The Functional Assessment of Cancer Therapy Scale: Development and Validation of the General Measure

By David F. Cella, David S. Tulsky, George Gray, Bernie Sarafian, Elizabeth Linn, Amy Bonomi, Margaret Silberman, Suzanne B. Yellen, Patsy Winicour, Judy Brannon, Karen Eckberg, Stephen Lloyd, Sandy Purl, Carol Blendowski, Michelle Goodman, Madeline Barnicle, Irene Stewart, Marnie McHale, Philip Bonomi, Edward Kaplan, Samuel Taylor IV, Charles R. Thomas, Jr, and Jules Harris

Purpose: **We developed and validated a brief, yet sensitive, 33-item general cancer quality-of-life (QL) measure for evaluating patients receiving cancer treatment, called the Functional Assessment of Cancer Therapy (FACT) scale.**

Methods and Results: **The five-phase validation process involved 854 patients with cancer and 15 oncology specialists. The initial pool of 370 overlapping items for breast, lung, and colorectal cancer was generated by open-ended interview with patients experienced with the symptoms of cancer and oncology professionals. Using preselected criteria, items were reduced to a 38-item general version. Factor and scaling analyses of these 38 items on 545 patients with mixed cancer diagnoses resulted in the 28-item FACT-general (FACT-G, version 2). In addition to a total score, this version produces subscale scores for physical, functional, social, and emotional well-being, as well as satisfaction with the treatment relationship. Coefficients of reliability and validity were uniformly high. The scale's ability to discriminate patients on the basis of stage of disease, performance status rating (PSR), and hospitalization status supports its sensitivity. It has also demonstrated sensitivity to change over time. Finally, the validity of measuring separate areas, or dimensions, of QL was supported by the differential responsiveness of subscales when applied to groups known to differ along the dimensions of physical, functional, social, and emotional well-being.**

Conclusion: **The FACT-G meets or exceeds all requirements for use in oncology clinical trials, including ease of administration, brevity, reliability, validity, and responsiveness to clinical change. Selecting it for a clinical trial adds the capability to assess the relative weight of various aspects of QL from the patient's perspective.**

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CONCERN FOR THE psychosocial needs of patients receiving treatment for cancer has increased in recent years.[1-14] The advent of multimodality treatments that combine surgery, radiation therapy, and chemotherapy has markedly improved the prognosis of many forms of cancer. However, this success has not been without cost. Acute, chronic, and delayed treatment toxicity have been associated with many of the experimental and proven treatments implemented over the past two decades. Due to the chronic, often incurable nature of cancer, investigators of new treatments are frequently as concerned with toxicity as they are with efficacy. Quality of life (QL) has become an important aspect of the cost to utility ratio in evaluating treatment recommendations based on clinical trial data.

Because of the complex relationship between treatment efficacy and toxicity in oncology, careful measurement and documentation of patient function has become a necessary component of outcome evaluation in many clinical trials. The term QL has emerged to summarize the broad-based assessment of the combined impact of disease and treatment and the trade-off between the two. As a clinical trial end point, QL at times has value equal to disease-free survival and even actual survival time.[15]

Recently, four edited books,[1-4] a National Cancer Institute monograph,[5] and many review articles,[6-11] as well as editorials,[16-18] have made strong statements on behalf of measuring QL in oncology clinical trials. There are now growing numbers of available measures of health-related QL, which have been summarized and presented elsewhere.[4,7,9] However, extensive reliability and validity data are available to interested investigators on only a few available measures.[19-22] Furthermore, few of the available measures were developed with careful attention to principles of test construction and evaluation. Common test construction strategies that have clinical relevance include generating a large pool of questions, or items, from which to derive the most appropriate and sensitive set. Beginning with a sufficiently large pool of items, one can derive the best smaller combination by subjecting patient responses to the items to analyses to determine how the items fit together into a meaningful underlying concept, and how these items correlate with one another and the underlying concept. Important test construction strategy also includes defining a patient-as-expert approach in which item der-

From the Rush-Presbyterian-St Luke's Medical Center, Chicago, IL; the Psychological Corporation, San Antonio, TX; and the Cancer Wellness Center, Skokie, IL.

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Address reprint requests to David F. Cella, PhD, 1725 W Harrison, Suite 817, Chicago, IL 60612.

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ivation is driven not only by clinical experience and investigator viewpoint about QL, but also patient input. This is consistent with the view of QL as fundamentally subjective.

