know what better is, and how to systematically assess it.

Many researchers have noted this task is complex.[4–10] Dying patients and their families confront unique challenges that span a broad range of quality of care and quality-of-life issues including symptom management, support of function and autonomy, advance care planning, appropriate utilization of resources, patient and family satisfaction, global quality of life, family burden, survival time, provider continuity and skill, and bereavement.[5] Many of these components of experience are not addressed with usual health care assessment tools. In response, several researchers and clinicians have developed instruments specifically designed for the end of life, including the McGill Quality of Life Questionnaire, the Missoula-VITAS Quality of Life Index, McMaster Quality of Life Scale, the adapted EORTC QLQ30, the FACIT-Pal, and the SEIQoL.[7,11–18]

Each was designed to accommodate the unique experiences of dying patients and departs from previously used quality of life instruments in several ways. Most have reduced the dominant emphasis on physical subscales and created more balanced multidimensional assessment including psychosocial and, often, spiritual or transcendent issues. As a result, most are able to document not only functional decline but accommodate the possibility of personal growth at the end of life.[11] Medicine has increasingly emphasized the importance of patient-centered care and, although some of these instruments are largely expert-derived, several measurement tools evolved from the collection of patients' perspectives; the FACIT series may be the most extensive example. Furthermore, two instruments include individually rated weights for each subscale, thereby acknowledging both between-person and within-person differences in defining quality of life.[7,19] Another patient-centered strategy is found in the McGill Quality of Life Questionnaire; rather than respond to a predetermined list of symptoms, individuals choose their most troublesome symptoms.

However, each of these recent instruments was designed to assess the experiences of patients with either a specific diagnosis or stage of illness. For example, most end-of-life scales have been developed within cancer populations, whose relatively predictable disease trajectory is markedly different from the acute-episodic illness course of advanced congestive heart failure or chronic obstructive pulmonary disease.[15,19–21] Although not disease-specific, other measurement tools are designed for patients who have acknowledged the terminal nature of their illness or are receiving care in a hospice or palliative care unit.[7,11] Many dying patients never elect such care and may not identify themselves as terminally ill.

The purpose of this study was to create and validate an instrument to assess the quality of life of patients with a range of diseases (cancer, congestive heart failure [CHF], chronic obstructive pulmonary disease [COPD], and end-stage renal disease [ESRD]) in a variety of care settings, who may or may not have acknowledged the terminal nature of their disease, but who, nonetheless, are grappling with end-of-life issues. To this end, we sought to develop a new inductively derived assessment tool and, where appropriate, build on the strengths of earlier instruments. The development of this instrument began from the "ground up" with the collection of qualitative accounts from seriously ill patients, recently bereaved family members, and various health care providers regarding what is important at the end of life.[22] A national survey followed to affirm or reject those attributes.[23] In this paper, we describe the initial assessment of this new instrument designed to measure quality of life at the end of life (QUAL-E).

METHODS

Design

This was a cross-sectional study to ascertain the instrument's psychometric properties and inform item reduction.

Subjects

Patients with stage IV cancer, CHF with ejection fraction of 20% or less, COPD with forced ex-

piratory volume in 1 second (FEV_1) of 1.0 liter or less, or dialysis-dependent ESRD were eligible for the study. To identify potential patients for initial instrument validation, we reviewed weekly rosters for the oncology, heart failure, pulmonary, and dialysis clinics at the Durham Veterans Affairs and Duke University Medical Centers. We randomly assigned a recruitment order to all eligible patients and enrolled as many patients as time allowed for each clinic half day. Written informed consent was obtained at the time of recruitment. We administered the Short Portable Mental Health Status Questionnaire (SPMSQ) at the time of enrollment and excluded patients with scores less than 8 of 10.[24] We continued to recruit subjects until we accrued a total of 200 patients, a number considered sufficient for factor analysis.[25–28]

The study was approved by the institutional review boards of both the VA and Duke University Medical Centers.

Instrument design

Instrument items were derived from two studies designed to identify attributes of quality at the end of life. First, we conducted focus group discussions and in-depth interviews with seriously ill patients, recently bereaved family members, physicians and other health care providers (nurses, social workers, chaplains, and hospice volunteers) to elicit, qualitatively, attributes of a "good death."[22] Subsequently, we distributed a survey to national samples of the aforementioned groups to affirm or reject those themes quantitatively.[23] A detailed description of the methods can be found elsewhere.[22,23]

Analysis of focus group and survey data revealed six domains of experience at the end of life: pain and symptom management, communication about treatment decisions, preparation for death, completion, contributing to others, and being known as a whole person. As expected, both qualitative and quantitative analyses indicated the six domains were interrelated, and therefore, not in all instances, empirically distinct. For example, contributing to others may be an expression of offering a legacy and an important part of achieving a sense of completion. Being known as a whole person was most often identified in the context of physician–patient relationships. Each domain was represented by multiple items.

