This article focuses on the routine use of patient-reported outcomes measures in oncology clinical practice to monitor patient progress and inform decision making; and in particular, on measuring patient-reported health-related quality of life (HRQOL). The article summarizes the current literature on the acceptability to patients and clinicians of HRQOL measurement and on the effectiveness of feedback to clinicians about their patients’ concerns and quality of life. It also describes the experiences recounted by clinicians and researchers who have been implementing such efforts and concludes that in the United States, little HRQOL measurement occurs in oncology practice. That is, much methodological development has occurred, but many challenges to its widespread adoption exist. These challenges include limitations in knowledge about how to apply outcomes instruments, and clinician, patient-related, and health system issues. That effort deserves significant attention now. The way forward, however, does not lie simply in adding HRQOL measurement to other tasks that are part of everyday practice. Rather, attention to principles of effective dissemination and new information infrastructures and technologies, combined with redesign of care, should embed the routine use of patient-reported outcomes in the care process to provide timely response to patients’ needs for information and services. [J Natl Cancer Inst Monogr 2004;33:155–67]

In 1995, one of the foremost outcomes research clinicians in oncology predicted, “It is likely that in the early years of the 21st century, the completion of a quality-of-life questionnaire at a patient visit will be as routine as the taking of vital signs” [p. 65 (1)]. Now that those years have arrived, it is worthwhile to take stock of this prediction and what might lead to its fulfillment. The first article in this monograph (2) describes the “arenas of application” for outcome measures and summarizes three overall uses: macro-, meso-, and microapplications (3,4). This article focuses on the third (micro) use of outcomes measures—the routine use of patient-reported outcomes measures in oncology clinical practice for the purpose of monitoring patient progress and informing decision making for individuals. It describes the current state of practice and the opportunities for and challenges to routine use of outcomes measurement in clinical settings and proposes how this field might advance. Because routine use in clinical practice is not likely to be found in research-oriented peer reviewed journals, this current article includes reports of feasibility studies, personal reports by clinicians and researchers, and examples provided by vendors of practice-based management software.

Physicians have always been concerned about patient outcomes—they are, after all, the reason for follow-up visits. What is different here is the systematic use of validated instruments to gather patient-reported data for use in clinical practice, rather than for research studies. Recent interest in monitoring patients’ health-related quality of life is at least in part a response to the increase in multimodal therapies with diverse toxicities. Improvements in cancer survivorship also make monitoring late effects in patients beyond initial treatment an important focus of follow-up care. To be clinically useful, data on patient health status should be tied to something that a treating clinician can do or provide information for monitoring a patient. It may be that because of their specificity, disease- or even treatment-specific instruments will be more useful than generic ones in the clinical setting. Patient-reported outcomes that might be useful in clinical practice include a variety of measures that include symptoms and side effects of disease and treatment (such as pain, fatigue, and shortness of breath) as well as measures that combine symptoms, functional performance, and social well-being—collectively referred to as health-related quality of life (HRQOL). HRQOL is generally considered to include a number of domains: physical functioning; psychological well-being (e.g., level of anxiety, depression, fear of recurrence); and social functioning, recognizing that, in some cases, patients report positive effects of cancer diagnosis and treatment as well as negative ones (5). Other patient-focused outcomes not addressed in this article include satisfaction, the patient experience of care, and the quality of death including symptom control, psychological distress, the setting of death, and caregiver experience (6–10).

Four questions are addressed in this article: What have we learned about outcomes measurement in clinical oncology practice—is it feasible, acceptable, and useful to patients and clinicians? Does anyone currently use HRQOL measurement in routine oncology practice? What are the challenges to widespread adoption of this arena of outcomes measurement in clinical practice? Finally, what might foster the routine use of outcomes measurement in oncology practice?

METHODS

Three methods were used to locate information: peer reviewed and other published literature, interviews with experts, and the Internet. The literature search included peer reviewed and other published literature written in English between January 1990 and December 2002 and found in Medline, CINHAL, and the Cochrane Collection, and “related articles” linked to them in Medline. Search terms included the MESH terms outcome assessment (Health Care) in combination with other terms including patient care, ambulatory care, outpatient services, hospice, long-term care, palliative care, cancer, neoplasms, oncologic care, quality of life, health status, decision support.

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systems, clinical feasibility studies, patient-centered care, patient–physician relations, medical informatics, and computers (handheld). Papers not in English or published before January 1, 1990, were excluded.

The literature review focused on outcomes measurement in outpatient and acute inpatient settings but also included applications in hospice, home-care, and long-term care settings. Other articles addressed outcomes measurement for clinical decision support, quality-of-care measurement and improvement, end-of-life care, and opportunities to integrate outcomes measurement and newly emerging information technologies. Papers were identified by combining searches of electronic databases and hand searches of relevant references cited in those papers. A search of the Internet included the Web pages of health care software vendors and management companies, professional societies, and patient advocacy organizations, and follow-up inquiries to relevant groups or companies. Relevant Listservs were also queried.

A “snowball” contact strategy was used to identify and contact quality-of-life measurement experts, oncologists, and other health care practitioners in the United States and Europe to learn about their experiences in implementing outcomes measurement in clinical settings and to ask them to identify other experts who were knowledgeable or who might have implemented routine use of outcomes measures in their practices.

HRQOL

Researchers have developed health status measures for a broad array of health conditions (including cancer) and have described many potential uses for HRQOL information in the clinical setting (1,4,10–15). Such uses include help in patient monitoring, diagnosis, treatment, and communication (Table 1).

In addition to individual patient care, such information might be used at the clinic or group practice level to measure the quality of care and design system interventions, reallocate resources and research efforts, train health care personnel, and characterize a patient population.

The purpose of assessment may affect the choice of instrument, patient population, timing, and frequency of administration (16). For example, HRQOL measures for screening might be used as part of initial evaluation for all patients having a first visit (17) or for high-risk patients. Monitoring disease progression or response to treatment, in contrast, might occur at set intervals or during a particular phase of care.