When evaluating health-related QL in cancer patients, tension arises between the need to obtain general information about health status, which is relatively independent of the nature of the illness or treatment being delivered, and the need to obtain information about health status that is specific to a given illness or treatment. Aaronson et al[23] have described an approach in which a core (general) measure can be supplemented with site and treatment (specific) modules. The instrument development project described here was guided in part by this modular approach, treating QL as a subjective (ie, patient-rated), multidimensional concept.[5,6,11,12,24-26] The approach to developing the measure used a combination of empirical item derivation/refining strategies and a theoretical approach to item selection, which helped to ensure adequate validity.

Following is a presentation of the development and initial validation of the core (general) measure.

METHOD AND RESULTS

From October 1987 through February 1992, development and validation of the general component of the Functional Assessment of Cancer Therapy (FACT) scale (version 2) took place in five phases. These phases were (1) item generation, (2) item review/reduction, (3) scale construction/piloting, (4) initial evaluation, and (5) additional evaluation. Each phase will be presented in sequence.

Phase I: Item Generation

Items were generated using semistructured interview input from 45 patients with cancer and 15 oncology specialists. Patients currently receiving treatment for advanced breast (n = 15), lung (n = 15), and colorectal (n = 15) cancer were approached to participate in a brief interview, "to help develop a measure of quality of life for people with your illness." To increase the likelihood that patients in this phase would have had sufficient experience with cancer symptoms and treatment side effects, eligibility was restricted to patients currently receiving treatment (including hormone therapy) for advanced (stage III or IV) cancer. It was also required that patients be able to read and speak English and that they have no known evidence of brain metastasis, delirium, psychosis, or severe depression. All 45 patients who were approached agreed to participate. Median age of the patients was 60 years (range, 27 to 76).

After gathering demographic and treatment information, patients were asked to complete a brief version of the Profile of Mood States[27] and two QL scales: The Functional Living Index-Cancer (FLIC)[21] and the Quality of Life Index (QLI) developed by Spitzer et al,[28] modified for self-administration. Overall QL, as measured by the FLIC, was similar across groups. In cases where the groups differed, lung cancer patients reported the poorest QL and colorectal patients reported the best QL.[29] After completing the questionnaires, patients were asked to report as many QL items as they could imagine, given their experience with the disease and treatment. Patients were advised to use the scales they had just completed as guides, but not to feel limited by them.

Oncology specialists had to meet the following qualifications to be eligible: (1) MD or RN degree, and (2) minimum of 3 years' experience treating at least 100 patients with the tumor type in question. These 15 specialists (eight physicians and seven nurses) were given samples of existing QL measures (FLIC and QLI) to review before and during the open-ended item-generation interview. The specialists were then asked to endorse any items they chose to from the sample measures. They were also asked to name any QL issues that did not receive adequate coverage in the existing set of questions.

Patient and specialist responses were combined. Three judges reviewed these tabulated items and rated them independently for overlap and/or irrelevance to QL. The judges then met to combine their ratings of each item and derive lists of QL items for each of the disease sites. The resulting initial item pool contained 137 items for breast cancer, 126 for colorectal cancer, and 107 for lung cancer. Subsequent review of item content by three independent raters found approximately 40% overlap across disease sites.

Phase II: Item Review/Reduction

The initial item pool was reduced based on data obtained from a new sample of 90 patients receiving chemotherapy (30 lung, 30 breast, 30 colorectal). The strategy for item reduction was guided by a desire to ensure item relevance and fit with patient values. To incorporate input about patient values, each patient was asked to evaluate items on a 4-point scale for their relative importance to QL. Items that were generally rated as very and extremely important were retained. The majority of the items retained were common to patients across all three disease sites. The items that were common across disease sites were reviewed for redundancy by an independent panel of oncologists, oncology nurses, and social scientists, and similar items were eliminated. To ensure representative-

ness across all dimensions of life considered to be relevant, the remaining items were reviewed for content. It was noted that the retained items were lacking in two areas (physical and sexual). Items that emphasized overall physical well-being and intimacy/sexuality were therefore readded to form a final core of 38 general items. This balancing of criteria simultaneously assured item relevance and representation of important dimensions (content validity). The resulting 38 items constituted version 1 of the FACT-General (FACT-G).

