Chapter 25

Measures of Function and Health-related Quality of Life

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INTRODUCTION TO FUNCTION AND HEALTH-RELATED QUALITY OF LIFE (HRQL) MEASURES

Definitions

There are many approaches to assessing the health of a person. Most include measurements in several domains. The term domain is used to describe different aspects of an individual’s activities. These may include the physical, cognitive, psychological, and social aspects of an individual’s activities. It is generally accepted that each of these domains contribute to function and health-related quality of life (QoL). Function, in this context, implies the usual or customary activities or actions of a person. Functional status is the degree to which an individual can perform chosen roles without limitation in three key domains: physical, social, and psychocognitive function. These roles are seen within the context of the unique needs of the individual. The Centers for Disease Control and Prevention defined quality of life as the perception of physical and mental health over time (www.cdc.gov/brfss). Other health-related quality of life definitions have included measurements of a patient’s perception of his/her ability to perform functions such as work, the physical effects of the illness and concomitant psychological conditions (e.g., anxiety, depression, and aggressiveness), sexual problems and the patient’s relationships with family and health care providers. 1-3 In the health care literature, QoL is linked with function and/or health status, frequently referred to as health-related quality of life (HRQL). A standard definition for health-related quality of life has not reached a consensus yet.

Reasons for Measuring Function and HRQL

In 1948, the World Health Organization (WHO) prompted a major departure from the disease-driven orientation previously adopted, to define the concept of health and to assess outcomes. WHO defined health as the “physical, mental, and social well-being and not merely absence of disease,” thereby adopting a biopsychosocial approach. 4 This definition of health helped set the domains and dimensions required for measuring health outcomes, thereby acknowledging the importance of using outcome measures that would include domains of physical, mental, and social health, as well as measures of function and ability.

The relationships among these domains or dimensions provide many investigational opportunities. Domains may be connected causally or associated through complex societal,
economic or other relationships not necessarily disease dependent. Although it had been generally accepted that impairment drives disability, and disability leads to poorer quality of life, these relationships are neither linear nor unidirectional. For example, muscle atrophy may result from disuse as well as from a neurological impairment. If the atrophy is a result of disuse, reversibility is more likely. Treatment aimed at reducing disability is likely to reverse the impairment and result in increased muscle mass and strength.

It also validated the need for understanding the patient’s perspective on her/his own health. Initially, these measures were thought to be “soft,” unreliable and less valid than observer-measured objective evaluations. Now it generally is agreed that these measures provide valuable and reliable information about an individual’s health and function and have predictive value in terms of mortality.5

Patients’ own reports, designed to capture information about how they feel, what they are doing, and what their level of satisfaction is with their health and their lives are a requirement for clinical investigation. These measures, now called patient reported outcomes, have improved as well. Their psychometric properties have been tested and many demonstrate internal consistency and validity. Further, they have been responsive to the group being studied and are sensitive enough to demonstrate minimally important clinical differences. The requirements for useful patient reported outcomes often include that they be age, gender, and diagnosis neutral and have wide application. Many investigators have embraced this type of evaluation in part because they provide valuable information about symptom response that is valuable to the patient.6

The health care system is committed to reducing the burden of disease, but also has become increasingly aware of patient priorities, which include the desire to be independent, maintain valued activity, achieve a sense of well-being in all aspects of daily life and other factors contributing to the quality of patients’ lives above and beyond disease control and mortality. In fact, the Food and Drug Administration (FDA) requires functional measures to be included in clinical trials to demonstrate efficacy.

What do Function and HRQL Measure?

Measures of function determine a person’s ability to perform usual and customary activities. The measures can be observer-driven objective measures, such as walking, opening a jar, and/or dressing; or they can be self-reported such as saying that an individual can walk or dress. Customary activities can be the activity itself (activity of daily living (ADL) such as bathing, feeding and dressing) or can be an activity that requires an instrument to perform; these often include activities that are more complex functions, such as balancing a checkbook. These are referred to as instrumental ADL (IADL).