Once a need for measurement is recognized, the starting point in outcomes measurement in clinical settings has commonly been to consider the choice of instrument and mode of administration. These are but early steps, however, in a series of processes that include enlisting patients, scoring and providing results to clinicians, using the results to make decisions, implementing those decisions (including drawing on other resources as needed), and tracking change. For example, pain is a widely underestimated and undertreated cancer symptom (18,19) that might respond to actions such as in the following example. First, a patient identifies pain using a simple analog scale or symptom check list. Based on scoring rules, the patient’s duration or intensity of pain is above a given threshold. An oncologist or other health professional notes the result within an acceptable time; reviews possible actions with the patient in view of his or her history, course of therapy, and other medical conditions; and the two decide on the best course of action. The oncologist has timely access to chosen resources (such as prescribing pain medication, a pain management service, or equipment for patient-administered analgesia) and ensures they are implemented quickly. Repeated measures track how successful these measures have been and whether further actions need to be taken. Data about pain management for groups of patients are available for review and possible external reporting. This set of processes is likely to be stymied unless organizational systems have been put in place to accommodate efforts to measure and to act.

In 1992, participants in a conference on the use of health status measures in a variety of (noncancer) clinical settings concluded that routine clinical use of outcomes measurement was feasible and desirable but that health status measures were being used “mostly for purposes other than routine care” [p. MS1 (11)]. The same remains true in oncology today. Nevertheless, interest in patient-reported outcomes continues among clinical and health services researchers in noncancer and cancer care. Shortcomings in instruments available at the time of the 1992 conference have subsequently been addressed, and researchers have developed disease-specific and symptom-specific instruments. This has resulted in some instances of their use in routine, noncancer clinical practice, such as for assessing patients with eye problems and men with benign prostatic hypertrophy. For example, in some large ophthalmology practices, the VF-14 is

<table>
<thead>
<tr>
<th>Assess</th>
<th>Monitor</th>
<th>Diagnose</th>
<th>Treat</th>
<th>Facilitate communication</th>
<th>Reduce costs?</th>
</tr>
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<tbody>
<tr>
<td>Describe the status of patients entering care or therapy</td>
<td>Evaluate disease progression and response to treatment</td>
<td>Detect, measure, and identify the source(s) of decreased functional capacity</td>
<td>Apply results of clinical trials that have collected HRQOL data to choice of treatments</td>
<td>Foster shared decision making to improve treatment planning and guide changes in therapeutic plans that are consistent with patient preferences</td>
<td>More self-management, possibly more efficient use of resources?</td>
</tr>
<tr>
<td>Detect treatable problems that may be overlooked during patient care (e.g., rehabilitative services, education, nutritional counseling)</td>
<td>Detect, measure, and identify the source(s) of decreased functional capacity</td>
<td>Better differentiate physical, emotional, and other problems</td>
<td>Predict the course of disease (including survival)</td>
<td>Provide feedback to patients about their progress and explore goals and expectations</td>
<td></td>
</tr>
<tr>
<td>Evaluate disease progression and response to treatment</td>
<td>Better detect treatment toxicity and side effects</td>
<td>Better detect unexpected adverse effects of drug and other therapy</td>
<td></td>
<td>More timely reporting and management of symptoms, reduction in anxiety, fewer preventable visits/calls</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Foster patient adherence to therapeutic advice</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>Improve satisfaction with care, less litigation?</td>
<td></td>
</tr>
</tbody>
</table>

Table 1. Potential benefits of HRQOL measurement in clinical practice*

*HRQOL = health-related quality of life.

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widely used to assess the effect of limited vision on a person’s ability to function in order to determine the need for and the effect of treatments for a variety of eye diseases, including cataract; other disease-specific measures are being used as well (E. Steinberg, personal communication, December 2002). Similarly, in urologic practice, the American Urological Association’s AUA-7 (which measures symptoms in men with benign prostatic hypertrophy) as well as other instruments are used in clinical practice, and clinicians are familiar with their scoring systems and clinical interpretation (M. Barry, personal communication, December 2002). Other researchers have reported the use of outcomes measurement for patients with epilepsy (20), asthma (21), orthopedics (22), low back pain (23), and mental health services (24,25).

**Feasibility, Acceptability, and Effectiveness of Using HRQOL Measurement in Oncology Practice**

Several groups of researchers have reported on studies of the feasibility, acceptability, and effectiveness of outcomes measurement in oncology practice (see Appendix: http://jncicancerspectrum.oupjournals.org/jncimono/). These include Maunsell (26), Osoba and colleagues (27), Taenzner and colleagues (28–30), Velikova and colleagues (31–35), and Detmar and colleagues (36,37). This work is summarized by Davis and Cella (38). These groups of researchers found that in well-designed evaluations of the effect of reports on functional health assessment and well-being, clinicians have consistently reported positive findings about the feasibility and potential value of outcomes reporting in clinical oncology. They found that it improved clinicians’ ability to identify HRQOL problems, and they reported some changes in clinical practice, including better communication about quality-of-life problems. Both paper-and-pencil instruments and touch-screen computers are evidently acceptable even to patients without prior computer experience, and pilot studies have found no increased time required for patient visits. Physicians have repeatedly reported that printouts are useful to them. Researchers have also demonstrated some improvement in the process of care and patient health outcomes.

Publication bias, however, may favor positive results if researchers are either unwilling or unable to publish negative results, and several researchers have noted the difficulties in developing systems that would enable ongoing monitoring. For example, Houts concluded that although patients were willing and able to answer questions on the computer if someone was there to assist, his own project was eventually abandoned because clinicians did not use the results (P. Houts, personal communication, September 2002).

The University of Michigan’s comprehensive cancer center stopped using its HRQOL instrument in a project to improve care at the end of life after finding that many terminally ill patients were either unable to or refused to complete the instrument; however, a revised version is being developed by the instrument’s authors (M. Merriman, personal communication, December 2002).

Similarly, Wright et al. (39) reported incomplete patient participation in HRQOL assessment in the United Kingdom. They asked one group of new patients to complete the QLQ-C30 and HADS (40) at each visit for 6 months. The authors found partial patient compliance with touch-screen administration—82% of patients willingly completed the questionnaires at the initial assessment, but compliance substantially declined at subsequent visits, with median compliance for all visits reaching only 43%. A second group included patients in an adjuvant chemotherapy clinic, a medical oncology clinic, or hospital oncology wards. In this group, patient participation was 74%, but many patients said they were too unwell, distressed, uninterested, unable to speak English, or unfamiliar with computers to complete questionnaires. Completion rates were lowered because of problems with the technology and data that were missed by the researcher because visits were acute or unscheduled. Given these researchers’ experiences, questions of respondent burden, acceptability to patients (especially those who are very ill or distressed), need for repeated measurement over time, and effectiveness of feedback to oncologist still merit investigation.

