

## Applying Quality-of-Life Data Formally and Systematically Into Clinical Practice

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The systematic integration of quality-of-life (QOL) assessment into the clinical setting, although deemed important, infrequently occurs. Barriers include the need for a practical approach perceived as useful and efficient by patients and clinicians and the inability of clinicians to readily identify the value of integrating QOL assessments into the clinical setting. We discuss the use of QOL data in patient care and review approaches used to integrate QOL assessment into the clinical setting. Additionally, we highlight select QOL measures that have been successfully applied in the clinical setting. These measures have been shown to identify key QOL issues, improve patient-clinician communications, and improve and enhance patient care. However, the work done to date requires continued development. Continued research is needed that provides information about benefits and addresses limitations of current approaches.

*Mayo Clin Proc.* 2007;82(10):1214-1228

COOP = Primary Care Cooperative Information Project; COPD = chronic obstructive pulmonary disease; CRQ = Chronic Respiratory Questionnaire; ED = erectile dysfunction; EORTC QLQ-C30 = European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-30 items; FACT-G = Functional Assessment of Cancer Therapy-General; QOL = quality of life; SF-36 = 36-Item Short-Form Health Survey; SHIM = Sexual Health Inventory for Men

### CLINICAL SCENARIO

Mrs James, a 62-year-old woman with a 5-year history of renal cell carcinoma treated with nephrectomy, presented for a second opinion regarding lung nodules. The nodules were first seen 3 months ago, at which time observation was chosen as the course of management. Her other medical history consisted of hereditary peripheral neuropathy and ataxia, hypothyroidism, osteoarthritis, and hypertension. Examining her history, the physician assumed that her quality of life (QOL) was likely impaired. However, when Mrs James walked into the office with a steady gait, cane in hand but not using it, that assumption was challenged. She appeared to be doing well, was cheerful, and readily entered into a discussion about findings on her recent scan.

The physician discussed the fact that no change had occurred in the nodules located in her lungs and concurred that they should continue watchful waiting. Mrs James reported that she was reassured by this information. The physician then asked Mrs James if she had additional questions or concerns that she would like to discuss. On receiving the answer of “no,” the physician systematically collected QOL data composed of linear analog scale assess-

ment global QOL items (10 items) and the Functional Assessment of Cancer Therapy-General (FACT-G; 33 items).

Mrs James gave the following scores on the linear analog scale assessment (high scores being favorable): 9 of 10 for overall QOL, mental well-being, emotional well-being, social activity, spiritual well-being, and support from friends and family and 8 of 10 for fatigue. However, her scores were 4 for overall physical well-being, 2 for frequency of pain, and 3 for severity of pain. Thus, Mrs James was doing fairly well with the exception of physical well-being and pain.

On the FACT-G (higher scores being favorable), Mrs James scored 19 of 28 for physical, 11 of 24 for emotional, 21 of 28 for social, and 24 of 28 for functional well-being. A closer review of the FACT-G questions revealed that Mrs James had significant pain, rating it as “very much,” and significant trouble sleeping, reporting that she slept well “a little bit.” She also noted that she was “somewhat” feeling that she was losing hope in the fight against her illness and “somewhat” worried that her condition would get worse. A point of significance is that if the physician had not examined the individual item scores in the functional well-being area, the assumption would have been that Mrs James was doing well in this area because her score was 24 of a possible 28. However, it is from this scale that he identified her difficulty sleeping. This example illustrates the significance of examining more than scale scores.

The difficulties noted on the QOL measures had not been discussed during the initial assessment; yet, these were significant issues for her. These findings led the physician to the discovery that Mrs James was almost con-

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stantly in pain from her neuropathies, was being awakened at night from pain secondary to her osteoarthritis, was frustrated by her inability to both get around and at times grip a jar or open a container to make meals, was losing hope in the fight against her illness, was worried that her condition was getting worse, had trouble meeting family needs, and was concerned about the lack of family communications about and acceptance of her illness. This example exemplifies the importance of QOL data in providing a total picture of the patient.

This case study illustrates some of the advantages and difficulties with integrating QOL assessment into the clinical setting. In this setting, the clinician is consulted to provide a second opinion regarding her lung nodules. The identification of QOL issues not related to her cancer results in the need for a referral to the patient's primary care physician or other specialist, such as pain clinic practitioners, for management of these issues, but the oncologist can still formulate a treatment plan to alleviate symptoms. Meanwhile, her issues with losing hope, worry about her condition getting worse, and lack of family communication, which are all related to her disease progression, should receive attention. These issues can be addressed by the oncologist by discussing the natural history of this disease and the fact that some individuals may have a relatively indolent course with excellent functional status for prolonged periods and by carefully monitoring for changes and promising not to abandon the patient. Belief in the benefits of taking care of both the physical and the psychosocial needs of the patient, with referral to team members in fields such as social work, chaplaincy, nursing, and/or psychology, would be warranted.

Quality of life is an important end point in the care of patients with cancer.<sup>1,2</sup> However, the systematic integration of QOL assessments into the clinical setting lags behind its importance. This leaves us with the task of identifying how QOL data can be integrated formally, systematically, and efficiently into clinical practice to aid in patient care. This article focuses on this task and addresses the following topics: types of QOL data for use in the clinical setting, communication of QOL data, and possible approaches and effects of integrating QOL assessment into care for the individual patient.

### USING QOL DATA IN THE TREATMENT OF EACH PATIENT

Growing evidence suggests that optimizing processes and outcomes of care depends on implementing multicomponent interventions that change the prevailing system of care.<sup>3-5</sup> The Institute of Medicine's report,<sup>6</sup> *Crossing the Quality Chasm*, outlines 6 fundamental components of op-

timal care for illness: safe, timely, evidence based, efficient, equitable, and patient centered. The core of patient-centered care is the concept of self-management or patients' active and central role in managing their illness, including routine self-monitoring of symptoms and adverse effects, medication adherence, and functionality and QOL.