Similar to existing measures, the QUAL-E includes an assessment of patients' physical symptoms. However, previous data suggested the importance of understanding not only frequency and severity of symptoms but interference with daily life and anticipatory concern about symptom expression. We, therefore, chose a physical symptom assessment strategy built on combined techniques found in the literature and augmented by our previous studies showing patients concerns about future symptom exacerbations.[11,22,29] Patients were asked to choose up to three distressing symptoms and rate for each the frequency, severity, impact, and related future concern. We compared symptoms with overall quality of life and noted correlations among within-person symptom ratings. Because all three symptoms correlated consistently with other items, we report responses only for the first symptom.

The instrument completed by patients contained 54 items and was intentionally long to assess response distributions across items of similar substance but with different phrasing. For example, as part of the domain rating patients' life completion, we asked about a sense of peace. To understand religious and cultural variation and preferences we asked this question several ways including the extent to which they felt at peace with God, at peace spiritually, at peace with personal relationships, and at peace with themselves. Based on a comparison of response distributions, only one of these questions was retained for factor analysis.

Although all instrument items were derived inductively from previously collected qualitative and quantitative data, there is theme overlap between some of our questions and those found in other instruments or qualitative studies.[7,11,19,20,30,31] For example, questions about peace, spending time with friends and family, saying important things to loved ones, and having one's affairs in order are found in the Missoula-VITAS Quality of Life Index. Concerns about dying are in both the Missoula-VITAS and the FACT-G. The theme of a sense of meaning is in both the Missoula-VITAS and McGill instruments, although worded differently. This commonality demonstrates a growing consensus across sources about central attributes of quality at the end of life.

After each multi-item domain, patients were asked to evaluate its overall importance to their quality of life. For example, after completing

questions about the severity, frequency, etc., of their symptoms, patients rated the importance of physical symptoms in overall quality of life. Scale items were written in a five-point Likert format. Various anchor sets were piloted for comprehension and response distribution. In the final format, respondents rated their level of agreement with each statement. The questionnaire was targeted to a sixth-grade reading level.

The full instrument, containing a total of 54 items and including a single item rating of overall quality of life, was pretested for readability and interpretability. The initial pretesting, conducted with 25 patients, was an iterative process in which questions were administered to five patients, revised if necessary, and administered to another five patients. This refinement continued until no additional changes were required. During this process, response categories were examined for response frequency. Items with more than 95% endorsement of any one category were rewritten to improve sensitivity. After each interview, participants were asked to give feedback on both questionnaire length and content. Our goal was to assess sensitive topics of importance to seriously ill patients without evoking undue distress. For example, some patients became teary when discussing thoughts of dying, but no participant asked that the item be removed or stopped the interview.

Instrument administration

Patients demonstrating satisfactory cognitive status on the Short Portable Mental Status Questionnaire (i.e., < 2 errors) completed both a series of demographic questions and the 54-item instrument, administered in person by a trained interviewer. Interviews lasted approximately 15 minutes. All responses were entered directly into a Palm III personal digital assistant and subsequently downloaded into a Microsoft Access database.

Analysis

Response distributions. We examined descriptive statistics for all items with attention to mean, median, range, skewness, and kurtosis of response distributions. Items with more than 50% of the distribution in any one response category were marked for closer examination. Normality was assessed using the Shapiro-Wilkes test. Items not exhibiting normality were marked for further review.

Domain assessment. After reviewing item descriptive statistics, we reduced the original 54 items by removing the domain importance questions, the global quality-of-life item, highly skewed items, and redundant items, such as the multiple questions regarding peace and evaluation of patients' second and third symptoms. The remaining 30 items were retained for factor analyses.

Exploratory factor analysis with an oblique-rotated Promax solution was used to group attributes into domains and reduce the number of questionnaire items. An oblique rotation allows one to evaluate the reasonableness of the orthogonality assumption and can produce a more realistic presentation of the factors.[32,33] It is the most appropriate choice given our assumption that some conceptual domains may not be empirically distinct. Eigenvalues greater than 1.0 combined with a scree plot[28] were used to determine the number of domains. The scree plot was used to identify the number of factors that extracted the maximum amount of variance from the set of indicators.[34] Items not loading (>0.50) on the expected factors were removed. We sought simple structure as an indication of variables being related to appropriate domains.[35] That is, we looked for high loadings for variables expected to relate to certain constructs and low loadings for unrelated variables and constructs.

The final model contained 24 items (see Table 1). Using this reduced model, we also compared items and domains in an interitem correlation matrix. If a domain is reliable, correlations among its constituent items should be high. We assessed internal consistency for individual domains and the full measure using Cronbach $_\alpha$. Items that did not have an item-to-domain correlation above 0.60 were marked for evaluation.[36] As noted previously, a sample size of 200 is well powered to detect such strong correlations (>0.50) among 30 items. Analyses were conducted using Proc factor in SAS version 8.0 (SAS Institute, Cary, NC).