Though not focused on cancer, two recent systematic reviews summarize the last decade’s findings on the effectiveness of feedback to clinicians about their patient’s self-reported health (41,42). Greenhalgh and Meadows (41) located 13 relevant studies published between 1987 and 1997. Although clinicians reported that patient-reported information was valuable, particularly in detecting psychological problems, the authors found little evidence of routine use or that such feedback changed patient management or improved patient outcomes. They underscored the need for implementation strategies that used well-grounded approaches to individual and organizational change.

Espallargues et al. (42) identified 21 studies published between 1966 and 1997 that assessed change in the process of care, health status, and patient satisfaction. They concluded that feedback about patients’ perceived health status seemed to have an effect on the process of care but not on patient function or health status including mental health status. Subsequently, Goldman (43) stressed the importance of both specificity of clinician feedback and resources for responding to patients’ needs. For example, Rubenstein et al. (44) successfully provided clinicians with patient management and resource suggestions linked to specific patient’s responses. These findings indicate that providing feedback to clinicians is a first step but not, by itself, an effective intervention without the provision of resources to respond to patient needs.

**Oncologist Views on Measuring Quality of Life in Clinical Practice**

Over the last 7 years, several groups have reported on surveys of oncologists. In 1998, Tanaka and Gotay (45) surveyed oncologists and medical students in Hawaii (response rate, 69%). Asked about their attitudes toward and measurement of HRQOL in clinical practice, all respondents reported assessing HRQOL at least informally with all patients, and they believed that HRQOL was at least as important as survival in treatment decision making. However, less than 10% of respondent oncologists used a HRQOL questionnaire, and medical students strongly preferred interviews to questionnaires (as might be expected because the students had not been trained in the use of such instruments).

Acceptance of HRQOL measurement appears to be more widespread in New Zealand, Australia, and Hong Kong (46) than the United States. Morris, Perez, and McNee (46) surveyed oncologists in those countries. Forty-seven percent of respondents said that they used either standardized questionnaires or a system derived in their unit to assess patients’ HRQOL, particularly at the beginning of treatment. Less than 50% of respon-
tions monitored HRQOL as a response to treatment, however, even when the treatment goal was palliation. Respondents identified time and resource constraints, perceived lack of an appropriate instrument, and a belief that HRQOL assessments were unnecessary as their reasons for not collecting HRQOL data. Given an appropriate instrument, however, the majority believed that HRQOL data could be collected on a routine basis.

Medical, surgical, and radiation oncologists completed surveys described in a series of reports by Bezjak and her colleagues (47–50). In their 1996 survey (47), a majority of Canadian and U.S. respondents perceived HRQOL as important. They reported gathering data informally and only in some situations, with HRQOL information most likely to be collected by nonphysicians. Seven percent collected and used HRQOL information themselves. Eighty-eight percent of respondents thought that HRQOL could be better defined, but they differed considerably in their own definitions. Although 85% of respondents stated that HRQOL could be formally measured, only a third perceived that current instruments provided valid and reliable data.

In 1997, Bezjak et al. (48) reported on a survey of an international group of 28, mostly gynecologic, oncologists. The majority of respondents believed that HRQOL can be measured, but that it should be measured by nonphysicians. In 1998, 67 staff oncologists (response rate 80%) at Princess Margaret Hospital (Toronto) responded to questions about their knowledge, attitude, current behavior, and willingness to use HRQOL information (49). Seventy-three percent agreed that, “QOL instruments give clinically relevant information for individual patients” [49], p. 232, and most respondents did not believe that nurses should bear the responsibility of collecting such information. In contrast, in a subsequent survey of participants in the National Cancer Institute-supported Eastern Cooperative Oncology Group (50), three quarters of respondents said they would be willing to use formal HRQOL assessment only “if required to do so by my institution or regulatory body.” [50], p. 7.

**ROUTINE USES OF HRQOL MEASUREMENT**

**Outpatient and Office Practice**

Despite the surveys indicating that oncologists outside the United States do use HRQOL measurement in their practices, it is difficult to identify documented routine uses of HRQOL measurement in oncology outpatient or office practice in the United States today. A few examples provide a sense of the range, if not frequency, of various uses of outcomes measures. One might expect a key area to be monitoring symptoms and side effects of patients undergoing adjuvant therapy such as chemotherapy or radiation therapy. In an illustrative example, US Oncology—a U.S. firm providing cancer center services, clinical research, and administrative support—provides a flow sheet for outpatient chemotherapy. An oncology nurse tracks symptoms as well as laboratory values and vital signs on the infusion flow sheet. Most of the symptoms are physical, but the flow sheet includes “coping problems” as well. It is not clear how those data are used.

James Zabara, a clinical oncology social worker, has been using the Brief Symptom Inventory (BSI-18) (50), a paper-and-pencil instrument, for about 10 years to identify cancer patients with elevated levels of distress who are in need of clinical intervention (J. Zabara, personal communication, November 2002). Six questions deal with somatic symptoms, six with anxiety, and six with depression. Staff sum patient responses, and patients are triaged to further assessment or possibly a 90-minute problem-solving skill class. A notation that the patient has completed the BSI-18 is documented in the patient’s medical record.

Barr et al. (52) have reported on the use of information about the global health status of children with brain tumors to track the effect of disease and treatment and as an aide for discussions with patients and their families.

In another U.S. example, Chang and his colleagues at Northwestern University have an ongoing study using a handheld touch-screen computer in a clinic. Patients with lung cancer complete the FACT-L (Functional Assessment of Cancer Therapy—Lung) (53) in the waiting area, and a profile is printed out or available on the personal computer to treating clinicians. To enable clinicians to interpret results rapidly, Chang uses a color-coded graphic display to indicate whether a patient’s score on a given scale is improving, the same, or significantly worse (54). Another project incorporates similar features but uses interactive voice recognition (55). Patients with breast cancer call in to the ComPASS system and answer a prerecorded FACT-B (Functional Assessment of Cancer Therapy—Breast) (56) questionnaire; a summary report is generated. Finally, in another setting, the Familial Cancer Clinic at the Mayo Clinic (Rochester, MN) routinely uses the SF-36, Profiles of Mood States, and trait anxiety measurement as screening instruments for new patients being assessed for genetic cancer risk (M. Frost, personal communication, November 2002).