Self-management is an important concept in patient care, for example, when adverse effects and symptoms must be proactively managed and tradeoffs are routinely weighed between treatment risks and benefits. Clinicians can play an important role in communicating and reinforcing patients' active and central role in their care. In addition to treatment management, specific clinician roles include the following: assessing patients' levels of functionality, skills, and confidence to manage their illness; referring patients to effective behavioral change programs that reinforce self-management activities (such as those offered through psychology or psychiatry, education departments, and condition-specific community programs); and collaboratively setting goals and defining care plans.<sup>7</sup> The role of the clinician also becomes one of communicating about QOL issues when the patient chooses informed or shared decision-making models.

Assessment of patient functionality and QOL in clinical trials has generated group-level (aggregate) data that provide clinicians and their patients with valuable information to substantiate the possible functional and QOL consequences of various treatments. This information, combined with other efficacy information, promotes shared and informed decision making. The absence of QOL and functionality data makes it difficult to weigh the risks and benefits of treatment on outcomes other than survival, for example, whether patients are willing to trade several weeks or months of nausea, vomiting, fatigue, and time spent away from family or other activities while receiving therapy if there is only a 2% to 4% chance of response to treatment or extension of life.

Recently, QOL instruments have been used in the clinical setting to help focus patient visits on key problems (eg, symptoms and functional limitations that affect QOL). These instruments can be sent to patients before their visit or completed in the waiting room. The QOL data are then reviewed by clinicians or summarized by a technician; scores are subsequently shared with patients and clinicians. Problem areas can be targeted and used to collaboratively set goals with patients. The proactive administration of QOL questionnaires can therefore become a formal mechanism for increasing the efficiency of visits, while working collaboratively with patients to identify problem areas.

In the following sections, we discuss the use of group-level (aggregate) vs individual-level QOL data to aid in patient decision making and guide patient self-management

activities, different mechanisms for collecting individual-level QOL data in clinical settings (eg, computer administration vs paper-and-pencil questionnaires), and evidence of the effects of QOL administration on processes and outcomes of care. We then provide sample QOL questionnaires that have been administered in the clinical setting with individual patients and for which group-level data are available.

### WHAT CLINICIANS NEED TO KNOW TO EFFECTIVELY USE QOL DATA

We begin by reviewing group-level data from published studies that have compared the QOL of one group of patients with those of another. The following section will then focus on individual-level data collected from patients at the time of their visit. For these 2 data sources, we address approaches to communicating QOL information to patients.

#### GROUP-LEVEL DATA

Group-level data have been aggregated from individual patients. Most group-level data are derived from clinical trials. The biggest obstacle faced when using group-level data in the clinical setting is interpretation. Specifically, comparison of QOL scores among groups may result in statistically significant differences, but often little guidance is available on whether these differences are clinically meaningful. When presenting group-level data to individuals, it is important to emphasize that not all patients included in the sample responded in the same manner. That is, although average scores tend to be emphasized, most patients will have reported better and some worse outcomes as evidenced by the variability of individual scores.

To illustrate the use of group-level data in the clinical setting, we use the example of prophylactic mastectomy. Women at high risk for breast cancer because of a strong family history may consider undergoing prophylactic mastectomy. When considering this procedure, clinicians should ascertain whether women are aware of not only the efficacy data on this procedure but also the data on potential QOL consequences. The clinician might share a summary of results of studies that indicate that only a few women, ranging from 6% to 19% across studies, who elect prophylactic mastectomy are subsequently dissatisfied.<sup>8,9</sup> However, in one study, more than one-third of the women reported disturbed body image after prophylactic mastectomy.<sup>9</sup> Conversely, 74% of women reported decreased concern about the development of cancer as a result of this procedure.<sup>9</sup> Thus, although preventive surgery is likely to significantly reduce concerns and anxiety about developing breast cancer, it may have adverse consequences for women's body image and related issues. This information may be useful in helping women decide among available options.

A second example of the useful group-level data in the clinical setting is research that addresses conservative breast surgery compared with mastectomy in women with breast cancer. There was great hope that breast conservation would minimize the psychological and sexual consequences of surgical treatment of breast cancer. However, studies have consistently found no significant differences in general psychological distress, marital satisfaction, or sexual function reported by women who underwent breast-conserving therapy vs those who opted for a mastectomy.<sup>10,11</sup> On the other hand, breast-conserving therapy may result in a better body image and fewer difficulties with clothing.<sup>10,12</sup> Interestingly, perceiving oneself as having had a choice may influence outcomes to a greater extent than the type of surgical procedure performed. Women who were offered a choice between breast conservation and mastectomy experienced less depression at 1 year compared with women who were not offered a choice.<sup>13</sup>

#### INDIVIDUAL-LEVEL DATA

The second type of data are collected and interpreted at the individual level, that is, QOL questionnaires are completed by individual patients and interpreted collaboratively by clinicians and patients at that time. Communication of individual QOL results requires consideration of whether a single-item or a multiple-item QOL measure was used. In the case of a multi-item questionnaire, the scores on 2 different subscales might be diverse, resulting in a low score on one subscale, which cancels the effects of a high score on another subscale. Such global assessments need to be followed up with either a closer look at the subscale or item score information or, in the case of a single item, further evaluation.

The attractiveness of multi-item measures, such as the Dartmouth Primary Care Cooperative Information Project (COOP) charts, the 36-Item Short-Form Health Survey (SF-36), the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire-30 items (EORTC QLQ-C30), and the FACT-G, is that they provide detailed information on QOL in specific life areas. Ideally, the patient's self-reported QOL can serve as a basis for further discussion about functioning and specific problem areas. When patients complete QOL questionnaires before their visit, various appointments could be made proactively with appropriate health care professionals to address problem areas (eg, pain, psychological distress).