Phase III: Scale Construction/Piloting

Format of the initial scale (version 1). The item presentation format for version 1 of the FACT was derived from the investigators' earlier definition of QL, which included a comparison between actual and expected functional status.[12] As a result of pilot experience, the format used in version 1 was Likert (0 to 4 scale) for the actual functioning rating, and categorical (better, worse, as expected) for the expectation rating. Version 1 of the FACT scale can be found elsewhere.[4] In the interest of reducing administration time and preparing the measure for clinical trials, the expectation rating in version 1 was eliminated from version 2. Results comparing actual and expected item scores are not relevant to this report and will therefore be presented at a later time.

Format of version 2. On the basis of data to be presented in the next section, the 38 items of version 1 were reduced to 28. The 28 preserved items are formated precisely the same as the actual functioning items of version 1. In addition to these items, there is an experimental item at the end of each subscale that assesses patient appraisal of the extent to which each aspect of QL affects overall QL. These items are rated on a 0 to 10 numerical analog scale. Version 2 of the FACT-G is presented in the Appendix.

Phase IV: Initial Evaluation

After using the input of 135 patients and 15 oncology specialists to determine the content and format of the scale, the 38-item FACT-G was administered to a previously untested heterogeneous sample of patients with cancer (39% breast, 15% lung, 12% colorectal, 8% leukemia/lymphoma, 8% head and neck, 6% prostate, 2% ovarian, 10% other/unknown primary). Patients came from four sources: group 1 consisted of inpatients at Rush-Presbyterian-St Luke's Medical Center (RPSLMC), Chicago, IL (n = 121); group 2 consisted of outpatients receiving chemotherapy and/or radiation therapy at RPSLMC (n = 195); group 3 consisted of patients receiving services from the Cancer Wellness Center (CWC), Skokie, IL, which is a freestanding, nonprofit community support center (n = 139); and group 4 consisted of inpatients and outpatients entered on a funded intervention study to improve QL in patients with advanced breast, lung, and colorectal cancer (n = 90). Only patients with documented CNS metastases or overt clinical signs of psychopathology (delirium, psychosis, etc) were excluded. Of 630 patients approached, 545 (87%) provided assessable data. Patients in groups 3 and 4 were not given the entire validation packet (as described below), but were included in the item and factor analyses of the FACT for two reasons: (1) to increase the item and factor analysis sample sizes beyond the recommended[30,31] 10 cases/item; and (2) to help produce the most heterogeneous (and therefore generalizable) sample of patients possible.

The validation packet of questionnaires was administered to the 316 patients in groups 1 and 2. It included the following: The FLIC,[21] the Eastern Cooperative Oncology Group (ECOG) performance status rating (PSR),[32] and shortened forms of the Profile of Mood States (Brief POMS),[27] the Taylor Manifest Anxiety Scale (TMAS),[33] and the Marlowe-Crowne Social Desirability Scale (M-CSDS).[34] In addition to this, most patients in groups 3 and 4 were given the FLIC and FACT, according to internally consistent study designs relevant to those sites. Therefore, sample sizes of results reported range from 316 to 545.

Item analysis. The responses of all 545 patients to the 38 original items were analyzed for their fit to the presumed underlying concept of QL. It was decided to use a Rasch Model[35] rating scale analysis to examine the properties of the resulting scale. Using a procedure described by Wright and Linacre,[36] and the TESTAT computer program,[37] patients' scores on each question were evaluated for their consistency with other responses. Ten items, covering areas such as hope and spirituality, were rejected due to poor fit, which left a total of 28 items comprising version 2 of the FACT-G.

Factor analysis. Factor-analysis was conducted on the entire sample of 545 patients. Six significant[30] factors were extracted, accounting for 51% of the total variance. Table 1 lists the item-to-factor loadings for the 28 items of the FACT-G.

Creation and testing of subscales for internal consistency. As a result of the factor analysis, five subscales were created: physical well-being (factor 1), social well-being (factor 2), emotional well-being (factor 3), functional well-being (factor 4 + 6), and relationship with doctor (factor 5). For simplicity, items that loaded heavily on factors 4 and 6 were combined into one subscale because

Table 1. Logit-Transformed Factor Loadings on 28-Item FACT-G (N = 545)

