

# Quality-of-Life Assessment for Routine Oncology Clinical Practice

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In recent years, quality of life (QOL) has become a common concern in medicine. QOL is considered to be implicit in healthcare practice and has been the focus of considerable research. Nevertheless, many clinicians lack familiarity with its use and have little idea of how to apply it to clinical practice.<sup>1</sup> One reason for this situation is that QOL is a broad term with many definitions, which may confuse physicians and other healthcare providers. Another reason is that the tools needed to make its assessment a part of routine clinical practice have been developed only recently.

The purpose of this article is to answer questions frequently asked about QOL by clinicians. Why is QOL assessment worth the effort? What kind of information does it provide? What is the value added by QOL data for the practicing clinician? How can QOL information be gathered in real time so that it is available during an office visit? What are the pitfalls to avoid when making QOL assessment a part of routine patient care?

Because much of the pioneering work in QOL has been accomplished in the field of oncology, this article focuses on examples from the medical literature on cancer. QOL issues are particularly important in the treatment of the oncology patient because of the potential for considerable toxicity of treatment and the life-threatening nature of the disease. In fact, the importance of QOL is emphasized by the American Society of Clinical Oncology,<sup>2</sup> which has designated QOL second in

**Abstract** Quality of life (QOL) is a concept that appears with ever-increasing frequency in the oncology literature. To date, QOL has largely centered on the research arena. Thus, many clinicians lack familiarity with the clinical utility of QOL measurement in clinical practice. Much work has been done on QOL in clinical trials. QOL data can be a useful predictor of patient response to treatment and survival and can affect decision-making about therapeutic options. Several randomized trials have shown the feasibility and benefits of QOL assessment in the clinical setting. Issues related to QOL data collection exist for those attempting to use QOL instruments within their practice. This review addresses the questions frequently asked by oncology care providers about the value of QOL assessment and issues related to it.

importance only to survival. Although we have drawn our examples from oncology, QOL is equally important for other types of healthcare practice.

## Why Is QOL Assessment Worth the Effort?

QOL information is primarily obtained through self-report from patients; thus, it has, in general, been considered inferior to hard clinical indicators, such as histologic findings or weight loss. However, substantial progress has been made in QOL assessment, and more recent measures have shown surprising predictive power regarding survival and treatment-related toxicity. In studies of advanced cancer, QOL data sometimes even have had more predictive power than do traditional clinical factors.

## PREDICTING SURVIVAL

In a study of 206 patients with advanced non-small-cell lung cancer treated in a clinical trial, survival was predicted by baseline QOL scores for pain, appetite loss, fatigue, cancer symptoms, and physical functioning and by overall QOL.<sup>3</sup> When clinical factors such as histologic findings, weight loss, and dyspnea were controlled statistically, self-rated pain was still more predictive than were traditional clinical factors. Similarly, Montazeri et

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**Table 1****Uses of Quality-of-Life Information in Clinical Decision-Making**

Determine whether a new therapy is preferable to the standard therapy
Compare two standard therapies with similar survival outcomes
Determine the balance between positive and negative effects of therapy
Identify the need for supportive care
Facilitate communication in clinical practice

al<sup>4</sup> also found that patients' ratings of their global QOL before diagnosis was the most significant predictor of survival time, even after adjustment for other known prognostic factors in patients with advanced lung cancer ( $P < 0.04$ ).

In patients with metastatic colorectal cancer, Efficace et al<sup>5</sup> studied whether baseline, self-reported, health-related QOL (HRQOL) parameters could predict survival better than could key biomedical prognostic factors. Their analysis of 299 patients identified four variables as independent prognostic factors for survival: white blood cell count, alkaline phosphatase level, number of cancer sites, and the patient's score on the social functioning scale. The hazard ratio associated with the functioning score was 0.991 (95% confidence interval, 0.987–0.996;  $P < 0.001$ ), which translated into a 9% decrease in the patient's hazard of death associated with any 10-point increase.

The effects of interferon alfa-2b (Intron A) on progression-free survival (PFS), overall survival (OS), and QOL were studied in elderly patients with multiple myeloma who reached a plateau phase after induction therapy.<sup>6</sup> QOL was assessed as a secondary end point with the Rotterdam Symptom Checklist, which measures psychological and physical distress in cancer patients, including physical and emotional capability and performance of activities of daily living. Interferon- $\alpha$  (IFN- $\alpha$ ) maintenance therapy was found to prolong PFS. However, 37% of patients stopped therapy because of adverse events. Yet despite the high occurrence of toxicity, the study showed no difference in the QOL of patients who received IFN- $\alpha$  compared with that of those who did not. Thus, these data provide valuable information beyond that on toxicity alone about the impact of treatment on QOL, which could aid the decision-making process of patients with myeloma.