Patient completion of QOL questionnaires before intervention is useful in providing a baseline in which the patient serves as his or her own control. Administering QOL questionnaires at each return visit can display the improvements or negative effects that result from the disease process and interventions. These data over time allow

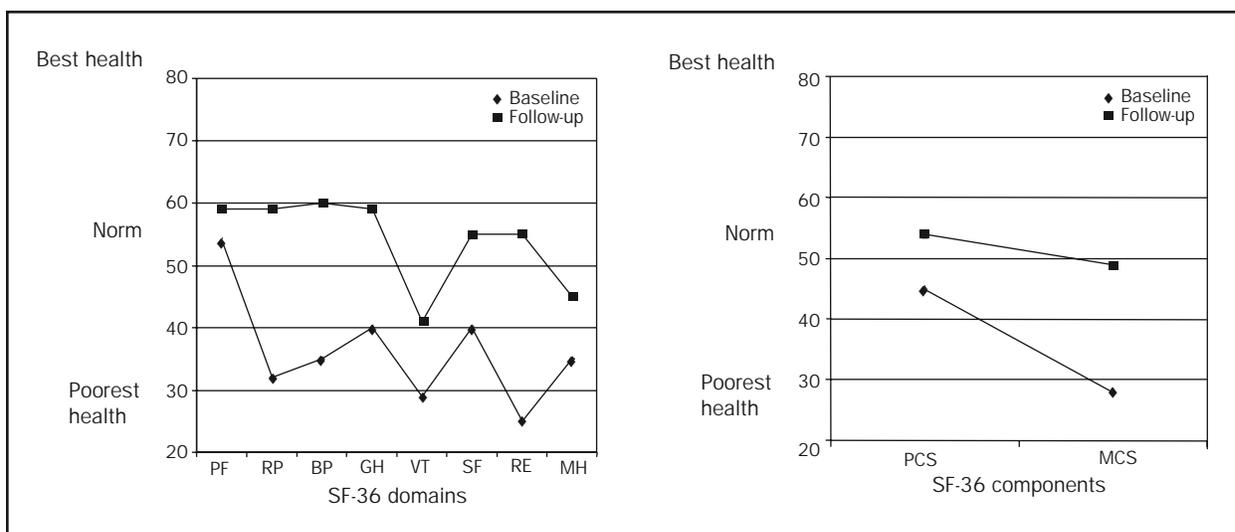


FIGURE 1. The 36-Item Short-Form Health Survey (SF-36) results for an individual patient as generated by entering each of the SF-36 subscale scores into an Excel spreadsheet. This patient's depression was down and vitality was up, among other health gains. BP = body pain; GH = general health; MCS = mental component summary; MH = mental health; PCS = physical component summary; PF = physical function; RE = role—emotional; RP = role—physical; SF = social functioning; VT = vitality.

one to see a trajectory of the disease and its treatment and how these impact on the individual. However, as a clinician examines these scores, it is important to realize that there is some normal fluctuation of scores. As a general rule, half an SD change suggests a clinically significant alteration in the patient's QOL and does not reflect simple normal fluctuations.<sup>14</sup> For example, on a 100-point scale with an SD of 10, a score change of 5 points would reflect a clinically significant difference. Normative or instrument-specific estimates may be used to determine the score range and SD. Although some concern has been expressed about using group-level data to determine the threshold for individual change, it has been argued that when the purpose is to determine change vs no change, the use of a score difference that reflects the minimal important difference for determining clinical significance is fairly accurate.<sup>15</sup> Another approach is demonstrating that the score changed enough to reflect a change from one anchor to another (eg, from "a little better" to "somewhat better").<sup>16</sup>

### COMMUNICATION OF QOL DATA TO PATIENTS FOR THEIR USE

Informative communication approaches provide patients with data about the likelihood that a single aspect of QOL will improve with treatment, the meaningfulness of the QOL improvement in respect to the patient's ability to function, and the importance of the QOL change to the specific person.<sup>17</sup> This information can be communicated as the number of symptom-free days, the percentage of

persons experiencing improvements of a specified amount, and the time required to experience a minimally important change.<sup>18</sup> Likelihood of improvement may be communicated in terms of the percentage or number of persons who experience a benefit and those who experience a loss of function or deteriorated QOL. The patient's score or the group's average score alone provides patients with limited information. Additionally, communication of relative risks has been found to be confusing and should be avoided.<sup>19</sup>

A simple display of data using a line graph that documents group means or individual scores over time, similar to that in Figure 1, has been documented as an approach that patients prefer over text data, stacked graphs, and side-by-side bar graphs. Patients also report a higher level of understanding with the line graphs compared with these other methods of presenting data.<sup>20</sup> However, when presenting data that compare groups, side-by-side graphs are helpful.<sup>21</sup> For instance, with line graphs, the 2 group lines would be put on the same graph for comparison. Similarly, researchers should avoid complex statistical modeling that impedes clinicians' understanding of the health-related QOL data.<sup>22,23</sup> Frequencies,<sup>23</sup> change in scores over time, and numbers of patients reporting clinically meaningful changes in scores should also be reported.<sup>22</sup>

### INTEGRATING QOL ASSESSMENT INTO EACH PATIENT'S CARE

Thus far, we have discussed the importance of QOL concerns and the various types of data that are available to help

patients make decisions about treatment or to proactively manage their disease such as cancer. This section summarizes studies that have evaluated the effect of QOL data collection on processes and outcome of care. These studies were identified as a result of a systematic search of the literature with MEDLINE, CINAHL, and PsychINFO. Additional references were identified through references of reviewed studies. Some of these investigations have been purely descriptive; others have been randomized controlled trials or have used other comparative study designs, which are available online ([eTable 1](#)<sup>24-58</sup> is available at [www.mayoclinicproceedings.com](http://www.mayoclinicproceedings.com) linked to this article).