What establishes an instrument as QoL or HRQL is the inclusion of a component of measuring patient satisfaction. There are two major types of health-related quality of life (HRQL) instruments—general health status that is often diagnosis neutral and disease specific. Instruments that measure the former can compare results across a variety of cohorts. Some can provide normative data from which to interpret results. The disease-specific instruments ask questions that focus more on the diagnosis, syndrome or treatment under study and have more specificity. Each has a place in the assessment of HRQL in chronic illness. Many schemes have been proposed that purport to identify the necessary and sufficient domains for HRQL indices. Because HRQL cannot, strictly speaking, be observed, it must be inferred from behaviors. To do this, these measures usually use self-reports that relate symptoms (e.g., pain and fatigue) with aspects of physical, mental, and social function (disability) and often demographic, vocational, and environmental impact on life (handicap). This helps us devise a set of characteristics of symptoms or a profile unique to individuals. HRQL helps answer the question, “Have we added life to years?” by ultimately assigning value to this profile.7 There are several examples of the domains included in such HRQL measures:

- The five “Ds”—death, disease, disability, discomfort, and dissatisfaction.8
- Genetically, anatomy/physiology, physical function, mental function, and health potential.9
- Measurements of disease, physical well-being, psychological well-being, social well-being, and general HRQL.10
- Clinical status, physical functioning/well-being, mental functioning/well-being, social/role functioning/well-being, and general health perceptions and satisfaction.11

One construct of HRQL that is particularly useful identifies five core domains:12

- opportunity
- health perceptions
- functional status
- impairment and
- death/duration of life.

Several taxonomies have been developed that present an organizational strategy for considering how these multidimensional QOL and functional measures may be classified.13–15

The new classification scheme devised by WHO helps define the domains to be assessed and from which data can be collected in a consistent and reliable way.16 This has been updated17 and altered to reflect scientific advances in physiology and genetics as well as the importance of the individual with respect to his or her unique needs within the context of the environment in which he or she lives.
This approach derived from the International Classification of Functioning Disability and Health (ICF), and incorporates some aspects of the theoretical framework developed by Nagi, who created an expectation that health care must go beyond managing morbidity and reducing mortality. The ICF has integrated the standard objective, disease associated parameters with self-reports of symptoms and perceptions, providing an opportunity for assessing disease and health in its broadest sense (www.who.int/classifications/icf/en/).

The ICF incorporates many of these features into its classification scheme and is being increasingly used worldwide. It has four domains of measurement:

- body functions (cardiovascular, hematological, digestive, neuromusculoskeletal, and voice/speech)
- body structures (nervous system, gastrointestinal, systems pertaining to movement, and genitourinary)
- activities and participation (learning and applying knowledge, communication, mobility, and self-care)
- environment, products, and technology (natural environment, human-made changes, and support).

Acceptance of this classification scheme demonstrates that the health care system is committed to reducing the burden of disease, but also has become increasingly aware of patient priorities. This shift is an advance in traditional thinking in which function and quality are linked to one’s ability to perform activities of daily living, walk and talk. These are certainly necessary, often desirable outcomes but they are no longer seen as the only elements in the mix of what is important to patients and families and society.

Utilization of the ICF or other classification schemes has created significant burden on investigators and subjects involved in studies because of the time it takes to complete questionnaires. The National Institutes of Health (NIH) funded a multi-year effort to coordinate primary research sites and coordinating centers in an effort to revitalize clinical research. The approach was an attempt to streamline the effort to measure self-reported outcomes, reduce redundancies and identify key factors in the process. The project Patient Reported Outcomes Medical Information System (PROMIS) resulted. Investigators participating in this project developed core questions, common metrics, and item banks. The item banks permitted applying this project developed core questions, common metrics, and item banks. The item banks permitted applying item response theory employed by this project. 19

The framework applied to patient reported outcomes (PROs) usually has multiple dimensions, each of which has specific assessments. Typically these include:

- Physical health: symptoms and function or activity
- Mental health: affect, behavior and cognition
- Social health: interpersonal relationships and function.

What often is lacking are measures of quality of life, health-related quality of life, and life satisfaction. Many investigators use QoL and HRQL adjunctively. With the adoption of a biopsychosocial model of health, health assessments have been expanded to include measures of personally held beliefs and values, in order to understand the impact of disease on behaviors such as coping, participation, and motivation. This has increased the variety of information obtained and raised confidence in data collected from quality of life (QoL) and health-related quality of life (HRQL) measures, both self-report and observer-administered instruments. Instruments to measure these phenomena have improved significantly during the past decade. They have become more quantitative and more reliable. Most have been standardized, have been tested for content validity and inter- and intra-rater reliability, and have been studied for application to specific diseases.