**GUIDING TREATMENT DECISIONS**

Compared with observation, QOL data may provide added information on the effects of therapeutic intervention. In a randomized trial by Slotman et al,<sup>7</sup> the benefit of prophylactic cranial irradiation versus observation was evaluated in patients with extensive small-cell lung cancer. End points of the study included QOL and the development of symptomatic brain metastases, survival, and toxicity. In addition to demonstrating a decrease in brain metastases and improvement in survival, QOL data demonstrated that this progress did not come at the expense of such important factors as global health status.

Amemiya et al<sup>8</sup> evaluated activities of daily living in elderly patients with gastric and colorectal cancers who underwent definitive surgery. This patient population may receive less aggressive surgical intervention because of the subjective concerns of surgeons about the patients' ability to recover adequate function in daily life. The investigators found that the QOL of patients actually recovered to a level either equal to or greater than their preoperative status, although the patients' activities of daily living transiently decreased.

QOL information can play a crucial role in clinical care, through its contribution to decision-making, targeting of problems, and improved physician-patient communication (Table 1). For example, when there is a choice to be made between a new therapy and standard therapy, QOL data have been used to help determine the better treatment in terms of potential treatment-related side effects. In a phase III trial of imatinib (Gleevec) compared with IFN- $\alpha$  plus low-dose cytarabine in patients with newly diagnosed chronic myeloid leukemia, imatinib was shown to be superior. Patients treated with imatinib reported less fatigue; fewer cognitive problems; and better emotional, social, and daily functioning.<sup>9</sup> In addition, patients who were later crossed over to imatinib also experienced an improvement in QOL.

QOL data may not always be necessary for decision making when a specific treatment is clearly more effective. For example, Citron et al<sup>10</sup> reported the results of different adjuvant chemotherapy schedules for women with node-positive breast cancer. A dose-dense regimen versus conventionally scheduled chemotherapy and a sequential versus a concurrent chemotherapy combination were studied. The dose-dense regimen provided a 4-year disease-free survival (DFS) of 82% versus 75% for the other regimens. Severe neutropenia was less frequent in patients with the dose-dense regimen. No QOL data were gathered in this trial, because DFS and OS were the primary end points. Thus, the focus was on determining whether the dose-dense regimen was indeed superior to standard therapy. However, with incorporation of this regimen into standard practice, patients and clinicians may want to understand its long-term QOL implications.

Unlike the treatment situation in which one regimen clearly is superior to another, those with two equally effective regimens may lend weight to QOL as the key determinant of treatment. For example, in the treatment of localized prostate cancer, there are equivalent survival rates for patients treated by radical prostatectomy or radiotherapy.<sup>11</sup> However, comparison studies of QOL outcomes have consistently found that men who undergo radical prostatectomy have substantially worse urinary and sexual functioning than do those who receive radiotherapy.<sup>9,12–15</sup> In contrast, men treated with radiotherapy have worse bowel functioning due to radiation damage to the rectal mucosa, although the difference is not as great as for urinary and sexual functioning. Such findings are important for clinicians to consider and discuss with their patients when determining the best treatment choice.

QOL information may add value when one treatment pro-

duces better survival rates than another but is more toxic, particularly when the average survival time is short. For example, patients with advanced lung cancer have a relatively short average survival.<sup>16,17</sup> Compared with no treatment, systemic chemotherapy may extend survival by 2 to 3 months. Such treatment may help to ameliorate symptoms, but it may be accompanied by treatment-related side effects.

For example, a randomized phase II trial compared a regimen of single-agent gemcitabine (Gemzar) followed by docetaxel (Taxotere) with a regimen of docetaxel followed by gemcitabine.<sup>18</sup> QOL stayed near the baseline with the initial gemcitabine-docetaxel arm but deteriorated after only 2 cycles of the docetaxel-gemcitabine arm, despite the comparable toxicity of the two combinations. The median time to disease progression in the gemcitabine-docetaxel arm was 4.3 months, compared with 2.2 months in the docetaxel-gemcitabine arm; the median survival was 9 months versus 5 months, respectively ( $P = 0.029$ ). Oncologists may use this type of information to discuss with patients to aid their decision making about which regimen to pursue, given the relatively short life span that might be expected in either case.