Integrating QOL assessment into the clinical setting can result in a variety of both short-term and long-term outcomes. Integrating QOL assessment into practice may result in such immediate effects as increased awareness of and identification of specific issues and concerns and increased satisfaction with communications and care. In addition, such integration may have an impact on practice by decreasing the amount of time needed to identify patient concerns and altering the referral pattern to other specialists. Longer-term effects would include changes in QOL, patient-reported outcomes, patient management, and overall satisfaction with management of care.

Review of the literature suggests the absence of strong theoretical frameworks for guiding research in this area. Thus, there is insufficient basis at this time to guide researchers in developing interventions through which QOL data can affect process and outcome of care. Despite the lack of a theoretical foundation, more recent studies are better designed, providing more convincing data than older studies.

#### PROCESS

Review of various processes used to successfully integrate QOL assessment into the clinical setting provides clinicians with approaches that can be customized to fit their setting. Common methods of collecting QOL data in the clinical setting include the administration of paper-and-pencil questionnaires, computer-assisted (eg, touch screen) self-administration of questionnaires, and computerized interviews. Studies of these different administration modalities indicate that clinicians maintain a positive attitude toward the availability of QOL information derived directly from their patients<sup>31,34</sup> and consider them a useful supplement to information obtained via a typical clinical encounter.<sup>34</sup> As early as 1949, the Cornell Medical Index was used to collect information on patient function via paper-and-pencil questionnaire.<sup>59</sup> Computer-assisted data collection and touch screen technology have been shown to obtain data consistent with those received by interview<sup>47</sup> and rated positively by clinicians and patients,<sup>24,39,50,54,59</sup> with many patients noting their preference for providing

information in this manner compared with an interview.<sup>27</sup> Thus, the method used to collect data can vary according to the capabilities of the health care setting.

In selecting intervals to administer QOL instruments for the process of information collection, the most common approach has been the administration of a questionnaire before an appointment. An alternative approach is administration of questionnaires at set time points, such as 3, 6, and 12 months after diagnosis when these time points do not coincide with an appointment with a clinician. The disadvantage of this approach is that data obtained at such fixed intervals may no longer be relevant when the patient has a clinic visit.

Although instrument selection affects the length of time required to complete data collection, most QOL data can be obtained in an efficient manner. For instance, one research group reported that patients completed a set of 3 instruments in just 15 minutes,<sup>43</sup> whereas others have reported that it took an average of 5 to 7 minutes to complete 1 or 2 instruments.<sup>25,28,58</sup> In the latter section of this article, we provide sample QOL measures. A review of the research revealed that favored instruments included the SF-36,<sup>27,29,44,49,56</sup> the EORTC QLQ-C30,<sup>25,28-29,43,50,51,53-55,58</sup> the General Health Questionnaire,<sup>33,35,57</sup> and the Dartmouth COOP/World Organization of National Colleges, Academies, and Academic Associations of General Practitioners/Family Physicians charts.<sup>45,57</sup>

A limited number of studies are available that include education for clinicians in the interpretation of QOL scores<sup>28,29,32,42,48,49,52,56</sup> or provide information on available resources for addressing some of the problem areas identified in administering QOL assessments.<sup>42</sup> However, investigators do not consistently report how many clinicians actually participated in training. At the other extreme, some investigators have simply provided QOL profile scores, without providing any indication of how the scores might be used.<sup>49</sup> If the clinicians are not encouraged to use QOL data or do not know how such data should be interpreted, it is unlikely that the data will be used during clinical encounters. Several studies include sharing of QOL summary data with the patients themselves.<sup>28,29</sup> This strategy allows patients to track changes in their perceived QOL over time and may provide a trigger for them to raise specific issues or pose questions during clinical appointments.

An approach that incorporated many of the strengths identified in these studies, and controlled for the limitations, is that by Detmar et al.<sup>29</sup> Patients completed the EORTC QLQ-C30 at 3 consecutive outpatient visits. Graphic displays of the data were provided to both the clinician and the patient before the actual visit. The clinicians received a half-hour educational session on the interpretation of scores, and patients received a booklet that

explained the scores. A favorable component added by another research group<sup>42</sup> was that of providing information about resources and ways to manage areas in which QOL deficits were reported by the patients.

### OUTCOMES

Several favorable outcomes resulting from the assessment of QOL in the clinical setting have been reported. The present summary of outcomes provides some guidance about realistic practice outcomes that may be used for evaluating the impact of QOL assessment in clinical practice. It is important to distinguish between those outcomes that can realistically be achieved within the evaluation period and those that may be too global, diffuse, or ambitious to be realized within the framework of a typical research project.

The most frequent outcomes identified have included increased identification of QOL problems and enhanced communication between patients and clinicians. These outcomes are important goals in any clinical practice. Psychosocial issues have often been identified and favorably influenced, including generalized distress or mental health,<sup>34,37,52</sup> anxiety,<sup>48</sup> stress,<sup>48</sup> or depression.<sup>30</sup> Patient-physician communication was consistently found to be enhanced in the studies in which it was measured.<sup>28,29,45,50,52,53,58</sup> An exception to this was the study by Nelson et al,<sup>46</sup> in which patients reported enhanced communication but clinicians did not. All but 1 study<sup>49</sup> that reported on health care professional's awareness of QOL problems identified an increased awareness of QOL problems.<sup>28,29,35,38,52,53,56-58</sup>

Satisfaction with care, valued by clinical setting, was measured in only 4 studies in which QOL assessment was integrated into the clinical setting.<sup>29,51,53</sup> In 3 studies, no difference was identified between the experimental and control group or from before to after the test,<sup>32,51,53</sup> and differences were identified on only 1 item in the other study.<sup>29</sup> However, the lack of significant findings may be a result of the ceiling effect often found with satisfaction studies, which makes it difficult to document any additional, incremental improvement in the outcomes of interest. Overextended clinical practices make consultation time important. Being able to document that care is improved with little effect on consultation time can minimize the barriers to integrating QOL assessment into the clinical setting. Consultation time was explored in 4 studies. Three reported no increase in consultation time,<sup>28,43,52</sup> 1 study reported an increase ranging from 0.5 to 2.7 minutes,<sup>56</sup> and in 1 study approximately half of the clinicians reported no increase in time and the other half reported an increase of approximately 4 minutes.