**HOW ARE FUNCTION, QOL, AND HRQL MEASURES USED?**

In the ICF model, it was suggested that health care outcomes should measure well-being, a state dependent on physical and functional status. As the field has matured, health services researchers have pointed out that the degree of family support, social activity, and friendships, as well as vocational and financial security, are likely contributors to well-being.20 This made it necessary to measure “individuals’ perceptions of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards, and concerns.”1,21 Hence, health care providers were encouraged to take a broad view of health.

For example, an individual with rheumatoid arthritis might have evidence of 10 swollen, hot joints with pain on palpation. The joints may have limited range of motion. This describes the impairment. The physician also is interested in the impact of these findings on mobility and function. The individual is unable to walk 50 feet because of pain, limited joint motion, and fatigue. Her inability to walk is the functional limitation, and can be observed or can be reported as a problem by the patient. The patient reports that she is unable to get to work, and cannot perform her job, hence creating a disability. Her unemployment status is her societal limitation or handicap. Measuring the impact of her impairments provides a compelling story about the impact of the anatomical and physiological abnormalities. Typically, clinical examinations measure physical and biological phenomena, mood, and mental status. The correlations between these measures and function are not always high, and they omit questions pertaining to one’s status with respect to cultural and value systems and goals.22 Since they assess different domains, all of
which are thought to be important, clinical trials should include measures of all. Functional limitation often will correlate with disability, but does not necessarily correlate with personal values, goals, or expectations. Adding assessments that measure the latter components introduces the QoL and HRQL instruments. A substantial body of data supports the view that physical findings and disease severity do not always correlate with patient self-report about QoL.

Instruments have been devised that rate specific activities based on their value to an individual and also assess the impact of these activities on the individual’s feelings of satisfaction and competence. Controversy exists about whether HRQL is more about life than health and whether health care should even include the domains that often highly influence QoL, such as social, financial, and societal dimensions. Table 25-1 contrasts the differences between health status measures and HRQL. As treatment choices become broader and individuals participate more in decision making, an ever increasing number of studies include HRQL measurements as outcomes, and investigators suggest they provide meaningful information that informs clinical practice and is helpful in decision making.

**EXAMPLES OF FUNCTIONAL MEASURES AND HEALTH-RELATED QUALITY OF LIFE MEASURES**

**Functional Measures**

There are a significant number of valid, reliable, and sensitive instruments that measure health-related events from a less value-driven or less comprehensive approach with respect to domains. Sometimes these are more appropriate for application to a clinical trial and may be more specific to the unique needs of a particular patient population or have greater sensitivity. These include activity of daily living scales, usually focused on self-care and mobility. One of the first functional measures was the Barthel Index, a measure limited to assessing functional independence in self-care and mobility. It was developed to assess function in patients who were confined to hospital for long periods of time. The Index is a 10 item scale with good validity, and it has been used widely and served as a basis for the development of other functional assessments including the Functional Impact Measure.

In the United States, the most frequently used functional outcome measure assesses functional level and burden of care following discharge from the hospital. The Functional Impact Measure (FIM) has seven levels of assessment and 18 items designed to measure patient disability and rehabilitation functional outcome. This measure is used by many rehabilitation facilities, and is thought to provide reliable and valid information about caregiver burden and ADL. It also measures communication and social cognition, although this is less sensitive than other standard instruments.

The Health Assessment Questionnaire was designed as a disability measure. It measures self-care and mobility, hence it qualifies as a functional measure. In addition, because it asks questions pertaining to treatment side effects and economic impact of disease, it has been used as an HRQL measure. Some instruments measure only one domain, such as social health or psychological well-being, or life satisfaction. Many measure a particular symptom, such as depression, or a particular function, such as mental status. There are a host of visual analog scales to measure fatigue, pain, and global health. An excellent review of these instruments is available.