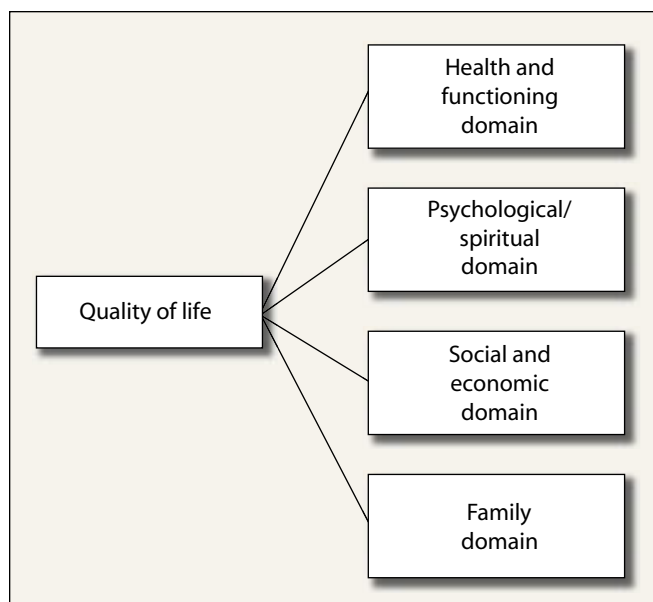
#### ASSESSING ADJUVANT THERAPY FOR PREVENTING RECURRENCE

QOL data can also be useful in weighing the impact of adjuvant therapy for prevention of disease recurrence. For example, an increasing number of patients with hormone receptor-positive breast cancer will pursue systemic therapy with either tamoxifen or an aromatase inhibitor such as anastrozole (Arimidex) or letrozole (Femara).<sup>19-22</sup> Although the results of the ATAC (Arimidex, Tamoxifen Alone or in Combination) trial suggested improved survival for patients taking anastrozole compared with those taking tamoxifen, the side-effect profile was also found to be more favorable for anastrozole.<sup>23-25</sup> Except for the prevention of fractures, anastrozole appeared to be superior. However, in addition to survival factors, patients with breast cancer take into consideration the relative impact of the side effects associated with these medications (eg, hot flashes and weight gain).<sup>26</sup>

Similarly, for men with high-risk prostate cancer, the question of adjuvant therapy is just as important because of the 30%–50% risk of either clinical or biochemical failure within 3–5 years.<sup>27</sup> Androgen deprivation in such patients may improve outcomes, but it is not without side effects such as hot flashes, sexual dysfunction, and fatigue.<sup>28</sup> According to a study of 1-year treatment with adjuvant androgen deprivation, this therapy did not have an overall impact on QOL, despite producing a decrease in sexual functioning.<sup>29</sup>

#### What Kind of Information Does QOL Assessment Provide?

Confusion abounds as to what QOL actually means. However, the consensus is that QOL is more than just the physical health status of a patient. Characterizations of QOL commonly include multiple domains, such as physical, psychological,



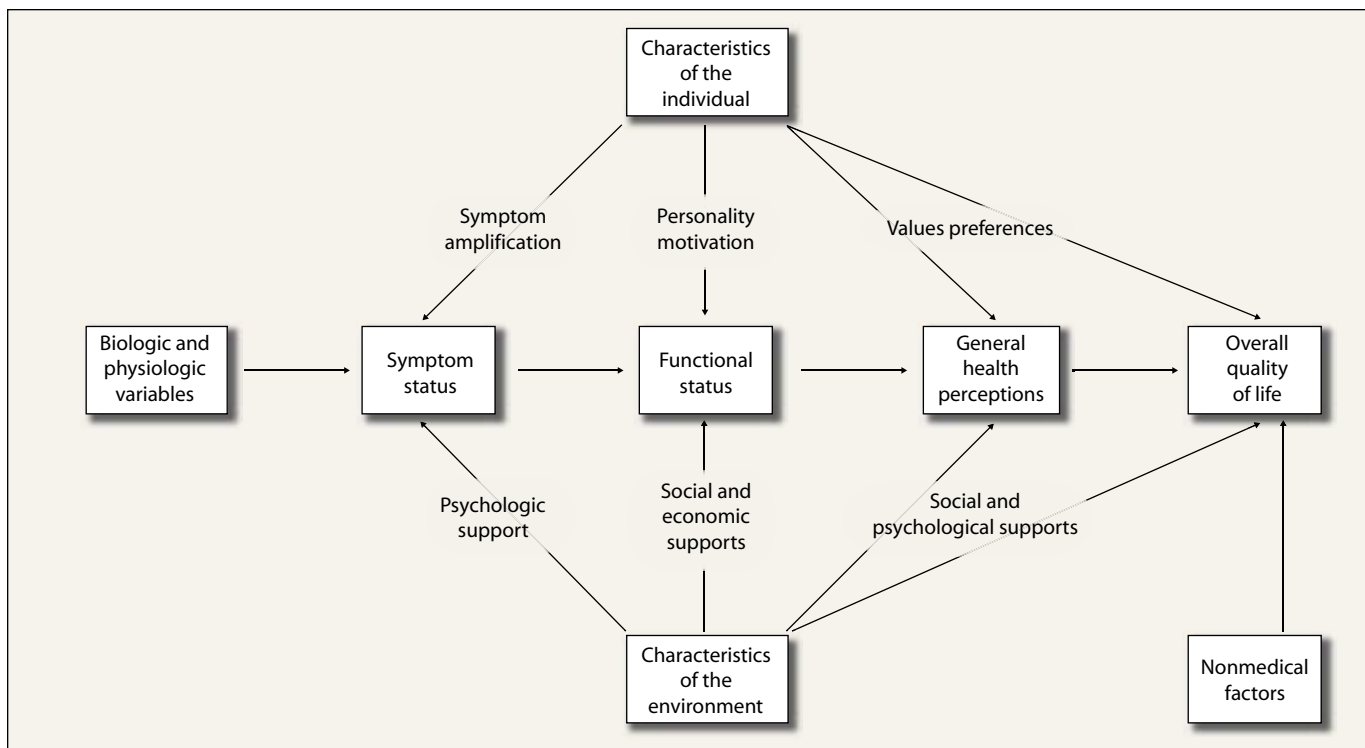
**Figure 1** The Ferrans Conceptual Model of the Four Domains That Comprise Quality of Life

