The FACT-G7: a rapid version of the functional assessment of cancer therapy-general (FACT-G) for monitoring symptoms and concerns in oncology practice and research

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Background: Health-related quality-of-life (HRQOL) assessments in research and clinical oncology settings are increasingly important. HRQOL instruments need to be rapid and still maintain the ability to capture the most relevant patient issues in a valid and reliable manner. The current study develops and validates the FACT-G7, a rapid version of the Functional Assessment of Cancer Therapy-General (FACT-G).

Patients and methods: Oncology patients with advanced cancer (N = 533) from 11 diseases sites ranked the symptoms and concerns they viewed as ‘the very most important’ when undergoing cancer treatment, completed the FACT-G, and additional HRQOL measures. Oncology patients’ scores were referenced across a general US population sample (N = 2000).

Results: We selected the highest priority cancer-related symptoms and concerns endorsed by patients for inclusion in the FACT-G7. Fatigue and ability to enjoy life were ranked the most highly. The results provide preliminary support for the FACT-G7’s internal consistency reliability (α = 0.74) and validity as evidenced by moderate-to-strong relationships.
with expected criteria. The references for the general population are summarized.

Conclusions: The FACT-G7 can be used to assess top-rated symptoms and concerns for a broad spectrum of advanced cancers in clinical practice and research.

Key words: cancer, health-related quality of life, patient-centered outcomes, symptom index

introduction

As cancer treatments have extended overall and progression-free survival over the past two decades, clinical researchers and practicing oncologists have turned their attention towards understanding the quality of life associated with those improvements. A multidimensional concept, health-related quality of life (HRQOL) includes self-reported symptoms and concerns that relate to the health status in the physical, psychological, social, functional domains, and more recently spiritual well-being [1, 2]. The increasing frequency of including HRQOL assessment in research and clinical settings, coupled with its recognition as an accepted end-point in clinical trials, signifies the importance of this outcome in oncology settings.

In response to the growing interest in HRQOL outcomes in oncology settings, cancer researchers have developed general symptom/concern checklists that assess a broad range of symptoms and concerns relevant to most oncology patients (e.g. nausea) and disease-specific assessments that assess symptoms and concerns specific to a particular cancer (e.g. shortness of breath in lung cancer). HRQOL assessments need to be rapid, facile, and still be aggregated in a clinically meaningful and psychometrically acceptable manner to capture the most relevant patient issues. However, clinical researchers and practicing oncologists acknowledge the absence of a gold standard among HRQOL assessments [3, 4]. The development of a rapid symptom/concern scale that can be applied broadly in oncology settings may help clinicians systematically identify meaningful and psychometrically acceptable manner to capture the most relevant patient issues. However, clinical researchers and practicing oncologists acknowledge the absence of a gold standard among HRQOL assessments [3, 4]. The development of a rapid symptom/concern scale that can be applied broadly in oncology settings may help clinicians systematically identify and address a broad spectrum of cancer patients’ symptoms and concerns.

Patient-reported outcomes of HRQOL provide distinct information beyond standard clinical measures and can be used to effectively manage patient symptoms and concerns [4–9]. Provider understanding of patient-reported symptoms and concerns is an important aspect of cancer treatment and is related to salutary outcomes and improved patient–provider interactions. Systematic symptom/concern assessment and reporting to the provider is associated with reduced distress, better symptom management, and improved symptom communication [10–13]. However, when symptoms and concerns are inadequately relieved, the patient’s well-being and navigation through the treatment experience can be compromised.

Most validated measures of cancer-specific HRQOL such as the Functional Assessment of Cancer Therapy-General (FACT-G) [14] and the European Organization for Research and Treatment of Cancer Quality-of-Life Questionnaire (EORTC QLQ C30) [1] incorporate an assessment of certain prevalent symptoms such as nausea, pain, and fatigue. These symptoms are embedded within several domains of quality of life (e.g. physical, emotional, social, functional), yielding lengthy 27–30 core item long questionnaires. The FACT-G and EORTC QLQ C30 then add more detailed, cancer site-specific symptom/concern subscales to the core questionnaire [1, 14]. As a result, the standard oncology HRQOL assessments used today tend to be lengthy, combining long core questionnaires with sometimes equally long disease-specific subscales (see www.eortc.be and www.facit.org).