**HRQL and QoL Measures**

The prior discussion about HRQL and QoL has demonstrated the evolution of thinking about what is important in the delivery of health care from the medical professional’s view to the patient’s perspective. Not all studies or clinical trials use these measures, nor should they. For example, a drug trial assessing the appropriate dosage or toxicity of a new antibiotic (Phase I trial) or one that is seeking pilot

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**TABLE 25-1** Characteristics of Measures of Health-related Instruments

<table>
<thead>
<tr>
<th>Quality of life</th>
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<tr>
<td>Subjective</td>
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<tr>
<td>Composite, multiple domains</td>
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<tr>
<td>Self-report</td>
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<tr>
<td>Well-being model</td>
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<tr>
<td>Generic</td>
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<tr>
<td>Sociomedical</td>
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<tr>
<td>Produces a profile or indicator</td>
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<tr>
<td>Value or satisfaction measures</td>
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<tr>
<td>Health status</td>
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<tr>
<td>Objective or subjective</td>
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<tr>
<td>Single item or composite</td>
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<tr>
<td>Observer measured or self-report</td>
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<tr>
<td>Sickness or well-being model</td>
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<tr>
<td>Disease specific or generic</td>
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<tr>
<td>Diagnostic or prognostic use</td>
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<tr>
<td>Produces a score or health index</td>
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<tr>
<td>May have value or satisfaction measures</td>
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information about the feasibility of using a new device might need an instrument that is focused only on physiologic measures. Sometimes investigators are interested in disease severity or its extent rather than its impact. Health status is a term that refers to the degree to which an individual has a disease or symptom. In this case, the investigators are likely to use disease severity indices or measures of health status.

Use of QoL and HRQL measures in clinical trials is established,33 and these measures are being used for a variety of purposes, including the following:

- to assess health needs of individuals or groups
- to assess outcomes of treatments, health promotion, and disease prevention programs
- to assess cost effectiveness
- to develop health policy
- to monitor general health of groups of patients
- to influence an individual’s choice of a specific treatment plan.

Conceptual fuzziness and concerns over the metrics delayed the entry of QoL and HRQL instruments into the mainstream. A good review of the issues is available.34 These instruments have recently risen in favor and have been used more frequently during the past decade because of several important factors. A substantial number of instruments have been standardized, validated, and have good psychometric properties whose theoretical framework has been tested and found to be methodologically sound (Table 25-2).

In addition, patients are demanding more personalized care. They want their individualized functional needs addressed. They want “customer” satisfaction. There is an increasingly wide selection of treatment options for patients that require education about risks and benefits that may impact on function and QoL, as well as morbidity and mortality. The FDA requires investigators to measure treatment impact on function, not only on disease activity, in trials of investigational drugs.35

The methodologies and suitability of HRQL and QoL measures continue to be carefully scrutinized. In construction of these measures, several issues must be considered. First, which items should be included in the instrument? Often, this decision is made based on what the outcome of the study might look like or how the assessment will be used. For example, some instruments designed to assess effectiveness of care will have to be able to distinguish among differences in subjects at a moment in time or be able to measure change over time (even in those without significant disease or illness). They may have to predict future outcome resulting from a new versus an established treatment.36

The second issue pertains to the methodological or measurement characteristics of the instrument. Some use single indicators such as mortality. This is frequently considered a “hard”33 end point, very accurately recorded, leaving little doubt about verification. Using mortality as the “gold standard” for health outcomes ignores the fact that we have changed our health outcome expectations. The outcomes sought are not exclusively survival, because our population wishes to be disease free, disability free, and have a good QoL. As such, because mortality does not measure what many believe is the desired outcome of health care, it is not a sensitive indicator of health. Composite measures are needed to detect health changes as well as to generate policy models. The measurement characteristics can be presented as an index. Examples include Arthritis Impact Measurement Scales (AIMS)37 and the Functional Life Index (FLI).38 The data also can be summarized into a profile that describes each domain or area of measure separately. The Sickness Impact Profile (SIP) is an example of this type of instrument.39 The third consideration is to decide how to “weight” the responses. When a measure has several components, relative value needs to be assigned to each. Investigators, through a Delphi process or consensus, can assign weighting. It also can be assigned based on frequency of responses—those items more commonly selected get higher scores. It can be weighted based on preference of the respondents. The SIP39 is an excellent and frequently used HRQL profile and has become a gold standard for health-related