More distal effects of QOL assessments have also been explored. An improvement in self-reported QOL has also

been described in some studies, including improved mental function,<sup>29</sup> role function,<sup>29</sup> symptoms,<sup>35</sup> depression,<sup>43</sup> overall function,<sup>35,52,59</sup> physical well-being,<sup>52</sup> overall QOL,<sup>35</sup> and patient satisfaction.<sup>31</sup> Additionally, an increase in the number of referrals,<sup>42,45</sup> increased management of needs,<sup>33</sup> and changes in therapy were reported as a result of QOL assessments.<sup>31,56</sup> Only 2 studies reported no effect on any QOL dimension,<sup>32,38</sup> 1 study reported no difference in clinician detection of mental illness,<sup>35</sup> 1 study reported increased identification of depression in the control group,<sup>40</sup> and 1 reported trends in favor of the intervention group but no significant difference.<sup>26</sup> These later, negative findings may be explained by the fact that in 1 study two-thirds of the clinicians reported that they did not routinely review the questionnaire results.<sup>38</sup> In the other studies, most health care professionals involved were residents,<sup>26,32</sup> whose limited experience in practice may have limited their ability to integrate the additional dimension of QOL measurement results into their practice. Also, the reporting of global physical and emotional domains may obscure specific changes that have occurred within the physical or emotional domains.<sup>48</sup>

### STUDY DESIGN CONCERNS

Many of the QOL assessment studies reviewed included small numbers of physicians, nurses, or patients (6 clinicians and 18 patients,<sup>28</sup> 10 clinicians and 214 patients,<sup>29</sup> 10 nurses and 72 patients,<sup>35</sup> 11 clinicians and 113 patients,<sup>45</sup> 7 residents and 58 patients,<sup>49</sup> 13 clinicians and 114 patients,<sup>55</sup> 2 clinicians and 163 patients,<sup>56</sup> and 13 clinicians<sup>58</sup>). In some of the studies, patients' baseline scores demonstrated few functional limitations,<sup>25,43,44,50</sup> which may have resulted in few issues to bring to the clinician's attention. Additionally, in some situations the health care professionals knew the patients fairly well before the study,<sup>25,31,41,43,44,56</sup> a familiarity that may make information from a QOL measurement less useful. However, this is not always the case. In 1 study, favorable outcomes were shown despite several previous interactions between clinician and patient.<sup>29</sup>

Few studies provided longitudinal data so that a person's function from one time to another could be compared. Magruder-Habib et al<sup>41</sup> report that the likelihood of identifying depression increased over time. These comparisons are especially helpful in the clinical setting as new treatments or interventions are being introduced.

### IMPLEMENTATION INTO PRACTICE: EXAMPLES

Thus far, we have discussed the role of group-level vs individual-level data in the individual patient encounter, different administration modalities for collecting QOL

data, and the effects of QOL data collection on processes and outcomes of care. In this section, we present an overview of several QOL instruments that have been used in individual patient encounters and for which group-level data are available. The instruments identified here reflect only a few of the many that are available in the literature. Our examples include 4 QOL instruments: 2 measure multidimensional aspects of QOL, 1 measures only 1 specific QOL dimension, and 1 is disease specific. Disease-specific questionnaires are also available, for which we have included 1 example for use in patients with chronic obstructive pulmonary disease (COPD). Disease-specific questionnaires are of great value for clinicians who deal with a specific disease entity because they provide details on aspects of life most affected by the disease of concern. General QOL instruments often do not capture distress caused by disease-specific situations. Finally, we have identified an example of how group QOL data can be included in a decision aid to assist patients in their decision making.

There has been substantial debate regarding the measurement of symptoms when addressing QOL. Because of the strong association between symptoms and QOL,<sup>60</sup> measurement of symptoms should be included in a QOL assessment. Debate also surrounds the association between functionality and QOL. Although some individuals would argue that to tap QOL, questionnaires should address the degree to which symptoms or functional impairment bothers an individual; however, others argue that this makes instruments cumbersome. The most frequently used approach is to measure symptoms and functionality related to the QOL domains and to use this information as a means to initiate discussion with the patient.

To determine which questionnaires are useful, the clinician should examine well-designed instruments<sup>61</sup> to determine whether the questions appear at face value to be relevant to their patient population. Additionally, a judgment should be made regarding the extent to which the instrument represents QOL-related issues that are known to be affected by the disease.

### 36-ITEM SHORT-FORM HEALTH SURVEY

The SF-36 was designed for use in health policy evaluations, general population surveys, and clinical research and practice.<sup>62</sup> The SF-36 captures, in approximately 5 to 10 minutes, information about an individual's general health status in 8 areas: (1) physical functioning, (2) limitations in usual role activities because of physical health problems (role physical), (3) bodily pain, (4) general health perceptions, (5) vitality (energy and fatigue), (6) social functioning, (7) limitations in usual role activities because of emotional problems (role—emotional), and (8) general mental

health (psychological distress and well-being). On the basis of weighted composites of these concepts or domains, a mental summary component score and physical summary component score can also be generated.

Scores on the domains and components are compared with and referenced to a defined population, for example, individuals in the US general population.<sup>63</sup> In this norm-based scoring, each domain and component in the US general population has the same average score of 50, with scores greater than 50 indicating better than average health and scores less than 50 indicating worse than average health.

A graph of the SF-36 results for an individual patient over time can be generated by entering each of the SF-36 subscale scores into an Excel spreadsheet (Figure 1). Figure 1 depicts that a patient's depression was down and vitality was up, among other health gains. On the basis of this profile, a clinician and patient may decide to move forward more aggressively with treatment.