In an effort to shorten and focus one of these common measurement systems around the most important symptoms and concerns, we previously collaborated with the National Comprehensive Cancer Network (NCCN) to develop symptom/concern indexes for 11 common advanced cancers. The resulting NCCN/FACT symptom/concern indexes contain 16 to 24 priority items across 11 advanced cancers [15]. Concerns over patient burden, resource constraints, and the desire for easily-administered assessment tools in clinics are some practical barriers in current symptom/concern assessment that have catalyzed the need for a briefer symptom/concern index than the NCCN/FACT indexes for tracking patient cohorts across several primary sites [16]. Although a rapid symptom/concern index is available for use in cancer palliative care, there is no rapid symptom/concern index available for a broad spectrum of patients outside of palliative care settings [17].

To that end, the primary objectives of our study were to identify the highest priority patient-reported symptoms and concerns across the recently developed NCCN/FACT symptom indexes to construct a rapid index of the FACT-G which will evaluate the effectiveness of therapy for patients across a broad spectrum of advanced cancers. A secondary aim was to validate the rapid index across a sample of cancer patients and, using a second sample of participants, obtain general population reference values for the rapid index. These values will aid in interpretation and understanding of clinical and research data.

methods

participants

A sample of 533 patients with advanced or metastatic disease was obtained. Patients were eligible for the study if they were at least 18 years of age and had stage III or IV bladder, brain, breast, colorectal, head and neck, hepatobiliary/pancreatic, kidney, lung, ovarian, prostate or lymphoma cancer. Patients must have had prior experience with chemotherapy for at least two cycles (or 1 month for noncyclical chemotherapy), and no other primary malignancy diagnosed or treated within the previous 5 years with the exception of non-melanoma skin cancer.

Patients were recruited from two sources: (i) five NCCN Member Institutions, including Dana Farber Cancer Institute, Duke University Medical Center, Fred Hutchinson Cancer Research Center, H. Lee Moffitt Cancer Center, and the Robert H. Lurie Comprehensive Cancer Center of Northwestern University and (ii) members of the Cancer Health Alliance of Metropolitan Chicago, a coalition of four community support agencies serving the Chicago metropolitan area. They were selected to obtain
patient input from community-based practices to balance the preferences of patients from tertiary referral centers such as NCCN sites. In a separate study, a second sample of 2000 individuals from the general population was randomly selected from an internet panel [18]. Internet panels are an efficient method for recruiting large sample sizes and have been used in previous studies such as the Patient-Reported Outcomes Measurement Information System [19]. Participants from the general population were polled regarding specific health conditions. Approximately 22% of the sample reported no condition. Thirty-five percent of the sample reported one or two comorbid conditions, 13% reported three comorbid conditions, and 30% reported four or more comorbid conditions. The most commonly reported conditions were arthritis (n = 628) and depression (n = 503).

procedures and measures

While in clinic, oncology patients completed a checklist in which they selected the top five symptoms and concerns from among 23–45 items from the previously established FACT HRQOL questionnaire or nominated by clinician experts in the particular cancer type. Four versions of each checklist were used to control for response bias due to order effect. On the checklist, patients were first asked to select no more than 10 symptoms and concerns that they believed were ‘the most important symptoms or concerns to monitor when assessing the value of drug treatment for advanced <site>-cancer.’ Of the 10 symptoms and concerns nominated as ‘the most important,’ patients were then asked to select up to 5 as ‘the very most important.’ Space was provided for respondents to write in symptoms and concerns that were not already listed.