<table>
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<th>TABLE 25-2 Requirements for All Measures</th>
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<tr>
<td><strong>Practical:</strong> Administration time not burdensome, low risk to patient. Complexity of measures and scoring easily interpretable.</td>
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<td><strong>Validity:</strong> Measures what is intended to measure.</td>
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<td><strong>Content validity:</strong> Comprehensiveness of sampling of questions.</td>
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<td><strong>Criterion validity:</strong> Its congruence with “gold standard.”</td>
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<tr>
<td><strong>Construct validity:</strong> In quality of life and health status measures, there is no gold standard. Therefore, correlations and factor analyses are used to determine how well the items accord in measuring common items. Construct validity is determined based on an accumulation of such correlations, usually from several studies.</td>
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<td><strong>Reliable:</strong> Measures are consistent, having little measurement error. Able to distinguish between patients.</td>
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<td><strong>Internal consistency:</strong> The demonstration that similar questions are shown to correlate highly on repeated measure. How well the questions measure the same theme.</td>
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<td><strong>Reproducible:</strong> Test–retest is stable (Cronbach’s is a measure of this).</td>
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<tr>
<td><strong>Responsive:</strong> Measure is sensitive to change, has good evaluative properties. Assessment at the low and high ends of satisfaction and function is adequate for the population studied.</td>
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measures. The purpose of this index is to describe and quantify the impact that disease has on a person’s behavior. Its application is to measure the outcomes of care, which could be applied to health care program planning as well as patient management. The SIP was created through an interview process of those healthy and sick, to obtain descriptors of behavioral change that was associated with sickness. Sickness connotes a person’s experience of illness and was derived from the impact that change in status (i.e., from well to sick) had on daily routines and feelings. Categories of activities were established, and statements describing behavior were listed under each category. Twelve categories were selected (sleep/rest, eating, work, home management, recreation/leisure, ambulation, mobility, self-care, social interaction, alertness, emotional behavior, and communication). Statements within categories included “I laugh or cry suddenly,” “I walk shorter distances or stop to rest often,” and “I am not working.” Respondents checked only those statements that described them. One hundred evaluators reviewed the questions and participated in intervals designed to assess what they thought the relative impact or importance would be of each item under consideration. Each category was scored separately. There were correlations between SIP scores and criterion variables in a variety of diseases and other health indices ($R = 0.5$ in almost all). Reliability (test, retest, and internal consistency) was very high ($R = 0.8$).

**Criteria for Selection of HRQL Measures**

Many instruments currently in use meet the criteria described previously for reliability, validity, and ease of use. In making the proper selection for a particular situation, a number of additional considerations should be included. Some HRQL measures have been designed with specific populations of patients in mind and have not been applied to a broader range of patients/subjects. Most indices are developed using a disease severity, not a functional limitation orientation.

HRLQ assessment measures can be selected based upon the population the instrument was designed to measure, or the domains of interest to be measured (e.g., emotional well-being, economic status, etc.), as well as the ease with which it can be administered. Currently two types of measures, generic (global) and disease specific, are used frequently. These two types of instruments may measure different aspects of patients’ HRQL and therefore are considered complementary. In most recent studies, both types of health-related quality of life measure are used to cover the full spectrum of HRQL issues. The results of generic (global) HRQL measures can be compared across diseases, across studies in meta-analyses and with general or “healthy” population norms. Many generic measures of health-related quality of life will have a series of subscales and domains measuring different global contributors to health-related quality of life. Some have been designed to measure specific symptoms tied to health-related quality of life in great detail. Generic measurements are limited in that a generic instrument may not assess all issues relevant to HRQL in a specific disease state. The addition of a symptom-specific generic assessment to a test battery may be desirable for common symptoms or if a specific domain is believed to strongly impact HRQL in the study population. This type of measure includes factors such like sleep, fatigue, and depression. Disease-specific HRQL measures are designed to measure specific illnesses or categories of illness. By concentrating on the unique concerns and challenges of a specific population, disease-specific measures tend to be more responsive (able to detect small clinically relevant changes over time) than generic instruments.