Question	Factor 1	2	3	4	5	6
I have a lack of energy	**.59**	.00	−.01	−.13	−.13	−.17
I have nausea	**.71**	−.11	.11	.23	.12	−.01
I have trouble meeting the needs of my family	**.45**	.15	.13	−.17	−.18	−.06
I have pain	**.57**	.08	.13	−.05	−.06	−.01
I am bothered by side effects of treatment	**.71**	.02	.03	.23	.08	−.06
In general, I feel sick	**.65**	.01	.09	−.11	.00	.03
I am forced to spend time in bed	**.66**	−.01	−.10	−.26	−.05	.06
I feel distant from my friends	−.04	**.45**	.23	**−.31**	.22	−.02
I get emotional support from my family	.02	**.61**	−.10	.14	**.36**	.12
I get support from my friends and neighbors	−.13	**.52**	−.02	−.21	−.01	−.12
My family has accepted my illness	.00	**.70**	.08	.08	−.05	−.02
Family communication about my illness is poor	.15	**.64**	.07	.08	.06	.28
I feel close to my partner (or main support)	.02	**.42**	−.20	.11	**.31**	−.26
I am satisfied with my sex life	.11	.12	.09	−.14	.16	−.22
I feel sad	.18	.21	**.56**	−.03	.03	−.15
I am proud of how I'm coping with my illness	−.05	.05	**.44**	−.14	−.04	**−.42**
I am losing hope in the fight against my illness	.22	−.03	**.56**	−.06	.12	.11
I feel nervous	.05	.01	**.57**	−.14	.06	−.18
I worry about dying	−.03	−.01	**.75**	.20	.05	.02
My work (including housework) is fulfilling	−.04	.02	.06	**−.74**	.16	−.01
I am able to enjoy life "in the moment"	.05	−.14	.12	**−.53**	.29	−.26
I have been able to work (including housework)	**.40**	−.02	−.16	**−.61**	−.03	.06
I have confidence in my doctors	−.10	.09	.08	−.27	**.75**	.18
My doctor is available to answer my questions	.01	−.01	.06	−.02	**.75**	−.10
I have accepted my illness	−.13	.15	.26	.05	−.03	**−.57**
I am sleeping well	.19	−.12	−.04	.05	.04	**−.70**
I am enjoying my usual leisure pursuits	**.40**	.09	−.14	**−.35**	−.03	**−.37**
I am content with the quality of my life right now	.29	.07	.05	**−.30**	.03	**−.49**

NOTE. The factor analysis procedure assumes interval scaling of data (even intervals between response choices). Logit-transformed scores are scores that have been mathematically converted to an interval scale. In an oblique rotation factor analysis, factor loadings are regression coefficients that indicate the association between each factor and a given item. Higher coefficients (in absolute value) reflect stronger associations. All loadings greater than .30 are in bold type.

of the conceptual similarity of item content, and the relatively high correlation between the two factors ($r_{\text{factor } 4/6} = .25$). Table 2 lists subscale and total FACT-G means ± SD on the standardization sample. Table 2 also lists information on internal consistency (coefficient α) of each subscale and the total FACT-G score, as well as the percent of variance accounted for by each of the subscales in the factor analysis.

Table 2. FACT-G Subscale and Overall Scores (N = 466 mixed cancer patients)

Subscale	No. of Items	Range of Scores	Mean ± SD	α	Percent of Variance
Physical	7	0-28	20.49 ± 5.45	.82	22
Functional	7	0-28	17.96 ± 6.10	.80	9
Social	7	0-28	21.93 ± 4.77	.69	9
Emotional	5	0-20	14.82 ± 3.88	.74	6
Relationship with doctor	2	0-8	6.85 ± 1.51	.65	5
Total	28	0-112	82.06 ± 15.86	.89	51

Initial Validity Testing

Initial evidence for convergent and discriminant validity was evaluated using data from the 316 patients who completed the full validation packet. Convergent validity is evaluated by examining the association between scores on the FACT-G and those of other similar measures completed at the same time. Relatively high correlation coefficients are expected in these comparisons. Divergent validity is evaluated by examining the association between scores on the FACT-G and dissimilar measures completed at the same time. Low correlations are expected in these comparisons. As was expected, the Pearson correlation

Table 3. Pearson Correlations Across Measures in Validation Packet

	Measure				
	FLIC	B-POMS	TMA	ECOG-PSR	M-CSDS
FACT-G	.79 (n = 424)	−.68 (n = 297)	−.58 (n = 290)	−.52 (n = 433)	.22 (n = 298)
FLIC		−.66 (n = 286)	−.58 (n = 280)	−.60 (n = 416)	−.16 (n = 286)
B-POMS			.47 (n = 282)	.46 (n = 291)	−.18 (n = 289)
TMA				.32 (n = 282)	−.19 (n = 285)
ECOG-PSR					−.06 (n = 290)

with the FLIC was high (.79). Also, correlations with measures of mood distress were also rather high: $r_{FACT/TMAS} = -.58$; $r_{FACT/BriefPOMS} = -.65$. The correlation with activity level as measured by the ECOG 5-point PSR was moderately high ($r = -.56$), within the expected range. Also as expected, the correlation with social desirability, as measured by the shortened M-CSDS, was rather low ($r = .22$), supporting divergent validity. A full matrix of correlation coefficients is listed in Table 3.