Oncology patients were next asked to complete the FACT-G which contains four general subscales: physical well-being, social well-being, emotional well-being, and functional well-being. The FACT-G is a 27-item instrument containing four subscales: physical (e.g. I am forced to spend time in bed; seven items), functional (e.g. I am able to work (include work at home); seven items), social/family (e.g. I get emotional support from my family; seven items), and emotional well-being (e.g. I worry about dying; six items) on a five-point Likert-type scale ranging from 0 (not at all) to 4 (very much) with a recall period of the past 7 days. Responses are summed to create a total FACT-G score and individual subscale scores, with higher scores reflecting better HRQOL. Oncology patients also completed the single-item Eastern Cooperative Oncology Group Performance Status Rating (ECOG PSR) and the EuroQol group’s five-item health status measure (EQ-5D). The ECOG PSR is widely used to assess disease severity and provides a basic assessment of patients’ functional status, measured by the degree to which they are able to participate in typical activities without the need for rest, from 0 (‘normal activity without symptom’) to 4 (‘unable to get out of bed’) [20, 21]. The EQ-5D is a standardized measure of health status used to provide a generic measure of health [22]. The EQ-5D includes a descriptive system assessing five dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) on three levels (no problems, some problems, and severe problems) and is scored as a single summary index. Finally, patients’ sociodemographic data were captured through self-report.

Participants from the general population were recruited by an internet panel company, Toluna/Greenfield (see Butt [18] for company information and recruitment procedures) in Fall, 2011. The internet panel sent email invitations to invite eligible panel members from among its 536,000 US members. Panelists were provided with a link to a secure website where participants consented, completed selected FACT items (see Butt [18] for selected FACT items and item selection process), and provided demographic and medical information.

analytic plan

Oncology patient surveys were tabulated according to the frequency with which they selected a particular symptom or concern as one of the five most important symptoms and concerns. The criterion for item retention in the NCCN/FACT symptom indexes was based on the probability of chance endorsement as one of the top five symptoms and concerns. For each of the 11 cancer-specific scales, we determined the number of patients who would be expected to endorse an item by chance by dividing 5 (the number of important symptoms and concerns endorsed) by the number of items in each cancer-specific scale and then multiplying by the number of participants who completed that checklist. Items that were endorsed at a frequency that exceeded chance were retained as candidates for the final cancer-specific symptom indexes. In an effort to be as inclusive as possible with respect to patient-reported symptoms and concerns, we elected to retain items within one point of the designated chance threshold.

Next, we sought to identify the ‘very most important’ patient-reported symptoms and concerns across the 11 cancer-specific sites. Because we were primarily interested in retaining ‘the very most important’ items that were endorsed by cancer patients across numerous diagnostic sites, we aggregated data from all 11 site-specific indexes into one larger sample. An item was eligible for inclusion into the rapid index if it was endorsed by patients above, or within one point, of the designated chance threshold for each cancer-specific site. As a second eligibility criterion for the rapid index, items were included if they were endorsed by patients in at least 6, or more than half, of the 11 cancer-specific sites.

Cronbach’s coefficient alpha was calculated in both the datasets (cancer sample and general population sample) for the rapid index items to demonstrate the internal consistency reliability. Correlations between the rapid index and FACT-G subscales and total scores were calculated. Since the items in the rapid index are a subset of the FACT-G and this could produce inflated correlations, FACT-G total and subscale scores were recalculated with the overlapping items removed. Criterion validity of the rapid index was assessed with a one-way analysis of variance examining the relationship between the status classification and the ECOG PSR.

results

Table 1 summarizes the sociodemographic and clinical characteristics for both the samples. In the cancer sample, seven items met the pre-specified criteria for retention in the rapid index (in this article referred to as the FACT-G7) that consists of 3 items from the physical well-being subscale of the FACT-G (fatigue, pain, and nausea), one item from the emotional well-being subscale of the FACT-G (worry about condition worsening), and three items from the functional well-being subscale (enjoyment of life, contentment with QOL, and sleep). The FACT-G7 symptoms and concerns are the items rated the ‘very most important’ by patients with advanced cancer across 11 disease sites. Table 2 displays the frequency of the FACT-G7 items for the total sample by disease and the number of cancer-specific sites in which the symptom or concern was endorsed above or within one point of the designated chance threshold. Of the seven items retained, fatigue had the highest frequency of endorsement, whereas pain had the lowest frequency of endorsement. Not all symptoms and concerns were endorsed at or above the chance threshold by all cancer sites: nausea was not endorsed by kidney cancer patients; content with QOL was not endorsed by breast and head and neck cancer patients; sleep was not endorsed by kidney, lymphoma, and prostate cancer patients;
pain was not endorsed by bladder, brain, colorectal, lung, and prostate cancer patients. None of the patient self-generated write-in symptoms and concerns met the eligibility criteria for the FACT-G7.