Reprinted, with permission, from Ferrans<sup>30</sup>

spiritual, economic, social, and family. One such example is the Ferrans<sup>30</sup> model of QOL with its four domains (Figure 1). The broad nature of QOL is also evident in the popular definition from the World Health Organization,<sup>31</sup> which acknowledges the fact that an individual's QOL is affected in a complex fashion by numerous variables such as a person's physical health, psychological state, level of independence, social relationships, and relationship to the environment.

Within healthcare, the term HRQOL (health-related QOL) has been used to focus on how illness and its treatment affect QOL. This restriction in focus has helped to narrow the range of topics of interest, but numerous different concepts (eg, symptoms, functioning, and general health status) are all still referred to under that heading.

To help provide some clarification, Wilson and Cleary<sup>32</sup> developed a model of HRQOL (Figure 2). The model focuses on five types of patient outcomes, starting with biological and physiological variables as the most fundamental determinants of health status. They are assessed through standard clinical measures, such as physical examination, laboratory tests, and histologic findings. The second area includes symptom status, which refers to emotional and cognitive symptoms, as well as physical ones. The third area is functional status, including physical, social, role, and psychological functioning. The fourth area, general health perceptions, is an integration of all the preceding components in the model as perceived by the patient. The fifth area is overall QOL, which is described as "subjective well-being," or how happy or satisfied someone is with life as a whole. This model is particularly useful for clinical practice, because it not only reflects biological and physiological components but also spans the interrelation of



**Figure 2** Wilson and Cleary's Model for Health-Related Quality of Care

Reprinted, with permission, from Wilson and Cleary<sup>32</sup>

the differing components, thus illustrating the relationships among biological and physiological variables, symptoms, and the other components of HRQOL.

### What Is the Value Added by QOL Data for the Practicing Clinician?

For clinicians, the goal of collecting QOL data within their practice is to obtain additional information that will contribute to clinical decision making but that might be overlooked during the typical clinical examination. The value of QOL data in the clinical setting has been demonstrated in numerous studies.

In a randomized controlled trial, Detmar et al<sup>33</sup> collected QOL data on 214 patients undergoing palliative chemotherapy during three successive outpatient visits. Of these 214 patients, 100 were included in the control arm, and 114 were included in the intervention arm. The trial included 10 physicians, with 5 randomized to the control arm and 5 to the intervention arm. A longitudinal, randomized crossover design was used, with physicians initially assigned randomly to either an intervention or a control condition. At least 10 consecutive patients were recruited for each physician. The first study visit served as a baseline for both groups, and the intervention was begun at the second visit and continued through the fourth. Midway through the study, the five physicians assigned to the control arm switched to the intervention arm, and the five intervention arm physicians switched to the control arm. The study also included a second cohort of at

least 10 patients per physician who were followed in an identical manner after a buffer of 2 months between cohorts. Thus, each physician served as his or her own control. All patients received a standard visit with their physician before each cycle of chemotherapy.

Patients who participated in the intervention arm completed the EORTC QLQ-C30 (European Organization for Research and Treatment of Cancer Quality-of-Life Questionnaire-Core 30) version 3.0 questionnaire immediately before their physician visit. Their responses were optically scanned into a desktop computer and then scored and printed out in the form of a graphic summary profile. Physicians were trained to interpret the QLQ-C30 summary scores. Copies of these summaries were given to the patient and the physician during the intervention part of the study, immediately before the medical visit with the physician. For the subsequent two visits, the summary included both current and previous scores.