Differentiating known groups. The 28-item FACT-G total score derived from the above administration was able to differentiate patients according to stage of disease (I, II, III, IV), ECOG PSR (0, 1, 2, 3/4), and location of administration (RPSLMC inpatient, RPSLMC outpatient, CWC). Details of these comparisons are presented in Tables 4 through 6. FACT-G sensitivity to stage of disease was seen in the physical and functional subscales, and the total score. Consistent with expectation, these scores were significantly lower in stage IV patients compared with stage I and II patients, reflecting their poorer QL in physical (but not social and emotional) areas (Table 4). As for PSR, the total FACT-G score and all subscales except relationship with doctor were significantly higher (better) for patients with lower (better) PSRs. Table 5 presents the detailed analyses, including subgroup comparisons that identify the PSR groups whose scores differed. In all cases where differences between groups occurred, they were in the expected direction, reflecting poorer QL in patients with more impaired PSR.

Table 6 presents the comparisons across patient location. This comparison allowed an examination of the QL differences between inpatients and outpatients at a single institution (RPSLMC), with the latter expected to show better (higher) QL scores in all areas except relationship with doctor. This comparison also permitted a view of QL as rated by people seeking social and emotional support services at the unaffiliated CWC. This created an opportunity to address the validity of separate-but-distinct aspects of QL (physical, functional, social, emotional), since the CWC is a center that explicitly addresses social and emotional aspects of cancer. The results in Table 6 indicate, on the one hand, that total QL scores are significantly higher for RPSLMC outpatients than those for RPSLMC inpatients and CWC participants ($P < .0001$). Closer examination of subscale differences shows that the CWC participants resemble RPSLMC outpatients rather than inpatients in both physical and functional aspects of QL. However, their social and emotional well-being, is significantly lower than that of either RPSLMC group, supporting the fact that they are patients who have referred themselves to a center for social and emotional support.

Phase V: Additional Evaluation

After creating version 2 of the FACT as described above, two additional parameters were evaluated with subsequent studies on new (ie, previously untested with the FACT) groups of patients: test-retest reliability and sensitivity to change.

Test-retest reliability. The FACT-G was administered to a previously untested sample of 70 outpatients with mixed cancer diagnoses. A second administration was planned within 3 to 7 days. Timing was prearranged to avoid chemotherapy treatment between administrations of the FACT-G. Of the 70 patients who completed ad-

Table 4. FACT-G Differentiation of Stage of Illness

		FACT-G Subscale (mean ± SD)					
Stage	n	Physical	Functional	Social	Emotional	Relationship With Doctor	Total
I	27	22.3 ± 6.3	21.6 ± 6.3	22.9 ± 5.3	15.9 ± 3.2	7.1 ± 1.8	89.7 ± 17.6
II	70	21.8 ± 5.1	19.8 ± 5.6	23.3 ± 4.1	15.8 ± 3.7	7.0 ± 1.4	87.7 ± 15.3
III	65	20.8 ± 5.0	18.1 ± 5.8	22.8 ± 4.4	15.8 ± 3.6	6.8 ± 1.9	83.9 ± 14.4
IV	143	19.6 ± 5.4	16.5 ± 6.1	22.1 ± 4.3	15.5 ± 3.7	6.9 ± 1.5	80.7 ± 15.0
P, *F* test		< .01	< .0001	NS	NS	NS	< .01

NOTE. Stage is based on National Cancer Institute Surveillance, Epidemiology and End Results criteria. Scheffe comparisons of differences in physical, functional, and total scores showed that stage IV patients scored significantly lower than stage I and II patients.