RESULTS

Response and description

A total of 234 potential subjects were approached. We enrolled 200 patients from the Durham VA and Duke University Medical Centers (100 per site). Thirty-one refused and three demonstrated significant cognitive impairment

TABLE 1. SAMPLE PROFILE

Variable	Percentage
Gender	
Male	73.5
Female	26.5
Ethnicity	
African American/black	33.5
Asian-American	0.5
Caucasian/white	64
Native American	1
Education	
<High school	22
High school diploma	27
Associate's degree	23
Bachelor's degree	11
Graduate/professional degree	17
Marital status	
Married/living with partner	61.5
Widowed	14.5
Divorced/separated	20
Never married	4
Household Composition	
Living w/spouse	61
Living w/child	29
Living w/parent	4
Living w/other	17.5
Living alone	17
Diagnosis	
Cancer	64
COPD	6.5
CHF	19.5
ESRD	10

Approached: 234; refused: 31; Failed SPMSQ: 3.
COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; ESRD, end-stage renal disease.

on the SPMSQ, yielding a response rate of 85%. All 200 patients completed the interview. Fourteen did not report any symptoms; therefore, some analyses are based on the remaining 186 participants with "full" information. The subgroup not reporting symptoms was comprised of more males (87%), slightly older (mean age 68), nonmarried persons (60%), and with a higher percentage of congestive heart failure (40%) than the rest of the sample.

Participants had at least one of four life-threatening conditions: stage IV cancer (64%); CHF (19.5%); ESRD (10%), and COPD (6.5%). Approximately 74% of subjects were male, 64% were Caucasian, 33% African American (Table 2). The sample showed a broad educational distribution and a majority (61.5%) were married.

The mean age of patients was 62 (range, 34–84; median, 63).

Distributions

All questionnaire items showed responses across the full range of categories from "completely" to "not at all (Table 3)." The symptom assessment demonstrated the best distributions among all subscales with mean values close to 3 and standard deviations of 1.25 or more.

Five items in the original 54-item questionnaire had greater than 90% response in the fourth and fifth categories and were, therefore, removed prior to factor analysis. All remaining items displayed appropriate distributional characteristics for parametric analyses.

Five of seven importance items showed a full range of responses. In general, the importance items did not show broad variation with the exception of the item assessing importance of physical symptoms to overall quality of life (mean, 3.7; standard deviation [SD], 0.89) and were, therefore, not included in the factor models.

As a brief check on sample response variation, we used χ^2 Fisher's exact tests to evaluate subgroup differences in responses. Although women showed significantly ($p < 0.05$) higher quality of life, there were no overall quality of life differences (as measured by the global quality-of-life item) associated with site of recruitment, ethnicity, education, household composition, marital status, or diagnosis.

Domains

Factor analyses revealed five distinct domains (see Table 1) comprising a total of 24 items.

The first factor (6 items; $\alpha = 0.84$) measured a sense of life completion, particularly through contributions to others. It included (1) being able to help others, (2) making a positive difference in the lives of those, (3) saying important things to loved ones, (4) having a sense of meaning, (5) sharing with family, including time together, gifts or wisdom, and (6) being at peace. It was the strongest factor accounting for 23% of the variance.

The second factor (7 items; $\alpha = 0.77$) assessed relationships with the health care system. It included questions rating (1) a sense of control about one's treatment decisions, (2) knowing where to get information, (3) participating in one's own care decisions, (4) knowing what to ex-

TABLE 2. ITEM MEANS, STANDARD DEVIATIONS, AND MEDIANS (FIFTY-FOUR-ITEM INSTRUMENT)

Item	n	Mean	SD	Median
1. How often have you experienced symptom 1 (last week)?	188	3.73	1.45	4
2. How severe has symptom 1 been?	186	3.27	1.27	3
3. How much has symptom 1 interfered with enjoying life?	186	3.23	1.47	3
4. How worried are you about symptom 1 occurring in future?	186	2.81	1.51	3
13. How important are physical symptoms to your QOL?	200	3.68	0.89	4
14. I have as much information as I need about my illness	200	3.49	1.17	4
16. I have a sense of control about treatment decisions	200	3.96	0.90	4
17. I participate as much as I want decisions about my care	200	4.26	0.89	4
20. Beyond my illness, my doctor has sense of who I am as a person	200	4.04	0.97	4
21. My personal dignity has been maintained	200	4.41	0.79	5
23. How important are relationships with health care providers to QOL?	200	4.26	0.66	4
25. I spend as much time as I want with family	200	4.16	1.11	5
27. I have someone with whom I can share my deepest thoughts	200	4.35	1.14	5
29. How important are personal relationships to your QOL?	200	4.42	0.70	5
30. Thoughts of dying frighten me	200	1.80	1.06	1
31. I know what to expect about the course of my illness	200	3.92	0.99	4
32. I know where to get answer to my questions	200	4.26	0.89	4
34. I worry that my family is not prepared to cope with the future	200	3.52	1.32	3
35. How important is preparation for the future to your QOL?	200	3.94	0.82	4
39. I am at peace with myself	200	4.49	0.77	5
40. How important being at peace to your QOL?	200	4.41	0.76	5
41. I am able to say important things to those close to me	200	4.36	0.88	5
43. I have regrets about the way I have lived my life	200	4.02	1.16	4
44. Despite my illness, I have a sense of meaning in my life	200	4.20	0.78	4
46. How important sense of completion to your QOL?	200	4.04	0.72	4
47. I make a positive difference in the lives of others	200	3.89	0.09	4
48. I am able to contribute to others by time, gifts, wisdom	200	3.88	0.91	4
50. I worry that will be burden to family	200	3.58	1.20	4
51. I worry about the financial strain caused by illness	200	3.71	1.31	4
52. I am able to share import things with my family	200	4.18	0.88	4
53. How important is contributing to others to your QOL?	200	3.95	0.71	4
54. Rate overall QOL	200	3.82	0.79	4

QOL, quality of life; SD, standard deviation.

pect about illness, and (5) that one's physician has a sense of one as a person, beyond the illness.