For the intervention group, all medical visits were audio-taped, transcribed, and analyzed to determine whether QOL topics included on the QLQ-C30 questionnaire were discussed and what the total length of the visits was. QOL-related issues discussed significantly more often in this group than in the control group included an increased focus on QOL issues that were less directly observable, such as fatigue ( $P = 0.02$ ), dyspnea ( $P = 0.02$ ), and social functioning ( $P = 0.05$ ). All the physicians and 87% of the patients reported that the QOL data facilitated communication; both groups expressed interest in its continued use. A modest effect, primarily related to

increased levels of patient counseling, was observed.

Satisfaction with the intervention by both patient and physician was determined using the five-item Patient Satisfaction Questionnaire C, which was filled out after the first and fourth visits. Physicians rated their own global satisfaction by answering a single question about how satisfied they were with the communication during the patient visit. The patients in the intervention group were significantly more satisfied with the degree of emotional support than were those in the control group ( $P = 0.05$ ). This perception is also supported by other research indicating that patients are more likely to disclose information about their psychological functioning when physicians exhibit supportive behavior.<sup>34</sup> There was, however, no appreciable difference in the number of QOL-related management actions taken per patient by the physicians between the control group and the intervention group (0.5 vs 0.6).

Velikova et al<sup>35</sup> reported on the use of the computerized collection of QOL data in an oncology practice. This prospective study involved 28 medical oncologists, with 286 cancer patients randomly assigned to one of three arms: 1) an intervention group that completed several QOL instruments on touch-screen clinic computers just before their appointment, with results relayed automatically to their physicians; 2) an attention-control group that completed the same questionnaires without feedback to the physicians; and 3) a control group with no QOL measurement. Outcomes included clinical management and patient HRQOL over time.

Patients in the intervention and attention-control groups had a statistically significantly better QOL than did those in the control group ( $P = 0.006$ ), but there was no significant difference in QOL between the intervention and the attention-control groups ( $P = 0.8$ ). Data feedback to physicians was associated with a positive effect on the emotional well-being of patients, but the mere completion of the QOL instruments showed no resulting improvement. More frequent discussion of chronic nonspecific symptoms (eg, sleep, appetite, and fatigue-related problems) was found in the intervention group without prolongation of patient encounters. QOL improvement was associated with explicit use of QOL data, discussion of pain, and role function. Despite the increased discussion of problems, no detectable effect on patient management related to the frequency of patient referrals to other healthcare professionals was found in the intervention arm.

## UNRESOLVED ISSUES

Opinions vary as to whether patient self-assessment of QOL is necessary or physician assessment is adequate. To better understand the impact of illness from the viewpoint of the patient, healthcare providers should use patient-reported outcomes whenever possible. The information should also be obtained directly from the patient.

A major barrier to this approach is the acceptance of QOL data by physicians.<sup>36</sup> Skepticism exists about the validity and utility of these data, particularly in relation to formal QOL assessments in the practice setting. An exploratory study of

the physician perspective found that most of the 60 oncologists who were interviewed perceived QOL to be important but tended to use it informally and inconsistently.<sup>36</sup> Barriers to the use of QOL data included the perception by one-third of the respondents that current QOL instruments were not valid or reliable. There was also concern that inclusion of these data might have an adverse impact on decision-making processes.

Some clinicians are reluctant to use QOL measures because they believe that they can obtain all the pertinent information they will need during the clinical assessment of the patient. However, reports suggest that important information may be overlooked and that clinical follow-up may not occur in the care of cancer patients. Detmar et al<sup>37</sup> found that the problems were not discussed with the physician in 20%–50% of consultations with patients who experienced serious QOL issues. Psychosocial problems and symptoms such as fatigue were often left unaddressed.

Curt et al<sup>38</sup> assessed the impact of cancer-related fatigue on the QOL of oncology patients. A high prevalence of fatigue exists in the oncology patient population (more than 80% in most studies); it is the most common symptom reported by patients.<sup>39–42</sup> The investigators found that nearly 76% of patients experienced fatigue during chemotherapy and that nearly 90% noted a resulting alteration in their daily routine. Patient fatigue also had a substantial impact on caregivers. Despite the fact that nearly 80% of physicians were consulted about this symptom, nearly 40% of patients received no specific recommendations about how to address it. Admittedly, the evaluation of fatigue in cancer patients is difficult because of the subjectivity of the measure of functional performance.<sup>43</sup> Yet the explicit use of QOL questions (eg, as noted by Curt et al<sup>38</sup>) has revealed telling data about the nature and severity of this prevalent symptom.