### Preliminary validation data

The mean scores on the FACT-G7 and FACT-G are presented in supplementary Table S1, available at *Annals of Oncology* online. The FACT-G7 showed good internal consistency for group comparisons in the NCCN cancer sample and the general US population sample with Cronbach’s alphas of 0.74 and 0.80, respectively.

For the cancer sample, the FACT-G7 items were highly correlated with the FACT-G, the PWB, EWB, and FWB subscales, moderately correlated with the EWB subscale and the EQ-5D index, and weakly correlated with the SWB subscale (see supplementary Table S2, available at *Annals of Oncology* online). Correlations adjusting for the overlapping items were lower but remained significant with FACT-G highly correlated and FWB, EWB, and FWB moderately correlated with the FACT-G7.

The FACT-G successfully distinguished across ECOG PSR groups [F (2, 526) = 91.16, *P* < 0.001] (see Table 3). Scores on the FACT-G7 also distinguished across ECOG PSR categories [F (2, 530) = 87.43, *P* < 0.001] among the NCCN cancer sample and the general population sample [F (2, 1997) = 331.47, *P* < 0.001]. For FACT-G7 and FACT-G scales, scores across groups were in the expected direction, with patients in the lowest ECOG PSR (i.e. best performance status) categories having the highest scores. Table 3 presents effect-size estimates for ECOG PSR group comparisons which ranged from medium to large.

### Discussion

The primary aim of this study was to develop a rapid symptom/concern index for patients with advanced cancer for use in the clinical setting. In the present study, patients from 11 cancer-specific sites were surveyed to determine what they considered 'the very most important' symptoms and concerns when receiving the treatment for advanced cancer. Using a multistep process, we established a rapid index of 7 items which is a subset of the 27 items found in the original FACT-G. For this reason, we refer to it as the FACT-G7 (see supplementary Appendix, available at *Annals of Oncology* online). This rapid questionnaire can be completed in a few minutes, usually without assistance, and is responsive to the constraints of clinical and research settings. The resulting index represents symptoms and concerns that clinicians can focus on with patients in a clinically meaningful manner, either by administering this checklist to patients or by incorporating this into the existing clinical assessment tools such as history and physical.

The FACT-G has been normed in advanced and general cancer patients, demonstrated excellent reliability and validity, and is a widely used instrument in oncology quality-of-life assessment. We compared the original FACT-G with the rapid FACT-G7. Our results provide preliminary support for the FACT-G7. The FACT-G7 demonstrated good internal consistency reliability, convergence, and known-groups validity. The FACT-G7 was highly correlated with the FACT-G total score and, with the exception of the social well-being subscale, moderately correlated with the physical well-being, emotional well-being, and functional well-being subscales of the FACT-G. The FACT-G7 was moderately correlated with the EQ-5D. Of note, the EQ-5D measures somewhat different aspects of HRQOL than does the FACT-G so correlations were not expected to be high. The FACT-G7 was able to successfully differentiate between the known groups (defined by ECOG PSR scores), with medium-to-large effect sizes in the cancer and general population samples. The indexes from which this rapid FACT-G7 is drawn possess very good content validity, and is a widely used instrument in oncology quality-of-life assessment. We compared the original FACT-G with the rapid FACT-G7. Our results provide preliminary support for the FACT-G7. The FACT-G7 demonstrated good internal consistency reliability, convergence, and known-groups validity. The FACT-G7 was highly correlated with the FACT-G total score and, with the exception of the social well-being subscale, moderately correlated with the physical well-being, emotional well-being, and functional well-being subscales of the FACT-G. The FACT-G7 was moderately correlated with the EQ-5D. Of note, the EQ-5D measures somewhat different aspects of HRQOL than does the FACT-G so correlations were not expected to be high. The FACT-G7 was able to successfully differentiate between the known groups (defined by ECOG PSR scores), with medium-to-large effect sizes in the cancer and general population samples. The indexes from which this rapid FACT-G7 is drawn possess very good content validity, especially given that patients were encouraged to write in new symptoms and concerns that they felt were important.