The third factor (6 items; $\alpha = 0.77$) measured preparation or anticipatory concerns including (1) worry about being a burden, (2) that one's family is not prepared for the future, (3) fear of dying, (4) financial strain, and (5) regrets about life.

The fourth factor (4 items; $\alpha = 0.77$) captured symptom impact. Pain was the most commonly reported symptom followed by shortness of breath and nausea. Subjects gave information regarding symptom severity, frequency, the extent to which it interfered with enjoyment of life, and concern about its occurrence in the future.

The fifth and final factor (2 items; $\alpha = 0.60$) measured connectedness and affective social support by assessing (1) whether one had a confidant with whom to share deepest thoughts and (2) spending time with family. Of note, these two items loaded, albeit slightly less strongly, on factor 1.

Overall, the items presented in factors 1–5 loaded "cleanly" on their respective factors, demonstrating simple factor structure. Together, the five factors accounted for 51% of the variance in quality of life at the end of life.

DISCUSSION

Several excellent instruments have been developed recently to assess quality of life and quality of care at the end of life.[7,11,14–16,21,37–39] The instrument presented in this paper (QUAL-E) contributes to these measurement efforts in four distinct ways. First, it was developed inductively using systematically collected accounts and responses of a range of participants in end-of-life care including seriously ill patients (cancerous and noncancerous advanced diseases), recently bereaved family members, physicians, and other

TABLE 3. FACTOR LOADINGS (FINAL MODEL, TWENTY-FOUR ITEMS)

Questionnaire item	Factor 1 Completion	Factor 2 Relationship w/health care system	Factor 3 Preparation	Factor 4 Symptom impact	Factor 5 Affective social support
48. Able to help others	**0.76**	0.04	0.03	0.17	0.13
47. Make positive difference for others	**0.73**	0.03	0.07	0.01	0.05
41. Able say important things to those close	**0.71**	0.02	0.02	0.17	0.24
44. Sense of meaning in life	**0.70**	0.01	0.13	0.11	0.11
52. Able share important things with family	**0.66**	0.07	0.04	0.03	0.24
39. At peace with self	**0.58**	0.11	0.34	0.03	0.00
16. Control of treatment decision	0.09	**0.73**	0.08	0.02	0.08
15. Understand nature of illness	0.12	**0.70**	0.09	0.13	0.21
32. Know where to go to get answers	0.18	**0.69**	0.11	0.03	0.04
17. Participate in decisions regarding care	0.20	**0.62**	0.09	0.06	0.34
14. Have info regarding illness	0.32	**0.59**	0.07	0.11	0.38
20. MD knows who I am as a person	0.03	**0.57**	0.13	0.13	0.22
31. Know what to expect of illness	0.09	**0.53**	0.10	0.19	0.10
50. Worry about being a burden to family	0.04	0.02	**0.80**	0.00	0.14
34. Worry that family not prepare for future	0.11	0.07	**0.66**	0.04	0.19
51. Worry about financial strain	0.09	0.03	**0.61**	0.10	0.09
43. Regrets about way lived life	0.11	0.22	**0.58**	0.19	0.13
30. Thoughts of dying frighten me	0.02	0.13	**0.52**	0.10	0.27
1. Symptom 1—how severe	0.04	0.05	0.04	**0.80**	0.05
2. Symptom 1—interfere with enjoyment	0.02	0.05	0.09	**0.78**	0.08
3. Symptom 1—how often experience	0.03	0.18	0.07	**0.75**	0.01
4. Symptom 1—worry occur in future	0.11	0.23	0.16	**0.60**	0.05
27. Someone to share deep thoughts	0.48	0.08	0.19	0.04	**0.57**
25. Spend time with family	0.42	0.01	0.15	0.18	**0.56**
Cronbach α	**0.84**	**0.77**	**0.77**	**0.77**	**0.60**

health care providers. Second, it confirms the importance of two domains featured in existing instruments, namely physical symptoms and issues of spirituality. Third, it offers several new domains of experience including an expanded definition of life completion, the influence of interaction with the health care system, and preparation. Finally, it contains individual importance ratings that will allow the weight of individual domains to vary between individuals and within the same individual over time. The results of the preliminary validation phase suggest the QUAL-E is acceptable to seriously ill patients and exhibits excellent initial psychometric properties.