In the only published non-U.S. example found, Albert et al. (57) have described their implementation of an integrated, structured system of care for patients with breast or rectal cancer in the Marburg-Biedenkopf region of Germany. Using academic detailing, outreach visits, and continuing medical education, they trained oncologists in the interpretation of HRQOL results and then provided QLQ-C-30 and EORTC BR23 (for breast cancer) patient profiles presented in graphic format over a 5-year period. They also gave oncologists a list of resources in the region that were available to patients such as pain relief and therapy, physiotherapy, psychotherapy, improving physical fitness (sports and nutrition), and social rehabilitation.

One of the most widely suggested uses of HRQOL data is in predicting patient survival (58–66). That said, the review for this article revealed no documented examples of use for this purpose in routine clinical practice.

**Inpatient Care**

Review of the literature and searches for vendors and organizations have revealed little real-time online use and charting of patient-reported outcomes even for the most obvious application in inpatient services—pain management and assessment, a symptom that is required to be monitored by both the Joint Commission on Accreditation of Healthcare Organizations and the Department of Veterans Affairs. Only one personal digital assistant (PDA) or other software application has been identified that would permit assessment and charting of pain management as part of medication administration (66), and no users of this software in oncology services could be identified.

**Long-Term Care**

Although not directed specifically toward cancer patients, two instruments have been developed to monitor the progress of Medicare beneficiaries. Home-care organizations administer the...
Outcomes and Assessment Information Set (OASIS) on admission and every 60 days or at discharge. Its use in a multiyear demonstration project has documented improvement in patient outcomes (reduction in hospitalizations and targeted clinical outcomes), but Shaughnessy et al. (68) did not report how OASIS assessments contributed to these outcomes.

In nursing homes, the counterpart of OASIS is the Minimum Data Set (MDS) mandated for Medicare beneficiaries receiving nursing home care. MDS provides longitudinal data capture and is rich in data on functional status and comorbidities (69). MDS is administered by regulatory instruction on admission and periodically during the stay. It is not clear, however, how these data are used in patient management decisions.

**Palliative Care and Hospice**

Palliative care is appropriate across the continuum of cancer care, but especially during the final phase of illness (70). Several instruments have been developed for use with patients at the end of life, including Hospice Quality-of-Life Index (71) and The Missoula-Vitas Quality-of-Life Index (MVQOLI) (72). Some hospices use the MVQOLI for initial clinical assessment but have found it less useful for tracking patient progress, primarily because of short lengths of stay (M. Merriman, personal communication, November 2002). Other instruments include the Pain Assessment Tool and the Physical/Emotional Symptom Tracking Tool (73) used by grantees of the Robert Wood Johnson Foundation–funded program, Promoting Excellence in End-Of-Life Care (74).

For example, the Dartmouth-Hitchcock Medical Center focused on end-of-life care at the Norris Cotton Cancer Center and two New Hampshire rural communities. The team assessed the needs of the patients, coordinated services, and provided palliative care throughout the course of cancer treatment using FACT-L, MVQOLI, Symptom Self-Assessment, and (for family) the After-Death Interview (75). Using similar instruments, the next phase of this study is being conducted within the Norris Cotton Cancer Center. The investigators report they are pleased with the FACT-L and the Symptom Self-Assessment scale. The patients find them easy to complete, and they provide clinically relevant data.

Some symptom scales are used in both oncology and other fields of medicine. Extensive work has been conducted over the last 15–20 years to validate instruments, and the Medical Outcomes Trust (77) spearheaded work to develop, evaluate, and distribute standardized, high-quality instruments. In the oncology field, the Cancer Outcomes Measures Working Group, convened by the National Cancer Institute, is completing a 2-year assessment of the state of the science of available outcomes measures, including HRQOL (78). At a minimum, agreement about the domains of HRQOL may reduce the wide differences in views among clinicians about the scope of this term.

Several issues continue to be raised. First, the validity of these measures for tracking individual progress and guiding patient care is still under investigation. Use of identical items for all patients raises important questions about whether instruments adequately represent an individual patient’s expectations, perceived needs, and preferences (79). These points are especially relevant given the disparities that have been found between doctors’ and relatives’ ratings of patients’ quality of life and the ratings given by patients themselves—including patients with advanced cancer and those with moderate to severe disabilities.

**Table 2. Challenges to the routine use of HRQOL in clinical oncology practice**

<table>
<thead>
<tr>
<th>State-of-the-art of measurement instruments</th>
<th>Validity for tracking individuals rather than groups</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Validity of response weighting for a given individual’s preferences</td>
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<td></td>
<td>Clinical responsiveness/meaning of score changes for therapeutic management</td>
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<tr>
<td></td>
<td>Reliability for tracking individuals over time</td>
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<td></td>
<td>Evidence of value in improving patient care and patient outcomes</td>
</tr>
<tr>
<td>Clinician-related issues</td>
<td>Ease of use/interpretation</td>
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<tr>
<td></td>
<td>Agreement about best instruments for intended purpose and population</td>
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<tr>
<td></td>
<td>Effect on clinic work flow</td>
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<td></td>
<td>Resource constraints for data collection and management</td>
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<td></td>
<td>Reimbursement/coverage</td>
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<td></td>
<td>Legal issues</td>
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<tr>
<td>Health care delivery systems</td>
<td>Resources for data collection and management</td>
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<td></td>
<td>Resources for timely review of data</td>
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<td></td>
<td>Resources for response to patient needs</td>
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<tr>
<td>Patient-related</td>
<td>Access to and use of data by others who are not treating clinicians</td>
</tr>
<tr>
<td></td>
<td>Patient burden</td>
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<tr>
<td></td>
<td>Use of data by others who are not the treating clinicians</td>
</tr>
<tr>
<td></td>
<td>Effect on patient-clinician relationship</td>
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</tbody>
</table>

*HRQOL = health-related quality of life.
Such patients often rate their quality of life much higher than observers expect.