Several limitations are noted. First, the sample of 533 patients from whom the FACT-G7 was developed consisted of advanced cancer patients (stage III and IV) who received chemotherapy. The generalizability of these findings to patients...
with early-stage disease, as well as those who are not receiving chemotherapy, remains to be tested. The predominantly White sample also limits cross-cultural generalizability of the findings. Research findings may be influenced by sampling bias. We addressed this by maximizing the number of patients assessed per disease site (for most sites >50), which is well above the usual 15–35 patients typically required to stabilize the results [23]. Cronbach’s internal consistency reliability coefficients were above the recommended criterion for comparing groups of patients (recommended criterion of 0.70), but did not meet the stricter reliability criterion of 0.90 which is recommended for analyzing individual patient scores [24]. As a final limitation, the current sample did not include large numbers of patients who rated themselves 3 and 4 (the most impaired) on the ECOG PSR measure which may be because patients with such poor ECOG PSR ratings would be unable to participate in an outpatient survey since, by definition, they are able to engage in only limited self-care and spend >50% of their time confined to bed or chair.

Further work would be helpful to illuminate the appropriateness of this instrument for use with patients in palliative care or hospice settings. It is noteworthy that importance of symptoms may vary in different socioeconomic and demographic groups; therefore, evaluating the validity of this measure in different populations of advanced cancer patients could be an important next step. Additionally, future longitudinal research is needed to evaluate the sensitivity to change and reproducibility of the FACT-G7. Finally, our reference sample was drawn from an online panel and future testing should address the generalizability of such data to individuals who do not have Internet access.

The FACT-G7 is a newly developed rapid index for use in clinical and research settings for evaluating symptom/concern burden and quality of life in advanced cancer patients over time. Preliminary findings indicate that the FACT-G7’s strengths are its brevity, facile administration, and established validity and reliability for group comparisons in a sample of patients with advanced cancer. The broad nature of the cancer sites studied (11 cancer sites) can be viewed as a strength for providers seeking a rapid symptom/concern assessment across a wide range of patients that can be easily supplemented with previously validated cancer-specific FACT questionnaires when further symptom/concern assessment is required.

### Table 2. Frequency of concerns rated top 5* and inclusion in larger FACT scales

<table>
<thead>
<tr>
<th>Symptom/concern</th>
<th>Number of cancer sites</th>
<th>Frequency (% of N = 533)</th>
<th>In FACT-G</th>
<th>In FACT-NCCN/FACT cancer specific indexes</th>
</tr>
</thead>
<tbody>
<tr>
<td>I have a lack of energy (fatigue)</td>
<td>11</td>
<td>254 (48)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>I am able to enjoy life</td>
<td>11</td>
<td>142 (27)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>I worry that my condition will get worse</td>
<td>11</td>
<td>137 (26)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>I have nausea</td>
<td>10</td>
<td>111 (21)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>I am content with the quality of my life right now</td>
<td>9</td>
<td>82 (15)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>I am sleeping well</td>
<td>8</td>
<td>84 (16)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>I have pain</td>
<td>6</td>
<td>58 (11)</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>


*This list includes all concerns rated as ‘top 5’ by patients at or above the chance threshold.

### Table 3. Group comparisons by Eastern Cooperative Oncology Group Performance Status Rating (ECOG PSR)

<table>
<thead>
<tr>
<th>NCCN cancer sample (N = 533)</th>
<th>General population sample (N = 2000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>n</td>
<td>FACT-G mean (SD)</td>
</tr>
<tr>
<td>Total score</td>
<td>533</td>
</tr>
<tr>
<td>PSR = 0</td>
<td>122</td>
</tr>
<tr>
<td>PSR = 1</td>
<td>258</td>
</tr>
<tr>
<td>PSR = 2, 3, or 4</td>
<td>153</td>
</tr>
<tr>
<td>F-statistic (df)</td>
<td>91.16 (2, 526)</td>
</tr>
<tr>
<td>P value</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Overall SD</td>
<td>15.2</td>
</tr>
<tr>
<td>Effect size 0 versus 1</td>
<td>0.68*</td>
</tr>
<tr>
<td>Effect size 1 versus 2/3/4</td>
<td>0.62*</td>
</tr>
<tr>
<td>Effect size 0 versus 2/3/4</td>
<td>1.41*</td>
</tr>
</tbody>
</table>


*Pairwise difference P < 0.05.

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**disclosure**

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**references**


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