As noted, one of the new features of this instrument is the multifaceted nature of the first domain, completion. Other researchers have described the importance of transcendence expressed through connection with God, peace, or sense of meaning and as noted, it is present in most recent end-of-life instruments.[7,11,20,21,30] In

the QUAL-E, these aspects were supplemented by items showing contributions to others, for example, through time together, gifts, or wisdom. In a recent palliative care study, cancer patients reported that "feeling useful" influenced whether their days were "good" versus "bad."[40] Furthermore, the need to give of oneself to the well-being of others was noted by participants in our previous focus group study and confirmed in a national survey.[22,23] Interestingly, it was an attribute of quality at the end of life identified as salient to patients but less important to physicians. Experts in human development theory have long noted this need for "generativity," necessary growth achieved through giving.[41] Our data suggest that transcendence may be achieved in several ways: as one moves beyond the self either religiously (connected to others before death), spiritually (beyond the body, after death), and generationally in legacy passed to children and family. Furthermore, questions of meaning

and completion accounted for the most variance in overall quality-of-life at the end of life. Physical symptoms were clearly important but accounted for less variance in overall quality-of-life among seriously ill patients. This has been noted by other researchers who have suggested usual quality-of-life instruments, with the opposite domain weightings, do not account for patients growth, particularly existential growth, at the end of life.[6,11,40,42–47] The results from this study suggest that growth occurs, in part, through a sense of contribution.

The second component captured by the QUAL-E is the domain measuring patients' relationships with the health care system, specifically with regard to knowledge of illness, knowing what to expect about illness, and whether the patient felt the doctor knew him or her as a "whole person." In focus group discussions, the domains of "communicating about treatment decisions" and "being known as a whole person" were most often discussed together.[22] These data suggest the two concepts are empirically linked in a domain assessing patients relationships with the health care system. The significance of these relationships at the end of life is evident in some quality of care measures, particularly the after death family interviews but less prominent in pre-death patient quality-of-life tools.[37,39] More than a measure of patient satisfaction, this domain's salience suggests that information, expectations, and the extent to which patients' believe that formal providers perceive them as "whole persons" are crucial components of quality in the final phase of life. In focus groups, family members recounting the deaths of a loved ones were comforted by the personal interactions they witnessed between their relatives and physicians, saying the patient received personal care not only treatment for a disease.[22]

The third contribution of the QUAL-E is recognition of patients' preparation or anticipatory concerns. Worry about being a burden, financial strain, and whether or not families were prepared for the future, emerged as a coherent theme. Some existing tools measure concern about dying or financial strain, and others assess anxiety. However, items in the QUAL-E appear to measure a broader sense of preparation and anticipation, and as such, are novel. Patients' fears of their families' futures and the sense of burden they may bring was a common concern raised by patients in both focus groups and a national survey;

physicians were less likely to endorse its importance.[22,23] The inclusion of "regrets about the way I have lived my life" may seem dissonant with a theme of the future. However, many patients anticipate their dying as a time of reckoning. Looking back, perhaps with regret, appears part of the process of preparing for the future.[22]

Similar to most quality-of-life tools, responses on the QUAL-E identified a clear physical symptom domain or subscale. However, unlike other instruments, these questions combine ratings of symptom severity and frequency with impact on functioning and fear of future symptoms. Of note, fears about future symptom expression did not load highly on the preparation domain. Measurement of aspects of patients' physical symptoms beyond frequency and severity contributes new information to the multidimensional measurement of quality at life's end, and alerts clinicians not only to manage patients' current physical distress, but also allay fears related to symptoms and their expression in the future.

Items associated with affective social support were expressed as a fifth domain, and included whether the person had a confidant and spent time with family. The importance of social support or connectedness at the end of life has been identified by other efforts to measure components of a good death.[6,7,19,37,39,48] Both items in the fifth domain, loaded strongly on the first domain, perhaps indicating an important link to "completion." After the next phase of validation, we will examine the items' convergent and divergent validity with comparison measures to determine final factor structure.

Previously published quality-of-life indices tend to be divided *a priori* into biomedical, psychological, social, and spiritual concerns. However, these categories may reflect the divisions of research disciplines rather than distinctions spawned by patients' and families' experiences. A growing body of evidence suggests patients' and families' perspectives offer a more integrated view of death and dying.[22,49–51] The alternative conceptualization presented in the QUAL-E overlaps with previous studies, but we would argue, is qualitatively and quantitatively distinct.

The study has several limitations. Half of the participants were recruited from a Veterans Administration (VA) medical center and the other half from a private university medical center. As a result, more than half of respondents are male.

However, more than 25% were female; statistical analyses of subgroup differences based on gender, therefore, are adequately powered. Many patients had extended relationships with physicians, but these results may not be generalizable to those with longer term relationships with their physicians. All participants in the study had advanced disease but were ambulatory at the time of interview. This allowed initial assessment among a seriously ill population that was able to respond to the questionnaire. Three months after data collection with the first 100 patients 20% of that sample had died. Finally, because factor structure was analyzed using oblique rotation, multicollinearity may result if entering the full instrument in other analytic models. This will be tested empirically after the second phase of validation.

This was an initial validation of a new instrument. The study was primarily concerned with response distributions, and underlying factor structure. We do not report correlations with comparison measures assessing concurrent or divergent validity. Those assessments are underway in the second phase of validation using the revised shorter instrument (items in Table 1 plus the domain importance items and global quality-of-life question) on another sample of seriously ill patients. This phase also is evaluating test-retest reliability. A weighting scheme and a consequent scoring algorithm will be created after validity and reliability have been established.