A second issue is precision. Instruments to guide palliative care for individuals will require the highest level of precision and will likely need to be cancer-, cancer-site-, and possibly treatment-specific (4) if they are to have clinical utility (80). There is still need for a common understanding about the clinical significance of a change in score (1,81–85); that is, when a change in score warrants a change in patient management. Another concern is reliability; that is, the consistency of scores across repeated measurement. Reliability will need to be assured before clinicians can be confident that a change in HRQOL scores indicates a change in underlying health status attributable to the course of disease or treatment. This is especially important when measuring pediatric HRQOL because of expected age-related changes for a given child (86).

Clinician-Related Issues

Key questions that clinicians will need addressed are as follows: What is the use of HRQOL intended to accomplish? Is such measurement needed? If so, how will they know if its use is an improvement? Finally, what needs to occur to make this happen?

Evidence beyond current pilot studies needs to be marshaled that use of HRQOL information can and does benefit patients. There is little value to precise, reliable, and responsive measures if their use does not result in improved patient outcomes. If beneficial, fostering its use will require attention to clinician issues: their familiarity with and acceptance of HRQOL assessment in patient care, its ease of use and interpretation, the expected effect on patient flow and practice income, the effect on staffing for collection of data, any effect on legal vulnerability, and specifying who the appropriate users of such data are.

Acceptability of HRQOL assessment. Use of HRQOL in clinical practice depends on familiarity with and acceptance of this idea by an oncology team and its leadership. As described above, surveys of oncologists and medical students in the United States and especially in Europe and Asia indicate acceptance of the idea of measuring HRQOL, at least informally. The term still means many different things to clinicians, though, and there is not necessarily a broad acceptance that HRQOL is a multidimensional construct that can be measured using rigorously developed instruments (49,87).

As noted, use of HRQOL in clinical oncology practices for nonresearch purposes is still extremely rare in this country. Respondents have identified many reasons for not collecting HRQOL data, including a belief that HRQOL assessments are unnecessary and perceived lack of an appropriate instrument. It may be particularly important for acceptability of HRQOL measurement to achieve consensus among researchers and oncologists about a limited number of widely accepted instruments or core measures in those instruments that have been validated for clinical use and clinical trials.

Clinicians have not, to date, been trained in the use and interpretation of HRQOL instruments. It is difficult for oncologists to choose among instruments, determine the best timing of administration, or know when in the continuum of cancer care these instruments would be most appropriate or useful, and they will need assistance in choosing an appropriate instrument for a specific purpose, setting, and population in which it will be used. Although some researchers have trained oncologists in the use and interpretation of their instruments, few clinicians are likely to be familiar with the psychometric properties of various HRQOL measures or their interpretation.

Unlike laboratory values, imaging, or tumor response data with which they are very familiar, practicing oncologists view HRQOL assessment results as difficult to interpret in a clinical setting. It is not always clear how to interpret a change in score and to know whether or what intervention would be helpful (3,5). Ease of use and clinical relevance is crucial. In response, researchers have sought ways to make very brief, easily interpretable time-trend results available in graphic format in the patient record for monitoring patient progress or response to treatment. In addition, Ganz believes that, to be acceptable to clinicians, results need to be sensitive and specific and related to concrete actions that clinicians can take. The results should not, for example, be reported only as summary measures of global well-being (P. Ganz, personal communication, December 2002).

Time and reimbursement. Another possible barrier to use of HRQOL measurement in oncology practice is the time required and reimbursement for that time. In the United States, where care is frequently reimbursed by billable units of service, time spent gathering or interpreting HRQOL information as part of the clinical encounter is not built into reimbursement by third-party payers. Oncologists worry that any new activity may lengthen the patient visit by raising new patient issues, may impair their ability to see their patients in a timely way, may increase operational costs, and may reduce net income. In the United States, outcomes measurement will need to be reimbursed if this is not to remain a major obstacle to its use.

It is not clear whether HRQOL measurement will make visits more or less efficient. Some have argued that use of HRQOL information can quickly supplement the patient interview by covering a broader range of domains than patients may feel invited to discuss (e.g., social stigmatizing issues such as bowel problems or depression) or about which clinicians routinely inquire (8). However, some clinicians worry that use of a formal instrument may interfere with, or be meant to substitute for, the patient interview in which a patient is commonly asked a more global question such as, “How are you doing?” (88). Such an open-ended question invites the patient to choose his or own priorities for responding, and the clinician then uses his or her judgment to follow up, based not on a standardized quantitative score but on a given patient’s circumstances and experience of disease and treatment. From the perspective of practice management, the known efficiency of the traditional approach must be weighed against new ones that may open the brief time available for a clinic visit to many problems to which clinicians do not feel they can offer effective solutions.

A final issue is the possible creation of new standards of care and legal vulnerability. Once tools are shown to be clinically responsive, useful, and effective, their use may not only help to provide better cancer care—including mental health—but also to become a new standard of care that defines good medical care as including systematic measurement of HRQOL (89). Failure to respond to problems documented in an HRQOL instrument—such as severe depression or other symptoms for which effective interventions exist—might create new forms of practice liability.

Users of HRQOL data. Although most studies have focused on oncologists, oncology nurses have reported that HRQOL measurement may be useful (30). Depending on the team’s
structure and its members’ preferences, instruments might be used in a variety of ways. For example, users might include the oncologist during a patient visit, an oncology nurse specialist, nurse practitioner, care manager, or social worker who would screen and refer patients for further assessment or services or alert oncologists to out-of-range responses. Such use by other practitioners in home care and palliative care, for example, is well established and has been reported in other settings (90).

Health Care Delivery System Issues

Even researchers whose principal focus is HRQOL measurement have difficulty instituting change in their clinic practice and institutions. Major challenges include availability of resources for administering the instruments and incorporating data into clinic workflow. Other issues that may become important are access to and use of the data by those who are not treating clinicians.