Clinicians may not receive totally accurate QOL data when they do not come from the patients themselves. Proxy ratings, where someone other than the patient rates the patient's QOL, have inherent limitations, even when the rater is a close family member.<sup>44,45</sup> Proxies tend to underestimate QOL, as shown by Sprangers and Aaronson<sup>46</sup> in their review of 49 studies. If proxies must be used, such as for adults who are cognitively impaired or for young children unable to answer for themselves, it is best to obtain information from family members who live in the same household.

## How Can QOL Be Used in Routine Clinical Practice?

Until recently, QOL information was used almost exclusively within the research context. The idea that it might be a useful tool for everyday clinical practice is relatively new, as are the methods for its pragmatic implementation. In addition, only a few QOL measures have been developed to such an extent that their scores are interpretable in the standard clinical situation. As with any new tool, the use of QOL data requires experience in working with them, particularly because they are generated by patients. However, QOL data are not so different from other types of self-reported data, such as informa-

**Table 2****Commonly Used Quality-of-Life (QOL) Instruments\*†**

<p><b>Cancer Rehabilitation Evaluation System (CARES)–Short Form</b><sup>50,51</sup>  <i>Web site not available</i>            Overall QOL            Physical            Sexual            Psychosocial            Marital            Medical interaction</p>	<p><b>Quality-of-Life Index–Cancer Version (QLI)</b><sup>30</sup>  <i>www.uic.edu/orgs/qli</i>            Overall QOL            Health and functioning            Psychological/spiritual            Social and economic            Family</p>
<p><b>European Organization for Research and Treatment of Cancer Quality-of-Life Questionnaire (EORTC QLQ-C30)</b><sup>52</sup>  <i>www.eortc.be/home/qol/</i>            Overall symptoms            Physical functioning            Pain            Fatigue            Nausea and vomiting            Role functioning            Cognitive ability            Psychological functioning            Social interaction            Finances</p>	<p><b>Quality-of-Life Scale for Cancer (QOL-CA)</b><sup>57</sup>  <i>Web site not available</i>            Overall QOL            Physical well-being            Psychological well-being            Spiritual well-being            Social well-being</p>
<p><b>Functional Assessment of Cancer Therapy (FACT)<sup>54</sup> or Functional Assessment of Chronic Illness Therapy (FACIT)</b><sup>55</sup>  <i>www.facit.org</i>            Overall QOL            Physical well-being            Functional well-being            Emotional well-being            Social/family well-being</p>	<p><b>SF-36 Health</b><sup>53,58</sup>  <i>www.sf-36.org</i>            General health perceptions            Physical function            Physical role function            Vitality            Bodily pain            Mental health            Emotional role function            Social function</p>
<p><b>McGill Quality-of-Life Questionnaire</b><sup>56</sup>  <i>www.mywhatevery.com/cifwriter/content/41/downloads/mcgill_esrd.pdf</i>            Overall QOL            Physical symptoms            Psychological symptoms            Outlook on life            Meaningful existence</p>	

\*Instrument scales are listed in the following order: 1) overall QOL; 2) physical scales, including physical functioning and symptoms; 3) psychological scales; 4) social scales; 5) financial scales; and 6) family scales.

†All the instruments listed were developed for use with cancer patients, except for the SF-36, which was designed for use with the general population.

tion about symptoms and the ability to perform normal activities, which are part of standard clinical evaluations. Thus, one can make the argument that using QOL data in routine clinical practice should be analogous to the use of other medical data.<sup>47</sup> Just as clinicians must be trained to interpret laboratory and radiographic findings, so too can they be trained to use QOL data in an oncology practice.

Over the past decade, increased attention has focused on the development and use of numerous instruments with which to gather information about health, illness, and the effects of healthcare interventions from the patient's perspective.<sup>48,49</sup> Numerous measures contain a range of health-related questions on physical, psychological, and social functioning. These instruments are designed to assess broader constructs, such as impairment, disability, and handicaps.<sup>48</sup>

The breadth of existing QOL instruments is illustrated by the subset delineated in Table 2.<sup>30,50–58</sup> Although such instruments may seem similar, their outcomes differ by what is measured. For example, three commonly used instruments measure different QOL domains. The Quality-of-Life Index

measures life satisfaction, the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) measures functioning and general health status, and the University of California at Los Angeles Prostate Cancer Index measures specific symptoms.<sup>30,58,59</sup> Although all three instruments may be administered to the same patient, their results may vary greatly because different variables are measured. Thus, clinicians who are planning to use a QOL instrument need to know exactly what they want to measure and which instruments are best for that purpose.