Quality-of-life at the end of life is a multidimensional construct comprising a broad array of needs and influenced by one's interpersonal relationships, as well as personal reflections of the past, perceptions of the present, and expectations of the future. Patients come to the end of life with a range of illness trajectories, the relatively predictable pattern of functional decline among patients with metastatic disease, and the erratic crises that punctuate the functioning of patients with CHF and COPD. The instrument presented in this paper was designed to capture the experiences of patients with each of these illness courses. Furthermore, our goal is to validate a tool that is useful in a variety of care settings, irrespective of self-identification as "terminally ill." Future psychometric work will help understand the relative weights of domains and how they vary both between individuals and within individuals over time.

REFERENCES

1. Field M, Cassel C: *Approaching Death: Improving Care at the End of Life*. Washington, D.C.: Institute of Medicine, 1997.
2. Council on Scientific Affairs AMA: Good care of the dying patient. JAMA 1996;275:464–468.
3. Gibson R: The Robert Wood Johnson grantmaking strategies to improve care at the end of life. J Palliat Med 1998;1:415–417.
4. Teno J, Coppola K: For every numerator, you need a denominator: A simple statement but key to measuring the quality of care of the "dying." J Pain Symptom Manage 1999;17:109–113.
5. Lynn J: Measuring quality of care at the end of life: A statement of principles. J Am Geriatr Soc 1997;45:526–527.
6. Cohen S, Mount B: quality-of-life assessment in terminal illness: Defining and measuring subjective well-being in the dying. J Palliat Care 1992;8:40–45.
7. Byock I, Merriman M. Measuring quality-of-life for patients with terminal illness: The Missoula-VITAS quality-of-life Index. Palliat Med 1998;12:231–244.
8. Stewart AL, Teno J, Patrick DL, Lynn J: The concept of quality-of-life of dying persons in the context of health care. J Pain Symptom Manage. 1999;17(2):93–108.
9. Higginson IJ, Carr AJ: Measuring quality of life: Using quality-of-life measures in the clinical setting. BMJ 2001;322:1297–1300.
10. Steinhauser K, Clipp E, Tulsky J: Evolution in measuring the quality of dying. J Palliat Med 2002;5:407–414.
11. Cohen S, Mount B, Strobel MG EA: The McGill quality-of-life Questionnaire: A measure of quality-of-life for people with advanced disease. A preliminary study of validity and acceptability. Palliat Med 1995;9:207–219.
12. Cohen SR, Hassan SA, Lapointe BJ, Mount BM: Quality of life in HIV disease as measured by the McGill quality-of-life Questionnaire. AIDS 1996;10:1421–1427.
13. Cohen SR, Mount BM, Bruera E, Provost M, Rowe J, Tong K: Validity of the McGill Quality of life Questionnaire in the palliative care setting: A multi-centre Canadian study demonstrating the importance of the existential domain. Palliat Med 1997;11:3–20.
14. Sterkenburg C, King B, Woodward C: A reliability and validity study of the McMaster quality-of-life Scale (MQLS) for a palliative care population. J Palliat Care 1996;12:18–25.
15. Ahmedzai S, Arrasas J, Eisemann M, Kaasa S, Meyza

J, Nordenstamm M, Schraub S, Wright S: Development of an appropriate quality-of-life measure for palliative care. Qual Life Res 1994;3:57–64.

16. Cella D: *Manual of the Functional Assessment of Chronic Illness Therapy (FACIT Scales)—Version 4.* Evanston, IL.: Center on Outcomes Research and Education (CORE), Evanston Northwestern Healthcare and Northwestern University, 1997.

17. McGee HM, O'Boyle CA, Hickey A, O'Malley K, Joyce CR: Assessing the quality-of-life of the individual: The SEIQoL with a healthy and a gastroenterology unit population. Psychol Med 1991;21:749–759.

18. Hickey AM, Bury G, O'Boyle CA, Bradley F, O'Kelly FD, Shannon W: A new short form individual quality-of-life measure (SEIQoL-DW): application in a cohort of individuals with HIV/AIDS. BMJ 1996;313:29–33.

19. Cella DF, Tulsky DS, Gray G, Sarafian B, Linn E, Bonomi A, Silberman M, Yellen SB, Winicour P, Branon J, et al: The Functional Assessment of Cancer Therapy scale: Development and validation of the general measure. J Clin Oncol 1993;11:570–579.

20. Padilla G, Presant C, Grant M, Metter G, Lipsett J, Heide F: Quality of life Index for patients with cancer. Res Nurs Health 1983;6:117–126.

21. Waldron D, O'Boyle CA, Kearney M, Moriarty M, Carney D: Quality-of-life measurement in advanced cancer: assessing the individual. J Clin Oncol 1999;17:3603–3611.

22. Steinhauser K, Clipp E, McNeilly M, Christakis N, McIntyre L, Tulsky J. In search of a good death: Observations of patients, families and health care providers. Ann Intern Med 2000;132:825–832.

23. Steinhauser K, Christakis N, Clipp E, McNeilly M, McIntyre L, Tulsky J: Factors considered important at the end of life by patients, family, physicians and other care providers. JAMA, 2000;284:2476–2482.