Table 5. FACT-G Differentiation of ECOG PSR

PSR*	n	FACT-G Subscale (mean ± SD)					
		Physical	Functional	Social	Emotional	Relationship With Doctor	Total
0	204	24.0 ± 3.5	21.4 ± 4.7	22.5 ± 5.2	15.9 ± 3.4	6.9 ± 1.6	90.7 ± 12.9
1	109	19.9 ± 4.1	16.8 ± 5.4	21.9 ± 4.4	14.3 ± 3.8	6.9 ± 1.3	79.7 ± 13.1
2	86	16.8 ± 4.2	14.1 ± 5.3	20.7 ± 4.4	13.4 ± 4.0	6.6 ± 1.5	71.7 ± 13.3
3/4	38	13.9 ± 6.0	12.7 ± 5.7	21.7 ± 4.5	14.2 ± 3.7	6.9 ± 1.4	69.5 ± 15.5
P		< .0001	< .0001	< .05	< .0001	NS	< .0001
Subgroup differences†		0 > 1 > 2 > 3/4	0 > 1 > 2, 3/4	0 > 2, 3/4	0 > 1, 2, 3/4	—	0 > 1 > 2, 3/4

*PSRs were made by patients who were asked to place themselves into one of the following categories: 0, fully ambulatory without symptoms; 1, fully ambulatory with some symptoms; 2, requiring < 50% of awake time to rest (eg, in bed); 3, requiring > 50% of awake time to rest; 4, bedridden.

†Scheffe comparisons; > symbol separates groups that report significantly higher scores from those with lower scores.

ministration 1, 60 (86%) completed administration 2 within 3 to 7 days. Test-retest correlation coefficients for these 60 patients were as follows: physical well-being, .88; functional well-being, .84; social well-being, .82; emotional well-being, .82; relationship with doctor, .83; and total score, .92.

Sensitivity to change. Sensitivity to change is an important capability of any QL instrument that is proposed to evaluate treatment- or illness-related differences in a clinical trial. To a great extent, the performance of an instrument in the field will document its sensitivity. However, it was decided to obtain an early indication of whether subtests and the overall score would fluctuate as expected in patient groups that are known to change over time. A common (albeit global) parameter of change is PSR, and it was predicted that the physical and functional subtests would show the most significant sensitivity to change in this parameter, whereas other subtests might show marginal sensitivity to the related-but-distinct concept of PSR. The FACT-G was administered to an additional previously untested sample of 104 patients currently receiving chemotherapy for advanced breast, lung, or colon cancer. A second administration occurred 2 months later. Patient-reported PSRs[32] were also generated in an interview conducted before completion of the FACT. Patients were then categorized into three groups, according to change in PSR over time: those whose PSR declined (n = 27); those whose PSR improved (n = 17), and those whose PSR remained unchanged (n = 60). Multivariate analysis of variance confirmed a significant overall effect ($P = .002$), indicating that the FACT-G can clearly distinguish the three groups. Results of the follow-up univariate tests are listed in Table 7. These indicate, as expected, that the strongest contributors to sensitivity to change in PSR were the physical ($P < .001$) and functional ($P < .01$) subscales. Also sensitive to change in PSR was the emotional subscale ($P < .05$), but not the social or relationship with doctor subscales.

DISCUSSION

We report the development and validation of a measure of QL for use in patients with cancer. It is a 28-item questionnaire that can easily be completed in 5 minutes, usually without assistance. It is therefore responsive to the realistic constraints of a clinical trial setting in which simplicity and brevity are highly valued. Although brief, it is not so short that it loses sensitivity to such important characteristics as stage of illness, PSR, location of the pa-

Table 6. FACT-G Differentiation of Patient Location

Location	n	FACT-G Subscale (mean ± SD)					
		Physical	Functional	Social	Emotional	Relationship With Doctor	Total
1. RPSLMC inpatient	121	18.0 ± 5.2	15.3 ± 5.2	22.3 ± 4.3	14.5 ± 3.8	6.8 ± 1.4	76.9 ± 15.3
2. RPSLMC outpatient	195	21.9 ± 5.1	19.5 ± 5.9	22.8 ± 4.3	16.1 ± 3.5	7.0 ± 1.6	87.3 ± 14.9
3. CWC	139	20.7 ± 5.3	18.1 ± 5.5	20.5 ± 5.3	13.3 ± 3.9	6.6 ± 1.4	79.1 ± 15.4
P		< .0001	< .0001	< .0001	< .0001	NS	< .0001
Subgroup differences*		2, 3 > 1	2, 3 > 1	1, 2 > 3	2 > 1 > 3	—	2 > 1, 3

*Scheffe comparisons; > symbol separates groups that report significantly higher scores from those with lower scores.