Given that QOL relates to an individual patient, it is not unreasonable to define it totally from that patient's perspective. However, the reality is that QOL is often defined by clinicians taking care of the patient, who base it on such observable events as performance status or symptoms. Physicians have conducted QOL assessments informally for many years by asking the simple question, "How have you been lately?"<sup>60</sup> However, this informal approach does not address important dimensions of QOL, such as emotional, social, or sexual functioning. A patient may not voluntarily reveal concerns about these areas, and physicians may not ask questions that facilitate a discussion of them because of a lack of time, embarrassment, or a feeling that nothing can be done about such concerns.

Additionally, potential attitudinal barriers, such as skepticism on the part of the clinician, may affect the clinician's views about the relevance and value of psychosocial informa-

tion in the care of patients.<sup>48,61</sup> Physicians commonly conduct global assessments of patients to evaluate whether their condition has clinically improved, stayed the same, or declined. Many physicians may not be familiar with formal QOL measurements and thus may not use these tools in their routine clinical practice.<sup>62</sup> Patients' ratings of QOL may differ from those of their health care team and even from those of their family members, who have been shown to underestimate the impact of QOL on patients.<sup>63</sup> Patients and clinicians often have different treatment priorities and a different understanding of the effect the illness will have on patients' lives.<sup>64</sup> Important QOL factors, such as depression, fatigue, and pain, are often overlooked by the treating clinician.<sup>65</sup> Several studies have shown that oncologists frequently do not recognize psychological distress in patients.<sup>60-68</sup>

### Issues to Consider When Making QOL Assessment Part of Routine Patient Care

In addition to physicians' perceptions that QOL collection is unnecessary or that instruments to measure QOL are inadequate, numerous perceived barriers may prevent the collection and use of QOL data in routine clinical practice, including time and resource constraints related to data collection and analysis.<sup>69</sup> In an exploratory study of 60 oncologists, Taylor et al<sup>36</sup> examined the physicians' perspectives of QOL and found that most physicians perceived it to be important but tended to use it informally, if at all. One of the main reasons for not using QOL data was the belief that the currently available instruments were not valid or reliable.

However, much research has focused on the validation of QOL instruments.<sup>62,70,71</sup> For QOL to be measured accurately in clinical practice, "homemade" measures should be avoided. Many QOL instruments available today have been carefully developed and refined, often over a 10- to 20-year period. The reliability and validity of these instruments are well documented. Information about what an individual patient's scores mean is also known, and a patient's scores can be compared with those of other patients. The existing validated instruments lend confidence that they measure what they are intended to measure.

### OVERCOMING BARRIERS VIA TECHNOLOGY

Numerous barriers must be overcome before the collection of QOL data becomes routine in the clinical practice of oncology. For example, the practicing clinician must have data that are readily available and easy to use. Traditionally, QOL data have been collected through paper-based questionnaires that can be printed for clinicians. However, the manual collection of data and its analysis and entry into databases using a paper-based system can be difficult and laborious, consuming substantial resources. Yet such a collection system is possibly the easiest kind to implement.

Optical mark-recognition systems have also been used but have drawbacks as well. When scanning is used to transfer data from paper forms into a database, large amounts of

data can be processed. However, this method requires special forms, data may be missed, and the database must be verified to ensure accuracy.<sup>72</sup> Data collection should be robust, easy, and readily interpretable so as to facilitate the evaluation of its usefulness in clinical practice.<sup>73</sup>

Numerous reports have explored the use of automated data collection. Velikova et al<sup>72</sup> evaluated the QOL of 160 inpatient oncology patients by comparing a paper form of data collection followed by optical scanning for data entry with data collection by computer touch-screen questionnaires. An open, randomized, crossover design with two modes of administration was used: paper followed by touch-screen and touch-screen followed by paper. The methods of data capture were examined in terms of the patient's acceptance and preference, data quality, feasibility, and reliability. Feasibility included the logistics of administration and the time required for completion.

Overall, 76% of patients preferred the computer questionnaire to the paper questionnaire or found it equally acceptable. Age, sex, order of presentation, and time needed for questionnaire completion had no effect on preference. The use of a computer was mentioned by only one patient as a reason for nonparticipation, which suggests the acceptability of this method. The time required to complete the questionnaire on a computer was slightly shorter than that needed for the paper version (average, 8–10 minutes). The quality of the numerical data was excellent with the touch-screen method (no missing responses), because the system was designed so that the patient had to answer each question to proceed to the following question. With the paper questionnaire, problems were noted with missing responses, multiple answers, changed answers, and inability of the scanner to recognize responses. Of the 158 optically scanned questionnaires, 146 had various scanning, verification, and database errors, which led to considerably more work for the research staff. The mean differences between QOL scores obtained by paper versus computer questionnaires were small, suggesting equivalence for most scales and items, but there were statistically significant better scores in the functional scales with the touch-screen version.