24. Pfieffer E: A Short Portable Mental Status Questionnaire for the assessment of organic brain deficit in elderly patients. J Am Geriatr Soc 1975;23:433–441.

25. Fleiss J. *Statistical Methods for Rates and Proportions.* New York: John Willey & Sons, 1981.

26. Streiner D, Norman G: *Health Measurement Scales: A Practical Guide to their Development and Use.* 2nd ed. Oxford: Oxford University Press, 1995.

27. Kline P. A *Handbook of Test Construction.* London: Metheun, 1986.

28. Guadagnoli E, Velicer W: Relation of sample size to the stability of component patterns. Psych Bull. 1988;103:265–275.

29. Portenoy RK, Thaler HT, Kornblith AB, Lepore JM, Friedlander-Klar H, Kiyasu E, Sobel K, Coyle N, Kemeny N, Norton L, et al. The Memorial Symptom Assessment Scale: An instrument for the evaluation of symptom prevalence, characteristics and distress. Eur J Cancer 1994;930A:1326–1336.

30. Greisinger AJ, Lorimor RJ, Aday LA, Winn RJ, Baile WF: Terminally ill cancer patients. Their most important concerns. Cancer Pract. 1997;5:147–154.

31. Emanuel E, Emanuel L: The promise of a good death. Lancet. 1998;251(Suppl2):21–29.

32. Ford J, MacCallum R, Trait M: The application of exploratory factor analysis in applied psychology: A critical review and analysis. Psychol. 1986;39:291–314.

33. Rummel R. *Applied Factor Analysis.* Evanston, IL: Northwestern University Press, 1970.

34. Cattell R. The scree test for the number of factors. Soc Meth Res 1966;1:245–276.

35. Thurstone. *Multiple-Factor Analysis.* Chicago: Chicago University Press, 1947.

36. Pedhauzer E, Schelkin L: *Measurement, Design and Analysis.* New Jersey: Lawrence Erlbaum, 1991.

37. Curtis JR, Patrick DL, Engelberg RA, Norris K, Asp C, Byock I: A measure of the quality of dying and death: initial validation. J Pain Symptom Manage (in press).

38. Patrick D, Pearlman R, Starks H, Cain K, Cole W, Uhlmann R: Validation of preferences for life-sustaining treatment; implications for advance care planning. Ann Intern Med 1997;127:509–517.

39. Teno JM, Clarridge B, Casey V, Edgman-Levitan S, Fowler J: Validation of Toolkit After-Death Bereaved Family Member Interview. J Pain Symptom Manage 2001;22:752–758.

40. Cohen S, Mount B. Living with cancer: "Good" days and "Bad" days—What produces them? Cancer 2000;89:1854–1865.

41. Erikson E. *The Life Cycle Completed: A Review.* New York: Norton, 1982.

42. Byock I: The nature of suffering and the nature of opportunity at the end of life. Clin Geriatr Med 1996;12:237–252.

43. Byock I: *Dying Well.* New York: Riverhead Books, 1997.

44. Kubler-Ross E: *On Death and Dying.* New York: MacMillan, 1969.

45. Herth K: Abbreviated instrument to measure hope: development and psychometric evaluation. J Avd Nurs 1992:187–192.

46. Guyatt G, Cook D: Health status, quality-of-life and the individual. JAMA 1994;272:630–631.

47. Mount B, Scott J: Whither hospice evaluation. J Chron Dis 1983;36:731–736.

48. Cella DF, Tulsky DS: Quality-of-life in cancer: Definition, purpose, and method of measurement. Cancer Invest 1993;11:327–336.

49. Martin D, Theil E, Singer P: A new model of advance care planning. Arch Intern Med 1999;158:86–92.

50. Fowler F, Coppola K, Teno J: Methodological challenges for measuring care at the end of life. J Pain Sympt Manage 1999;17:114–119.

51. Singer P, Martin D, Merrijoy K: Quality end-of-life care: Patients' perspectives. JAMA 1999;281:163–168.

Address reprint requests to:
Karen E. Steinhauser, Ph.D.
VA Medical Center (152)
508 Fulton Street
Durham, NC 27705

E-mail: karen.steinhauser@duke.edu

APPENDIX

Measuring Quality-of-Life at the End of Life (QUAL-E): Thirty-One Items

I'd like you to think back over the last month. Please tell me the three physical symptoms or problems that have bothered you the most during that time. Some examples are pain, nausea, lack of energy, confusion, depression, anxiety, and shortness of breath.

Symptom #1_____ _

Symptom #2_____ _

Symptom #3_____ _

•If no symptoms were elicited, then state the following:
So, just to be sure, over the last month, you have had no physical or emotional symptoms that bothered you.

If correct, skip to question #5.

Which of these symptoms or problems has bothered you the most this past week?