Resources for outcomes data management and use. Ensuring that resources are available for routine data collection and management is likely to be a major challenge. An HRQOL research study may include funding for staff assistance to enlist patients, demonstrate the use of technologies, answer questions, troubleshoot technical problems, and insert results into patient records. However, institutions generally cannot add these new functions to the work of current support staff such as receptionists and nurse assistants. In addition, resources to respond to patient problems, such as pain services, mental health consultation, social services, nutritional counseling, and information about community resources, might need to be added or better coordinated. Such interventions also have implications for the cost of care, workforce capacity, and the increased administrative complexity that is created when various insurance plans do or do not cover certain services that patient reports indicate are needed.

Someone must be responsible for monitoring and acting on HRQOL data when specific patient needs are recognized (91). If data are collected routinely, mechanisms must also be developed to ensure that responses are reviewed and responded to in a timely way. Collecting information at the time of a patient visit and placing the results on or in the patient’s record is one method, but others are increasingly possible; for example, Web-based or other applications that allow patients to enter data off site using a home personal computer or wireless device. In such cases, administrative attention (and resources) must be devoted to ensuring a timely and effective system of review (another demand on resources) and, if possible, linking those data with the primary medical record.

Access to and use of data by users other than treating clinicians. Finally, medical and administrative leadership in these health care delivery systems will want to know who will have access to the results of measurement and for what purposes. Will results be available to researchers, purchasers, health plans, accrediting or regulatory bodies? Will aggregate information be available for reporting at the institutional, local, state, or federal level? Will results be used to judge individual and institutional performance?

All such issues will affect the adoption of HRQOL measurement. Removing one constraint may not be sufficient, and progress will surely require multi-level interventions that address the clinician–patient visit, the clinical “micro-system,” and the larger health care organization in which it may be embedded.

Patient-Related Issues

Patients will be faced with a number of issues when asked to complete HRQOL instruments, including their acceptance of the burden of data collection, use of data by those who are not treating clinicians, and how use of the instruments may change the patient–clinician communication and relationship.

Acceptability. Patient-reported measures will never be widely adopted unless they are acceptable to patients and are viewed as having some utility. Will patients be willing to complete instruments on a repeated basis, especially those who are very ill, and if so, how great a respondent burden does this pose? Acceptability will be affected not only by the length but also by whether an instrument taps domains that are important to the patient and allows for an appropriate range of responses. It will also be affected by whether their efforts to comply result in any benefit that patients can see.

Some researchers have reported that missing HRQOL data (5) is an ongoing problem encountered in clinical trials. In a practice environment that is not managed under protocols (as in clinical trials), will patient refusal or incomplete response be a greater problem? Feasibility studies have shown that most patients in such studies are willing and able to use a variety of input devices such as touch-screen tablets (19,27,92), though the viewing screen of a PDA may be too small. New measurement approaches such as computer-adaptive administration and item banking will make data collection more precise and efficient and will reduce respondent burden (93) by tailoring questions to the patient. Such computer-based technologies for administering instruments can ease respondent burden by automatically selecting appropriate questions and omitting irrelevant ones. Databases that store and display earlier responses for patients who are asked to complete repeated instruments may also reduce burden.

Use and failure to use patient HRQOL information. New questions arise after patients have completed their HRQOL instruments. Research studies (including clinical trials) begin with institutional review board approval and consent forms indicating that data will be collected for research purposes. Data collected for routine patient care, however, do not require such institutional review board–approved informed consent. If patients are formally queried about their HRQOL as part of their care, might they not reasonably expect that information to be given to their treating clinician and that such information will be used in their care? When patients provide personal health information for routine care, what should they be told about the use, storage, and confidentiality of their patient-identifiable information? Health Insurance Portability and Accountability Act–compliant policies and procedures will need be in place to safeguard data from unauthorized disclosure, especially if the data are collected and managed by vendors. Patients may justifiably wish to access their own data to track their progress and learn about options for their care, and they should have the option of doing so.

Effect on communication and the patient–clinician relationship. Helping patients monitor their own changes in HRQOL and discussing this with their oncologist may foster their involvement in their own care, providing more assurance about their ability to manage symptoms themselves. Studies by Velikova and her colleagues in the United Kingdom (34) and by Detmar and colleagues (37) in The Netherlands have shown that feedback to clinicians of HRQOL results has improved communication and recognition of problems. It will be useful to see whether these findings are replicated. In particular, will the
promise of HRQOL measurement in improving patient communication and shared decision making be realized in routine practice, or will it distract from the patient’s visit and impede the integration of medical information. Adding HRQOL measurement as a new data collection effort will require attention to the information infrastructure supporting it. Implementation of the long-awaited computer-based patient record (or at least an infrastructure that uses common data standards to link many clinical information systems) may foster the collection, incorporation of, and timely access to HRQOL data just as laboratory and pathology data are increasingly available as part of integrated clinical information systems. The use of structured terms, reference vocabularies, and values could also advance the use of HRQOL data in new computer-based information systems.

**POSSIBLE WAYS FORWARD**

Sederer et al. (94) have outlined the “ideal system” of HRQOL assessment for clinical practice. HRQOL measurement, they said, needs to be useful and timely, sensitive to change, culturally sensitive, low burden, and low cost. In addition, the ideal system needs to involve the patient, be built into the delivery of care, meet requirements for continuous quality improvement, and satisfy regulators, accreditors, payers, and the consumer community. Putting such systems in place should draw on principles of effective dissemination. If implementing complex systems all at once is not realistic, it may be possible to devise a “good enough” strategy and implement it on a small scale, evaluate its strengths and weaknesses, and increase its scope as warranted. As clinical leaders in some organizations devise successful structures, they could share their experience professionally and provide a “toolkit” of useful approaches.

Progress is being made. In Canada, recognition of the need for training and broader use has resulted in oncology residents having questions about HRQOL in their specialty certification examination. When instituted on a pilot basis and encouraged by members of a clinical oncology team, HRQOL reports have been accepted by colleagues as useful even if measurement has not, to date, been incorporated into routine practice.

This indicates that the major challenge to outcome measurement may lie less in opposition to the idea of measuring outcomes than in doubt or uncertainty about how to integrate such measurement into the health care process. That is, many clinicians and administrators view the collection of patient-reported data as an add-on to established systems of care that seem already to be working at capacity. Most cancer patients do not expect or demand it. In addition, patient-reported measurement in oncology is neither part of a shared understanding about a standard of care nor required in the United States by accrediting bodies or training programs. At this point it is unlikely to be useful to urge clinicians and their support staff to work yet faster or harder to add more activities to their daily work, particularly if collecting, accessing, and using such information requires unreimbursed time and effort.