Buxton et al<sup>74</sup> evaluated the experience of oncology patients who used a computerized program with a touch-sensitive video monitor. A total of 178 patients used the system and were interviewed about their perceptions of any difficulties in using the touch-screen system. Most patients found the system "very easy" to use; only 1%–2% experienced some difficulty. None ranked use of the computerized system as "very difficult." The median time to complete the EORTC QLQ-C30 questionnaire was 6.8 minutes, and 96% of patients indicated a willingness to complete a similar questionnaire in the future.

Allenby et al<sup>75</sup> evaluated the acceptability and feasibility of computer touch-screen technology for reporting psychosocial functioning in an ambulatory cancer clinic. A total of 450 patients participated in a randomized controlled trial that evaluated the collection and use of self-reported cancer needs, QOL, and psychosocial information. No patient declined to participate in the study because of the touch-screen technol-

**Table 3****Linear Analogue Self-Assessment-6 (LASA-6)**

DIRECTIONS TO THE PATIENT: PLEASE CIRCLE THE NUMBER (0–10, WITH 0 REPRESENTING “AS BAD AS IT CAN BE” AND 10 REPRESENTING “AS GOOD AS IT CAN BE”) THAT BEST REFLECTS YOUR RESPONSE TO THE FOLLOWING QUESTIONS THAT DESCRIBE YOUR FEELINGS **DURING THE PAST WEEK, INCLUDING TODAY.** HOW WOULD YOU DESCRIBE:

1.	Your overall quality of life?
2.	Your overall mental (intellectual) well-being?
3.	Your overall physical well-being?
4.	Your overall emotional well-being?
5.	Your level of social activity?
6.	Your overall spiritual well-being?

ogy. Many patients (55%) had no prior computer experience.

Overall, 99% of patients found the touch-screen system easy to use and the time to complete questionnaires acceptable. From 97% to 99% of the questions were answered. Completion time for questionnaires was largely determined by age, physical condition, educational level, and degree of prior computer experience. The cost was \$18,000 for software development and \$4,000 for each complete touch-screen system. However, this approach could potentially save money by eliminating the costs of data entry and the identification and correction of transcription errors.

Drummond et al<sup>76</sup> compared a pen-based electronic questionnaire with a conventional paper questionnaire in a randomized crossover study of 46 patients with gastrointestinal disorders. The electronic questionnaire had a high degree of acceptability; 57% of patients preferred it, whereas 13% preferred paper, and 30% had no preference. All patients found both the electronic and paper questionnaires easy to use. Data were 100% complete with the electronic version, which greatly simplified the data-handling process.

**ENHANCING THE REAL-TIME USE OF QOL DATA**

In the ideal clinical setting, the following parameters would be necessary for real-time use of QOL data:

- 1) Only well-developed instruments with substantial evidence of reliability and validity should be used for measuring QOL.
- 2) Laptop computers should be provided for patients to use

to complete the questionnaires in the waiting room, which would allow timely scoring compared with paper-and-pencil versions.

3) The only types of instruments suitable for paper administration would be those requiring no scoring (eg, stand-alone single-item surveys such as the Linear Analogue Self-Assessment-6 [LASA-6]; Table 3).

4) For all instruments requiring the calculation of scores, computation should be done by computer.

5) Computer software for the QOL instrument should present questions in a user-friendly manner, calculate scores, print out data in an easily understood display, and interpret the meaning of the scores so that clinicians will clearly understand their clinical significance.

6) Only those instruments for which the developers have provided specific guidance on the interpretation of scores in terms of their clinical significance should be used. For example, the Burden Interview Tool can be used to assess stresses experienced by family caregivers of elderly and disabled persons. Detailed instructions about its use and scoring are available.<sup>77,78</sup> Similarly, the Symptom Distress Scale<sup>79,80</sup> has a user's manual.

**Future Directions**

Concrete guidelines for incorporating QOL scores into clinical practice are still needed. Some guidelines on interpreting QOL scores have been provided to clinicians, but more work is needed in this area. As was the case with blood pressure readings, the more QOL is used in clinical practice, the more fully its usefulness will be realized. QOL information can contribute to clinical decision-making, supportive services, and health policy. The transition from instrument development and validation to the use of QOL data in clinical trials has been made with some preliminary use of QOL data in clinical practice. Assessment instruments can provide beneficial information to patients and physicians, as they discuss the trade-offs between toxicity and QOL, and they can aid in the determination of whether the small gains in life expectancy associated with treatment are worth the cost. The ultimate goal of all healthcare providers is the enhanced well-being of patients, and the use of QOL data in clinical practice should have a positive impact on that goal.

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