### DARTMOUTH COOP CHARTS

The Dartmouth COOP chart system is a simple, easily administered scoring system for screening, assessing, monitoring, and maintaining patient function.<sup>45,56,64</sup> Pictorial charts are used to measure health status in 9 areas (physical condition, emotional condition, daily work, social activities, change in condition, overall condition, social support, QOL, and pain) (Figure 2). Each of the 9 charts consists of a title (eg, pain), a question referring to the status of the patient during the past 2 weeks (eg, during the past 2 weeks...how much bodily pain have you generally experienced?), and 5 response choices (eg, 1 indicates no pain; 2, very mild pain; 3, mild pain; 4, moderate pain; and 5, severe pain). For each chart, a score of 4 or 5 represents an unfavorable or "abnormal" level.

The Dartmouth COOP charts have been developed for use in routine clinical practice and can be clinician administered (physician, nurse, medical assistant) or patient self-administered. Although these charts may lack the sensitivity of longer instruments, the validity and reliability of COOP charts have compared well with longer measures of function.<sup>64</sup> Once a clinician verifies a patient's score on a given health attribute (eg, social support), he or she can work collaboratively with the patient to identify necessary actions. Different sets of charts are available for adult, geriatric, and adolescent populations.<sup>65-67</sup>

The practical appeal of COOP charts stems from their ease of administration (5-7 minutes with paper and pencil), low cost of implementation, and simplicity of scoring. These favorable characteristics of COOP charts have stimulated their use for detecting, quantifying, and identifying the source(s) of decreased functional capacity, guid-

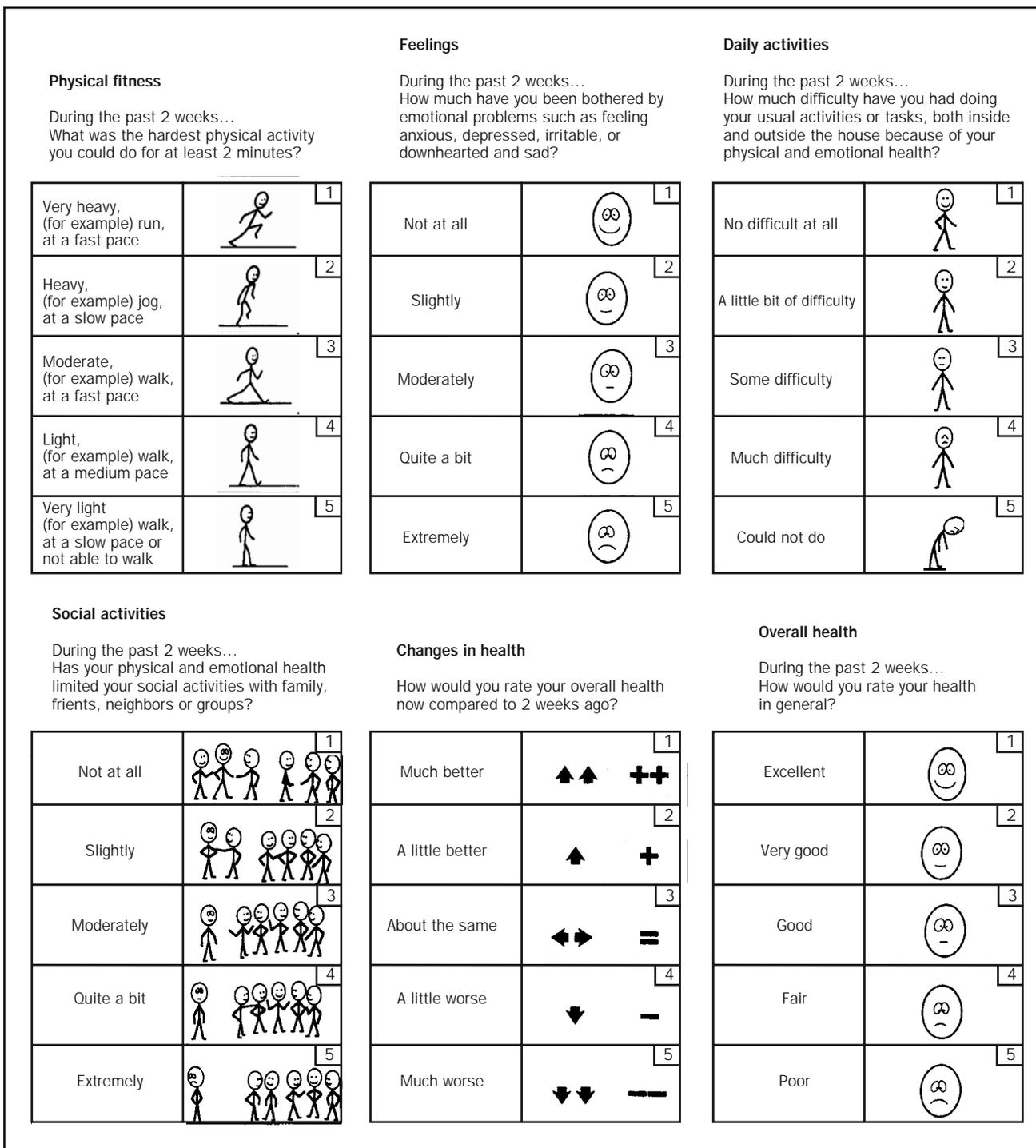


FIGURE 2. Dartmouth Primary Care Cooperative Information Project charts. Reprinted with permission from the Trustees of the Dartmouth COOP (Primary Care Cooperative Information Project) charts.<sup>57</sup>

ing management decisions, guiding the efficient use of resources, improving the prediction of the course of chronic disease, and improving patient outcomes.<sup>68</sup>

**SEXUAL HEALTH INVENTORY FOR MEN**

Sexual health represents one aspect of QOL. However, patients may be reluctant to discuss the topic of sexual

health with clinicians. Routine use of an inventory to assess this potential problem can help open communications on this sensitive topic. The Sexual Health Inventory for Men (SHIM),<sup>69,70</sup> developed and tested to diagnose the presence and severity of erectile dysfunction (ED), is an abridged 5-item version of the 15-item International Index of Erectile Function.<sup>71</sup> The 5 items selected were based on their ability to identify the presence or absence of ED consistent with the definition of ED by the National Institutes of Health as the inability to attain or maintain an erection sufficient for satisfactory sexual performance.<sup>72</sup> Thousands of primary care physicians worldwide have used the SHIM as a diagnostic tool or simple office screening measure for ED.