Achieving the potential for patient-reported outcomes to improve patient care may be advanced in some health care systems as the result of the leadership of energetic and committed individuals; however, on a broad scale this will almost certainly require specific attention to information technology and infrastructure and to systems of care designed to accomplish these objectives. Incarnation of HRQOL will likely require new attitudes not only toward patient-reported data but also to the function of medical records and patient encounters and may require new ways of organizing patient-clinician interactions, new ways of collecting data, and new flows of information (95). Two health care delivery issues will require particular attention: information infrastructure and technologies to support it, and redesigned systems of care that focus on patients’ needs and preferences.

**Information Infrastructure and Technology—HRQOL Data Collection**

Health care organizations and clinics are often thwarted by multiple, stand-alone, “legacy” or proprietary systems that impede the integration of medical information. Adding HRQOL measurement as a new data collection effort will require attention to the information infrastructure supporting it. Implementation of the long-awaited computer-based patient record (or at least an infrastructure that uses common data standards to link many clinical information systems) may foster the collection, incorporation of, and timely access to HRQOL data just as laboratory and pathology data are increasingly available as part of integrated clinical information systems. The use of structured terms, reference vocabularies, and values could also advance the use of HRQOL data in new computer-based information systems.

Furthermore, use of core HRQOL elements that span cancer types as well as noncancer conditions, such as diabetes and arthritis, may foster broader and more regular use of such data (98) in health care organizations (97). Just as treating clinicians no longer draw a patient’s blood for laboratory tests themselves, perhaps they could refer patients to a “QOL lab” that would select from an array of instruments tailored to the needs of a given patient. Using personal computers on site, patients would provide information to be returned to their physicians and to themselves. An alternative method of administration would use a patient’s own electronic technologies (such as a home computer) to complete instruments by logging into database applications on organizational Web sites.

New technologies that mitigate barriers to routine collection of patient-reported information are being evaluated for their acceptability and reliability, compared with traditional paper-and-pencil or interview methods, and with regard to their burden to patients and clinical staff (31,98–100). Technologies for patient assessment during an office visit include patient entry by touch-screen monitors and tablets. In addition, however, other technologies might be used; for example, telephone-based interactive voice entry; telephone-based touch pad; wireless PDA; or direct keyboard entry using a Web-based application or installed software, Web-enabled cell phone, kiosk, or WebTV. These technologies can also be coupled with monitors that are worn by the patient or attached to the device using systems devised for telemedicine and telehomecare (101,102). At least one demonstration project uses an Internet-based platform for asynchronous data collection. The CHES project (Comprehensive Health Enhancement Support System) gathers information from patients with breast or prostate cancer who use a home computer (103). One CHESS module uses the FACT-B to gather information from women with breast cancer. This project is being evaluated by researchers at a University of Wisconsin-based consortium and is available to oncology practices for their patients’ use. Another module administers the Edmonton Symptom Assessment Scale (104). In a pilot study, patients enter information about their symptoms once a week. If symptom scores reach a given threshold, this may trigger a variety of interventions.

As patients become more familiar with devices that are already used widely for other services, their use for patient reports seems promising. For example, wireless technology is used routinely by car rental agencies and by shipping companies to track packages, and consumers track the location of their own pack-
ages. Consumer use of Web-enabled cell phones and PDAs is expanding (105), and older individuals who until now have not used computers are increasingly using the Internet (106), often to access health information (107). At the same time, physicians have begun to use e-mail for patient care interactions and to send patients reminders (108). Increasingly, health care organizations provide Web access to patients for scheduling appointments, renewing medications, and requesting referrals. On their part, physicians and nurses commonly use PDAs (108,109); for example, to access chemotherapy regimens or for prescribing information.

Although patients often use the Internet to find health information, they have only rudimentary interactive decision support to get recommendations tailored to their own circumstances. What is missing is the coupling of a patient who seeks health information or provides information about his or her health status and clinician decision support systems and other clinical information systems, especially at the time of care. That is, archived medical record information in a paper or clinical information database has not yet been linked to systematic ongoing assessment of patient outcomes so as to guide patient care or to provide resources to patients for use in their own self-care. As a case in point, a report on information technologies available for small physician practices lists dozens of applications, but none for assessing patient symptoms, function, or HRQOL (110).

Some platforms could serve this objective. MIDAS+ (111) is a set of computer-based tools designed to integrate use and care management information across health care delivery networks, and it is used widely by hospitals and health systems. MIDAS+ modules include the SF-12 and SF-36, to be completed by patients, with either direct patient entry or scanned paper forms. Algorithms allow identification of high-risk patients. However, to date, no example of routine use of these modules in clinical oncology has been identified.

Measurement of patient symptoms and HRQOL is only one part of a possible clinical information system. A long-term objective for information systems is to achieve interconnected computer-based records (114) that include prescription ordering, personal medical records, longitudinal HRQOL data, e-mail queries and clinician recommendations in response, needs assessment, demographic data, and administrative data. Such a system would require secure transmission and strong protection for patient confidentiality. As a result, patients would not have to be questioned over and over for demographic and insurance information; patients could have records of their own HRQOL over time; all treating physicians would have access to current laboratory data, medications, and consultation results; and care could be seamlessly coordinated across settings of care. In addition, online, tailored decision support and resources could assist those clinicians who would like more information. In the longer term, securely connecting these data to registries, open clinical trials, and perhaps public health databases is a worthy goal.

**Systems of Care**

The patient-clinician encounter is one part of a small system of care that includes clinicians, other health care practitioners, support staff, their shared culture and norms, clinical technologies, and information systems. That microsystem (113) may be free standing (such as a community oncology practice) or part of a larger organization (such as an oncology clinic in a hospital or cancer center) that has its own policies, information technologies, and administrative and medical leadership. All function in a financial, legal, and regulatory environment that affects how practice is constrained or innovation encouraged. The microsystem, the larger organization in which it is embedded, and its external environment will all affect the use of patient-reported outcomes measures. Designing systems of care that incorporate patient HRQOL data will require attention to the microsystem of care and to ways of improving the dissemination (sometimes called the “translation”) of research into practice. Until now, much of the work in development of HRQOL measures has been addressed to other researchers rather than to practicing clinicians and has depended on passive diffusion to highly motivated recipients (114) through journals, scientific meetings, and the like.