Ease of scoring is a factor for clinical investigators. The clarity and number of questions must be considered for many populations, especially those with cognitive impairment or non-native English speakers. The purpose for which the data are being collected should influence selection. HRQL measures used as clinical outcome measures to assess treatment efficacy must include domains that the investigator believes likely will be affected by successful treatment. They should not be too general. These indices are not specific enough to be used as measures of drug toxicity (Phase I), may enhance information from Phase II trials, but are most frequently used for Phase III/IV trials.

Some HRQL measures are designed to determine the needs of given populations, whereas others are designed to monitor patients over time or assess the impact of a new health care program on a population of individuals (e.g., AIMS and the European Organization for Research and Treatment of Cancer (EORTC), which tend to be more disease specific than generic). It is best to review how a particular instrument has been used and then make the best fit for the needs of a specific trial.

The method of administration should be carefully considered. Many of the instruments are surveys that are patient-reported outcomes or self-reported outcomes (PRO/SRO). This is certainly efficient; however, misunderstanding questions and failure to complete all questions may result from this type of administration. It is important to know if there is a standardized method for handling missing data in PRO/SRO surveys. Some surveys offer very specific guidance on handling total survey non-response (survey not answered/returned at all), partial survey non-response (large parts of the survey not completed, or only certain pages), and item non-response (individual items unanswered in an otherwise completed survey). For some surveys, it is impossible to arrive at a score for important domains without full survey completion. Ability to review written survey for completeness while the subject still is
Specific Functional Measures, HRQL, and QoL Instruments

A summary of selected properties of 11 instruments, chosen from more than 100 to illustrate the kinds of measurements that can be used to measure HRQL in a clinical research setting, is provided in Table 25-3. These were selected because they have good psychometric properties, are generic (disease neutral) measures, have been used commonly, have a variety of applications, and are generally easy to administer.

Other measures of note—AIMS, FLI, the Quality of Life Index (QOLI), and EORTC—were designed to assess patients with a specific disease. AIMS measures domains of function for those with arthritis, and the others do the same for cancer patients. Arthritis and cancer diagnoses share a number of features; they are common, chronic, and complex and are associated with varying and fluctuating degrees of disability.

These disease-oriented measures were designed to assess the influence that treatment has on patient outcomes in multiple domains relevant to either the cancer or the arthritis patient. QOLI has also been used for program assessment. AIMS and QOLI have been used extensively in clinical trials. Existing instruments and how they did or did not meet the anticipated needs for health assessment influenced the domains selected by the instrument designers. Each of these measures has a significant proportion of questions at the performance or functional level and fewer measures of symptoms, feelings, or perceptions.

The Functional Status Questionnaire, Dartmouth Cooperative Measure, Duke—UNC Health Profile, and McMaster Index originally were developed for a primary care or outpatient, ambulatory population. Treatment outcome was of interest, but the instruments had to be able to measure the outcomes resulting from the delivery of health services and provide a good quantifiable assessment of health rather than disease. Each of these

| Table 25-3 General HRQL Instruments |
|-------------------------------|----------------|--------|-------|----------------|
| Name                          | Administration | No. of Items | Population | Objective                  |
| 15D                           | S              | 15      | 16 years | HRQL only                   |
| Assessment of Quality of Life (AQOL) | S, P         | 15      | Adult    | Include economic data       |
| Child Health Questionnaire (CHQ) | S, P          |         | Parents, 50; Youth, 87 | HRQL in children |
| Duke Health Profile           | S              | 17      | Adult    | HRQL and health status      |
| Functional Status Questionnaire (FSQ) | S            | 34      | Adult    | Principal, psychosocial, and role function in ambulation |
| Health Assessment Questionnaire (HAQ)<sup>a</sup> | S, P      | 20 visual analog scales | Adult | Ambulation, ADL |
| McMaster Health Index         | S, P           | 59      | Adult    | HRQL and social/emotional status |
| Nottingham Health Profile     | S              | 45      | Adult    | Patients’ perceived emotional, social, and physical health |
| Ferrans & Powers QLI          | S              | 66      | Adult    | QOL in terms of satisfaction |
| SF-36                         | S              | 36      | >14 years | Measures health concepts |
| Youth QOL                     | S              | 13      | 11–18 years | QOL |

ADL, activities of daily living; P, phone interviews; S, self-administered.