The SHIM asks men to respond to 5 specific questions about sexual functioning during the previous 6 months (Figure 3), a period suggested in the current National Institutes of Health guideline. Responses to the 5 questions are summed with a possible score range from 1 to 25. Patients who score 21 or less may be at high risk of ED. When administering the SHIM, physicians should ask patients about their desire and opportunity for sexual activity to ensure that low scores are truly indicative of severe ED. This simple tool provides a basis for discussing potential problems caused by other diseases, especially emerging or asymptomatic diseases.

#### CHRONIC RESPIRATORY QUESTIONNAIRE

The Chronic Respiratory Questionnaire (CRQ) is one of the most widely used instruments to assess QOL in patients with COPD. The CRQ includes 10 items across 4 domains: dyspnea (5 items), fatigue (4 items), emotional function (7 items), and mastery (4 items).<sup>73,74</sup> For example, questions about mastery or coping with the disease ask, "In the LAST 2 WEEKS, how much of the time did you feel very confident and sure that you could deal with your illness?"

Examples of other questions across the 4 domains are provided in Figure 4. Both interviewer and self-administered versions of the questionnaire are available.<sup>74-76</sup> When completing this instrument, patients rate their experience on a 7-point scale ranging from 1 (maximum impairment) to 7 (no impairment).

Although the CRQ is often used as an outcome measure in randomized controlled trials of COPD, one of its applications is monitoring efficacy of interventions such as respiratory rehabilitation. Clinicians who supervise respiratory rehabilitation programs compare the efficacy of their programs over time and with those of other programs by routinely administering the CRQ to patients. Because respiratory rehabilitation involves a multispecialty approach that addresses both physical and emotional domains, and

measurement of both domains is important in monitoring the rehabilitation effectiveness. The data also serve to demonstrate efficacy of rehabilitation programs to third-party payers.

#### HEALTH DECISION AIDS

Health decision aids facilitate shared and informed decision making by helping patients and clinicians make specific and deliberate health care choices (including the choice for the status quo).<sup>77-81</sup> They do this in part by providing group-level data about the experiences of others in a similar situation. Decision aids are superior to usual care interventions in improving knowledge and realistic expectations of the benefits and harms of various health care options, reducing passivity in decision making, and lowering decisional conflict due to feeling uninformed.<sup>81</sup> Some decision aids include a clarification of patients' values and preferences for certain health states as they pertain to the decision at hand.<sup>82</sup>

Although only a few studies have investigated the impact of integrating QOL information into decision aids, some evidence indicates that such aids can facilitate acquisition and presentation of QOL information as well as the integration of QOL outcomes into the medical decision-making process.<sup>83-86</sup> Thus, decision aids could support clinicians in presenting QOL information to patients and provide a basis of informed decision making. Future studies should focus on the impact of the different formats for presenting QOL information in decision aids.

For example, patients with moderate to severe COPD face the decision of undergoing long-term treatment with inhaled corticosteroids. Randomized trials suggest that inhaled corticosteroids may reduce exacerbations and hospitalizations and improve QOL, but their daily use may be burdensome to patients and is associated with considerable cost and adverse effects, such as ecchymosis and oral thrush.<sup>87</sup> Presenting QOL information in this context of decision making with decision aids is challenging.<sup>88</sup> One of the presentation formats for this QOL information is the use of absolute risk reduction or the number needed to treat to achieve a minimal important difference with inhaled corticosteroids on a particular QOL. An alternative format includes the time needed to use the medication to achieve an improvement in QOL. These different presentation formats can be compared in randomized trials of patients who make these decisions in which understanding, decisional conflict, and the greatest expected utility are outcome measures of interest.

PATIENT INSTRUCTIONS      SUBJECT'S INITIALS: \_\_\_\_\_      DATE COMPLETED: \_\_\_\_/\_\_\_\_/\_\_\_\_  
DD/MM/YR

Sexual health is an important part of an individual's overall physical and emotional well-being. Erectile dysfunction, also known as impotence, is one type of a very common medical condition affecting sexual health. Fortunately, there are many different treatment options for erectile dysfunction. This questionnaire is designed to help you and your doctor identify if you may be experiencing erectile dysfunction. If you are, you may choose to discuss treatment options with your doctor.

Each question has several possible responses. Circle the number of the response that **best describes** your own situation. Please be sure that you select one and only one response for **each question**.

OVER THE PAST 6 MONTHS:

1. How do you rate your confidence that you could get and keep an erection?

Very low	Low	Moderate	High	Very high
1	2	3	4	5

2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration (entering your partner)?

No sexual activity	Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always or always
0	1	2	3	4	5

3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?

Did not attempt intercourse	Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always or always
0	1	2	3	4	5

4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?

Did not attempt intercourse	Extremely difficult	Very difficult	Difficult	Slightly difficult	Not difficult
0	1	2	3	4	5

5. When you attempted sexual intercourse, how often was it satisfactory for you?

Did not attempt intercourse	Almost never or never	A few times (much less than half the time)	Sometimes (about half the time)	Most times (much more than half the time)	Almost always or always
0	1	2	3	4	5

SCORE: \_\_\_\_\_  
 Add the numbers corresponding to questions 1-5. If your score is 21 or less, you may want to speak with your doctor.

FIGURE 3. Sexual Health Inventory for Men.