Active dissemination, in contrast, includes systematic efforts to identify and provide assistance in overcoming barriers to application (115). Lomas (114) has summarized such effective dissemination strategies as synthesizing research by a credible and influential body, providing it in a user-friendly format that justifies the need for change; explaining how the change can be implemented by the intended users; communicating the existence and importance of the research findings in a variety of ways both locally and outside the local community; highlighting respected adopters; and identifying opportunities to meet with an influential local colleague or a respected outside authority. Using these strategies may not be effective, however, if adoption conflicts with the clinician’s economic or administrative incentives or with the expectations of patients.

Given this list, it is understandable that even excellent HRQOL instruments tend not to be incorporated by passive diffusion. Without attention to the sorts of strategies listed, neither innovative products nor software applications will, by themselves, be sufficient to ensure adoption of HRQOL. Rather, a systematic and informed active dissemination strategy will be required, coupled with a receptive medical culture, delivery capacity, and finally, economic or market incentives. Although the five strategies described by Lomas may be pursued using current health care processes, grafting demands for data collection and use onto current processes and incentives will likely be resisted as infeasible, and the lack of uptake should not be surprising. In fact, it is unlikely that even active dissemination, without changes in health care processes, will occur successfully within the current systems of health care in this country. The goal should be to make it easy, rather than difficult, to gather and use HRQOL data, and that will require change. Three changes in the process of care may be especially important.

**Changes Needed**

First, today the management of cancer care is organized around the patient visit. For this reason, much of the work of HRQOL development has centered on its use during the patient visit. Although face-to-face visits are an important form of clinician and patient interaction, many patient visits are not desired by the patient, who may be very ill, or by the clinician if he or she does not have complete patient information available. In addition, the timing of those visits may not match a patient’s acute symptoms or anxiety. For this reason, scheduling may not meet the needs of the patient for information or help, and the amount of time allotted may not allow for exploration of important issues. In addition, the one-on-one patient visit does not incorporate the work of many others who are part of the oncol-
ogy team or other oncology specialists, and multiple (sometimes exhausting) patient visits may have to be scheduled. Rather than viewing care as being grounded in a “visit,” the Institute of Medicine (IOM) suggests that care be understood as a “continuous healing relationship.” By this the IOM means that care can be made more effective and timely using a variety of electronic methods, such as fax, e-mail, and other electronic means, to allow patients to pose problems or questions and for their clinicians to address these problems when they are most salient. Using electronic technologies including collecting HRQOL data and responding when symptoms reach a given threshold or are urgent from the patient’s perspective can be far more efficient than trying to add this to a patient visit.

Second, patients are no longer regarded as passive recipients of services. They should be able to determine how much information they want and how much they want to participate in decision making and self-care. Use of patient-reported HRQOL information implies shared decision making because it requires that both patient and clinician be knowledgeable about the effects of disease and treatment to jointly decide which intervention may be useful (even if a patient prefers not to accept such services). The more patients are aware of and can communicate changes in their own health status, the more they can participate in self-care. Systems of interactive video and other ways to help patients understand the effects of various interventions were pioneered by Barry and others (116–120) for treatment of benign prostatic hypertrophy, prostate cancer, and breast cancer. Such patient-accessed systems can achieve goals of shared decision making without requiring longer patient visits. Similarly, processes that build in resources for referral or education of patients in self-management need not require the oncologist to provide these services personally. All such processes, of course, depend on the allocation of resources and, ultimately, on a reimbursement structure that encourages (or at least does not discourage) them.

Third, clinical information should not be viewed simply as an archive of stored medical data—documenting past events and findings. Rather, clinical information is the flow of knowledge to whoever needs it in caring for a patient, whether face-to-face or by various forms of electronic communication. With Internet-based applications, medical records can be held physically or digitally in a variety of locations to be accessed in whole or in part by the patient or anyone to whom he or she grants permission, as has been pioneered in Boston’s Care Group (121).

CONCLUSIONS

HRQOL measurement in routine practice is distinct from its use in clinical trials. For example, trials provide for research assistance in collecting information, patients must agree to participate in monitoring progress and treatment decisions. In contrast, the use of HRQOL in routine practice requires acceptance of its value by clinicians, patients, and administrators and resources devoted to data collection, analysis, and reporting. Using HRQOL data will also require a commitment to respond to identified patient problems. Tools are available for generic, disease-specific, and symptom assessment, but HRQOL measurement in routine oncology practice in the United States is rare in literature and anecdotally. Well-validated tools are necessary, but not sufficient. Before HRQOL assessment in clinical practice becomes widespread, it is imperative to address barriers at the level of the clinicians, the patients, and health care organizations as well as the financial, legal, and regulatory environments that influence and constrain practice.

For clinicians, this means not only demonstrating that such data are clinically useful but also addressing the effect on clinical work flow, constrained resources for data collection and management, reimbursement for their time and effort in monitoring HRQOL, and legal responsibility for follow-up of adverse findings.

For patients, this means addressing the acceptability of HRQOL assessment in light of response burden and possible concerns about confidentiality and unauthorized use. Importantly, patients will expect that the data they provide will be used to improve their care.

Health care organizations will need to deploy resources for outcomes data management and use, for timely review of patient data, and for responding to patient needs identified through QOL measurement.

The way forward lies not in exhorting clinicians to use HRQOL in addition to other tasks that are part of everyday practice, but in providing training in its use (122) and developing new information infrastructures and technologies, combined with redesign of care. This includes, for example, implementing new forms of data acquisition (beyond paper and pencil), designing new ways of organizing patient–clinician interactions (including electronic and Internet-based methods), and redesigning systems of care so that data collection is embedded in care as routinely as laboratory testing.

In 1963, the geneticist J. B. S. Haldane [p. 464 (123)] described four stages of acceptance for new ideas or methods: 1) This is worthless nonsense. 2) This is an interesting, but perverse point of view. 3) This is true, but quite unimportant. 4) I always said so. With wise implementation, the use of HRQOL measurement can reach Haldane’s stage 4.

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