Table 7. Sensitivity to Change in PSR (N = 104)

		2-Month Change Score in FACT (subscale)					
	n	Physical	Functional	Social	Emotional	Relationship With Doctor	Total
Declined PSR	27	−2.7	−2.3	−1.0	−0.8	−0.1	−6.8
No change in PSR	60	0.7	0.3	0.5	0.5	0.0	2.0
Improved PSR	17	3.2	1.6	−0.8	1.1	0.2	5.4
Univariate tests		$F = 12.6$‡	$F = 5.1$†	$F = 2.6$	$F = 3.9$*	$F = 0.4$	$F = 11.9$‡

NOTE. Overall multivariate $F(12, 190) = 2.67$.

*$P < .05$.

†$P < .01$.

‡$P < .001$.

tient, and change in clinical status over time. This last parameter is particularly important to the investigator setting out to evaluate changes in patient status due to a treatment intervention.

QL has come to be accepted as subjective, and thereby requires patient input for proper estimation. Growing evidence for its multidimensional nature[19,21,22,25,26] has been further supported by this study. Our factor analysis supported the creation of physical, functional, social, emotional, and relationship with doctor subscales, and these subscales were differentially responsive to criterion groups. For example, the physical and functional subscales were more responsive to stage of illness and PSR, whereas the social and emotional subscales were more responsive to patients who had entered a community cancer wellness program to enhance their social and emotional well-being. These data support the validity of the subscales.

The measure reported here can assist investigators who want to evaluate patient perceptions and values. Treatment decision-making can then occur at two levels: the individual clinical case, and the general population (policy-making). If policy is to be made regarding costs and values of the many treatments for cancer, then surely input from the recipient of these treatments is essential. Toward that end, this measure is unique in that it allows patients to assign personal weights to each QL area, making the integration of patient perception into clinical decision analysis a realistic possibility. No other QL measure available for oncology clinical trials allows for simultaneous evaluation of functional impairment and the perceived effect of that impairment on QL.

The clinical trial investigator faces a potentially overwhelming task when planning to include QL as an end point in a clinical trial. He or she must be responsive to constraints of time, cost, and burden to the patient and staff. Quite often, there are also specific cooperative group organizational needs and data management or statistician preferences for consistency of measurement across its trials. These pressures compel the typical investigator to search for a universal measure: short, simple, and sensitive to meaningful change. Unfortunately, more general scales are not likely to be sensitive to site-specific issues, unless they include an endless list of symptoms that are important in some diseases, but not in others. For example, swallowing ability is vitally important to many head and neck patients, but less relevant to a patient with leukemia. Shortness of breath, important to patients with advanced upper thoracic cancers, is not as compelling an issue in genitourinary cancers, and so forth. Therefore, tests that have been developed for chronic illness in general may be inadequate, either because they are too long or insensitive to clinical change. As one might expect, there are now measures available to examine QL in a variety of specific tumor types and circumstances.[1,19-23,39-46] Examples include early-stage breast cancer,[43] advanced breast cancer,[29,42] head and neck cancer,[44] lung cancer,[22,23,29] colorectal cancer,[29] bladder cancer,[45] and childhood cancer.[46] These inventories can provide specific information about the effects of disease or treatment that are relevant only within specific tumor sites or developmental circumstances.

A compromise position allows for the generalizability of the general measure and the sensitivity of the specific measure.[23] When combined with a general measure of QL that allows for cross-disease comparisons, site-specific measures may add substantial sensitivity without loss of the ability to compare across chronic conditions. More detailed site-specific subscales have been developed and are being tested by this investigative team. These will be reported at a later time. In time, the FACT evaluation system, by incorporating disease- and treatment-specific subscales with this general version, will offer the clinical investigator a range of choices within a single clinical framework. This will allow for simultaneous evaluation of functional level and value-based patient appraisal of the impact of that functional level on current QL.

It is unreasonable and short-sighted to suggest that the FACT-G (or any other QL measure) should be established as a universal standard. Depending on the site of the cancer and the expected side effects of treatment, the investigator might choose from among the FLIC,[21] the QLI,[28] an European Organization for Research and Treatment of Cancer questionnaire,[22,23] the Cancer Rehabilitation Evaluation System (CARES),[19,20] the Breast Chemotherapy Questionnaire (BCQ),[43] or one of the many brief linear analog scales.[39-42] However, some discussion of the relative advantages of the FACT-G is offered to place it in the context of currently available measures. There are four noteworthy advances seen in this measure compared with most. First, its items were systematically developed and represent a range of important aspects of QL, as indicated by patient review and statistical substantiation. Existing measures tend to overemphasize physical and functional aspects of QL. Second, validated subscales allow for a more detailed summary of specific aspects of QL. The total QL score can be broken down into five subscale scores, which are responsive to change and to known group differences. A third advantage over most other measures is the simple 5-point response scaling, which allows for a range of administration options, including interview and even telephone administration. A final advantage, and most unique of all, is the inclusion of patient-rated appraisal of the effect each dimension has on overall QL. This allows for the possibility of the measure's usefulness in cost-effectiveness studies.