**CRQ standardized dyspnea (domain) questions**

Below is a list of activities which make some people with lung problems feel short of breath.

For each of the items below, place an "x" in the box that best describes how much shortness of breath you have had while doing that activity during the LAST 2 WEEKS.

The last column has been provided for you to indicate if you have NOT DONE an activity during the last two weeks.

(Place an "x" in one box on each line)

ACTIVITIES:	Extremely short of breath	Very short of breath	Quite a bit short of breath	Moderate shortness of breath	Some shortness of breath	A little shortness of breath	Not at all short of breath	Not done
1. Feeling emotional such as angry or upset	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Taking care of your basic needs (bathing, showering, eating or dressing)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. Walking	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. Performing chores (such as housework, shopping for groceries)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Participating in social activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**Example of CRQ standardized emotional function (domain) questions**

These next questions ask you about your energy in general and how your mood has been during the LAST 2 WEEKS. Please put an "x" in a box, from 1 to 7, that best describes how you have felt.

In general, how much of the time during the LAST 2 WEEKS have you felt frustrated or impatient?

- 1. All of the time
- 2. Most of the time
- 3. A good bit of the time
- 4. Some of the time  (Place an "x" in one box only)
- 5. A little of the time
- 6. Hardly any of the time
- 7. None of the time

**Example of CRQ standardized mastery (domain) questions**

In the LAST 2 WEEKS, how much of the time did you feel very confident and sure that you could deal with your illness?

- 1. None of the time
- 2. A little of the time
- 3. Some of the time
- 4. A good bit of the time  (Place an "x" in one box only)
- 5. Most of the time
- 6. Almost all of the time
- 7. All of the time

**Example of CRQ standardized fatigue (domain) questions**

What about fatigue? How tired have you felt over the LAST 2 WEEKS?

- 1. Extremely tired
- 2. Very tired
- 3. Quite a bit of tiredness
- 4. Moderately tired  (Place an "x" in one box only)
- 5. Somewhat tired
- 6. A little tired
- 7. Not at all tired

FIGURE 4. Examples of Chronic Respiratory Questionnaire (CRQ) questions.

## FURTHER RESEARCH

In the previous sections we note the importance of QOL data for patient decision making. Several researchers have looked at the process of obtaining QOL information and providing that information to clinicians. We have documentation that computerized approaches are user friendly and are rated favorably by both clinicians and patients. The most frequently measured outcomes in QOL assessment studies were the frequency at which QOL problems were identified and whether communication was enhanced. Both these areas were frequently identified as being increased or enhanced as a result of the integration of a QOL assessment.

Several barriers need to be understood and addressed to implement QOL assessment into the clinical setting. The first and one of the largest barriers is the belief that QOL information can simply be obtained by asking patients how they are doing. As seen in our case example at the beginning of the article, patients make determinations about what they deem important to discuss with their clinician. They may have discussed specific issues in the past with their clinician with no action taken. The patient may interpret this as meaning that these problems are insignificant or that nothing that can be done. As a result, they do not mention these issues again in the future. Convincing clinicians to pilot this and meet in a few weeks to discuss any issues provides them input and the experience of using the instruments for noting additional areas identified with the QOL assessment.

A second barrier is the fact that many clinicians may feel inadequate in their ability to address some of the issues that are identified by patients. A referral process to various ancillary health care professionals needs to be clearly identified for problems not within the clinician's scope of practice. Referring to our case study at the beginning of the article, the patient is seeing an oncologist for a second opinion. Although the instruments used in this setting are useful in identifying oncology-related issues, patients' problems may be much more complex. Most of the issues identified in our case example are a result of concurrent chronic diseases. In this situation, it is important that these problems are identified and that the patient is referred back to her primary care clinician for management.

A third related barrier is the concern that with the identification of additional needs comes the responsibility of addressing those needs. In today's busy clinical practices, clinicians often have difficulty meeting the primary needs for which the patient is being seen. This requires the creative use of interdisciplinary teams to adequately address the patient problems. Setting up the process by which this will occur before initiating QOL assessment will minimize

this barrier. Finally, an approach is needed that requires minimal clinician time for interpretation. The QOL data need to be provided in a manner readily understood by the clinician.

Although work is now being conducted with different methods to generate computer administration of QOL measures, investigations are needed on the development of questions that most efficiently gather a spectrum of QOL information. Additionally, investigators are focused on how to smoothly integrate the assessment into clinical practice so that it is efficient and meaningful to clinicians and patients. Documentation of the most prevalent QOL problems among well-defined populations and the examination of trends in these problems over time are important. The development of guidelines is needed to enable clinicians to take appropriate actions when QOL deficits are identified.

Building research activities that implement QOL assessment into the clinical setting requires use of appropriate theory. Clinicians need to be involved in identifying which of the QOL instruments, at face value, have meaning to their patients. Likewise, clinician stakeholders should be identified to champion the integration of QOL assessment. Guidelines are also needed to enable clinicians to take appropriate actions when QOL deficits are observed for a given patient. Knowledge of available resources that can be used for referral of QOL deficits can decrease possible resistance to assessing a dimension of the patient's life for which the clinician may feel not well prepared to take action.

Although a good foundation of work indicates the benefits of adding QOL assessment into the clinical setting, more work is needed. The integration of QOL data into the clinical setting will occur only if the addition of such assessment data is deemed important in the treatment of patients.

## CONCLUSION

The routine assessment and use of QOL data in clinical settings are consistent with the Institute of Medicine's recommendation of ensuring patient-centered care for chronic illnesses. Patient-centered care can improve the interaction between patients and clinicians by placing the focus on shared decision making and patient self-management. We provided information on the types of QOL data (group vs individual level) available for aiding in shared decision making and improving patient self-management, the communication of QOL information in the clinical setting, different modalities and processes used to obtain QOL data at the individual level, and examples of QOL instruments that have been used to collect QOL data in the clinical setting.

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