1. During the last week, how often have you experienced _____?

Rarely	*A few times*	*Fairly often*	*Very often*	*Most of the time*
1	2	3	4	5

2. During the last week, on average, how severe has _____ been?

Very mild	*Mild*	*Moderate*	*Severe*	*Very severe*
1	2	3	4	5

3. During the last week, how much has _____ interfered with your ability to enjoy your life?

Not at all	*A little bit*	*A moderate amount*	*Quite a bit*	*Completely*
1	2	3	4	5

4. How worried are you about _____ occurring in the future?

Not at all	*A little bit*	*A moderate amount*	*Quite a bit*	*Completely*
1	2	3	4	5

5. In general, how important are your PHYSICAL SYMPTOMS OR PROBLEMS to your overall quality of life?

Not at all	*A little bit*	*A moderate amount*	*Quite a bit*	*Completely*
1	2	3	4	5

Below is a list of statements that other people with a serious illness have said may be important. Please tell me how true each statement is for you.

6. I have as much information as I want about my illness.

Not at all	*A little bit*	*A moderate amount*	*Quite a bit*	*Completely*
1	2	3	4	5

7. Although I cannot control certain aspects of my illness, I have a sense of control about my treatment decisions.

Not at all	*A little bit*	*A moderate amount*	*Quite a bit*	*Completely*
1	2	3	4	5

8. I participate as much as I want in the decisions about my care.

| Not at all | A little bit | A moderate amount | Quite a bit | Completely |
| 1 | 2 | 3 | 4 | 5 |

9. Beyond my illness, my doctor has a sense of who I am as a person.

| Not at all | A little bit | A moderate amount | Quite a bit | Completely |
| 1 | 2 | 3 | 4 | 5 |

10. In general, I know what to expect about the course of my illness.

| Not at all | A little bit | A moderate amount | Quite a bit | Completely |
| 1 | 2 | 3 | 4 | 5 |

11. As my illness progresses, I know where to go to get answers to my questions.

| Not at all | A little bit | A moderate amount | Quite a bit | Completely |
| 1 | 2 | 3 | 4 | 5 |

12. In general, how important is feeling like an ACTIVE PARTICIPANT in your HEALTH CARE to your overall quality of life?

| Not at all | A little bit | A moderate amount | Quite a bit | Completely |
| 1 | 2 | 3 | 4 | 5 |

13. I spend as much time as I want with my family.

| Not at all | A little bit | A moderate amount | Quite a bit | Completely |
| 1 | 2 | 3 | 4 | 5 |

14. There is someone in my life with whom I can share my deepest thoughts.

| Not at all | A little bit | A moderate amount | Quite a bit | Completely |
| 1 | 2 | 3 | 4 | 5 |

15. In general, how important are your PERSONAL RELATIONSHIPS to your overall quality of life?

| Not at all | A little bit | A moderate amount | Quite a bit | Completely |
| 1 | 2 | 3 | 4 | 5 |

16. In general, how important is feeling CONNECTED TO OTHERS to your overall quality of life?

| Not at all | A little bit | A moderate amount | Quite a bit | Completely |
| 1 | 2 | 3 | 4 | 5 |

17. I worry that my family is not prepared to cope with the future.

| Not at all | A little bit | A moderate amount | Quite a bit | Completely |
| 1 | 2 | 3 | 4 | 5 |

18. I have regrets about the way I have lived my life.

| Not at all | A little bit | A moderate amount | Quite a bit | Completely |
| 1 | 2 | 3 | 4 | 5 |

19. At times, I worry that I will be a burden to my family.

| Not at all | A little bit | A moderate amount | Quite a bit | Completely |
| 1 | 2 | 3 | 4 | 5 |

20. Thoughts of dying frighten me.

| Not at all | A little bit | A moderate amount | Quite a bit | Completely |
| 1 | 2 | 3 | 4 | 5 |

21. I worry about the financial strain caused by my illness.

Not at all	A little bit	A moderate amount	Quite a bit	Completely
1	2	3	4	5

22. In general, how important are CONCERNS ABOUT THE FUTURE to your overall quality of life?

Not at all	A little bit	A moderate amount	Quite a bit	Completely
1	2	3	4	5

23. I have been able to say important things to those close to me.

Not at all	A little bit	A moderate amount	Quite a bit	Completely
1	2	3	4	5

24. I make a positive difference in the lives of others.

Not at all	A little bit	A moderate amount	Quite a bit	Completely
2	3	4	5	5

25. I have been able to help others through time together, gifts, or wisdom.

Not at all	A little bit	A moderate amount	Quite a bit	Completely
1	2	3	4	5

26. I have been able to share important things with my family.

Not at all	A little bit	A moderate amount	Quite a bit	Completely
2	3	4	5	5

27. Despite my illness, I have a sense of meaning in my life.

Not at all	A little bit	A moderate amount	Quite a bit	Completely
1	2	3	4	5

28. I feel at peace.

Not at all	A little bit	A moderate amount	Quite a bit	Completely
1	2	3	4	5

29. In general, how important is CONTRIBUTING TO OTHERS to your overall quality of life?

Not at all	A little bit	A moderate amount	Quite a bit	Completely
1	2	3	4	5

30. In general, how important is the feeling that your LIFE IS COMPLETE to your overall quality of life?

Not at all	A little bit	A moderate amount	Quite a bit	Completely
1	2	3	4	5

Now, I have one last question.

31. How would you rate your OVERALL QUALITY OF LIFE?

Very Poor	Poor	Fair	Good	Excellent
1	2	3	4	5