In conclusion, although the emphasis of this report has been on assessment of QL in oncology, it is possible that with minor modifications, the FACT-G can be applied to the measurement of QL in other chronic or life-threatening medical conditions, such as heart disease, chronic obstructive pulmonary disease, renal disease, arthritis, or AIDS. Most of the concepts measured by the FACT-G are not specific to oncology and therefore lend themselves to evaluation in other diseases (Appendix and Table 1). This general (FACT-G) measure has already been administered without difficulty to patients with other chronic conditions (eg, renal failure, human immunodeficiency virus infection, fibromyalgia, urinary incontinence), with data forthcoming. However, for now, limiting its widespread use to oncology seems appropriate.

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APPENDIX
The FACT-G Scale

FACT-G (version 2)

Name: _____

Date: _____

Below is a list of statements that other people with your illness have said are important. By filling in one circle per line, please indicate how true each statement has been for you during the past 7 days.

During the past 7 days:	not at all	a little bit	some-what	quite a bit	very much
PHYSICIAL WELL-BEING					
1. I have a lack of energy	⓪	①	②	③	④
2. I have nausea	⓪	①	②	③	④
3. I have trouble meeting the needs of my family	⓪	①	②	③	④
4. I have pain	⓪	①	②	③	④
5. I am bothered by side effects of treatment	⓪	①	②	③	④
6. In general, I feel sick	⓪	①	②	③	④
7. I am forced to spend time in bed	⓪	①	②	③	④

8. How much does your **PHYSICAL WELL-BEING** affect your quality of life?

Not at all ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩ Very much so

APPENDIX (Continued)

FACT-G (version 2)

During the past 7 days:	not at all	a little bit	some-what	quite a bit	very much
SOCIAL/FAMILY WELL-BEING					
9. I feel distant from my friends	⓪	①	②	③	④
10. I get emotional support from my family	⓪	①	②	③	④
11. I get support from my friends and neighbors	⓪	①	②	③	④
12. My family has accepted my illness	⓪	①	②	③	④
13. Family communication about my illness is poor	⓪	①	②	③	④
If you have a spouse/partner, or are sexually active, please answer #14-15. Otherwise, go to #16.					
14. I feel close to my partner (or main support)	⓪	①	②	③	④
15. I am satisfied with my sex life	⓪	①	②	③	④

16. How much does your **SOCIAL/FAMILY WELL-BEING** affect your quality of life?

Not at all ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩ Very much so

During the past 7 days:	not at all	a little bit	some-what	quite a bit	very much
RELATIONSHIP WITH DOCTOR					
17. I have confidence in my doctor(s)	⓪	①	②	③	④
18. My doctor is available to answer my questions	⓪	①	②	③	④

19. How much does your **RELATIONSHIP WITH THE DOCTOR** affect your quality of life?

Not at all ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩ Very much so

During the past 7 days:	not at all	a little bit	some-what	quite a bit	very much
EMOTIONAL WELL-BEING					
20. I feel sad	⓪	①	②	③	④
21. I am proud of how I'm coping with my illness	⓪	①	②	③	④
22. I am losing hope in the fight against my illness	⓪	①	②	③	④
23. I feel nervous	⓪	①	②	③	④
24. I worry about dying	⓪	①	②	③	④

25. How much does your **EMOTIONAL WELL-BEING** affect your quality of life?

Not at all ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩ Very much so

During the past 7 days:	not at all	a little bit	some-what	quite a bit	very much
FUNCTIONAL WELL-BEING					
26. I am able to work (include work in home)	⓪	①	②	③	④
27. My work (include work in home) is fulfilling	⓪	①	②	③	④
28. I am able to enjoy life "in the moment"	⓪	①	②	③	④
29. I have accepted my illness	⓪	①	②	③	④
30. I am sleeping well	⓪	①	②	③	④
31. I am enjoying my usual leisure pursuits	⓪	①	②	③	④
32. I am content with the quality of my life right now	⓪	①	②	③	④

33. How much does your **FUNCTIONAL WELL-BEING** affect your quality of life?

Not at all ⓪ ① ② ③ ④ ⑤ ⑥ ⑦ ⑧ ⑨ ⑩ Very much so

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