<sup>a</sup>Also has a child-based questionnaire (CHAQ).
measures included domains measuring social, physical, and mental and general health. They also included more measures of perceived health, self-esteem, thoughts about future health and personal goals, and overall QoL.

The SIP, Nottingham Health Profile,⁴⁷—⁴⁸ and SF-36⁴⁹—⁵⁰ were designed to assess a wide variety of patient populations, be relatively disease neutral, and span a broad age range of patients receiving care in many different settings. Of the three, only SIP has no measures of satisfaction or feelings. Its construct was designed to assess the patients’ perceptions of loss of functions, and in a sense it is entirely structured around perception of how the current status differs from a previous one. It has no value qualifiers about this loss or change in functional status. It is scored by comparison with a varied sample. The other two, however, include several domains that address general perceptions and emotional reactions to illness or change in functional status. They can be used to assess change over time.

The Older American Resources and Services Functional Assessment⁵¹ and Comprehensive Assessment and Referral Evaluation⁵² are among the more complex and difficult to administer. They were designed to evaluate the elderly and are weighted heavily toward asking questions about services needed among individuals as well as groups of elderly patients. An observer or an informant administers these measures, they take 45 minutes to one hour to administer, and have 144 or 369 questions, respectively.

Two additional instruments also are recommended for consideration. They are designed for general populations and commonly used: the Quality of Well Being Scale⁵³ and the 15D.⁵⁴ Additional information about many of these instruments is available at www.rar.duhs.duke.edu. Researchers can obtain permission to use certain instruments (e.g., SF-36) at www.qmetric.com/products/assessments/license.

OTHER INSTRUMENTS TO CONSIDER

During the 1970s, the Rand Corporation developed an instrument to help assess the impact of various forms of health insurance on health. The Medical Outcomes Study (MOS) emerged as a valuable tool for assessing health status. It has been revised, shortened, and validated. The result has been the 36 item short form (SF-36), the SF-12 (12 items), and the SF-20 (20 items). The SF-36 has eight dimensions (physical function, physical limitations on role, pain, social function, overall mental health, emotional limitations on role, vitality (energy and fatigue), and general health perception). These sub-scales may be used independently, or all may be summed into a total score. These scores are normalized.⁵⁰,⁵⁵ This is a general health measurement, but has been referred to as a functional measure, a measure of health status, and a quality of life measure; in short, a “one size fits all.” It has been used in large population surveys and in small clinical trials. The instrument is well constructed, valid, reliable, and sensitive. The only cautionary note is to look carefully at the domains, questions and level of sensitivity, and decide whether they are what is needed to prove or disprove the hypotheses.

IMPORTANCE OF QUALITY OF LIFE MEASURES FOR HEALTH CARE

The universal application of the controlled clinical trial has established a standard by which the efficacy of therapeutic interventions is judged. These trials are essential for determining whether a treatment is effective in improving health. Treatment costs are also required to be assessed, whether this is the most effective way to use resources, and what value there is to individuals, their families, and society to use such treatments. The WHO defines healthiness as “a state of complete physical, mental, and social well-being, not merely the absence of disease.” There has been much discussion about the need to factor quality and not solely quantity of life in important decisions. Decisions about striving to cure chronic, complex, serious illnesses should be weighed against how this would impact on function and HRQL. Answers to these questions, which are now factored into decisions made by regulatory agencies, the pharmaceutical industry, legislators, and individual patients, require instruments designed to measure how treatment impacts what is valued by patients, and the instrument must provide relevant, reliable, valid, and sensitive data. Significant effort by NIH has been directed at improving this methodology (www.nihpromis.org).

There remain some unanswered questions and some deficiencies in the state of HRQL development, its methodologies, and its applications.⁵⁶—⁵⁷ The following are some of the issues in need of resolution. Many of the HRQL assessments use multiple and different domains. Should these be restricted? Should the methods of quantification and valuation be standardized? Should all domains be totaled or should (can) each component be separately analyzed? Who should assess—the patient, caregiver, health care professional, family, or all? Should HRQL measures be required for all trials? Should they be incorporated into clinical practice? How do cultural differences influence HRQL assessment? How do we translate information obtained into improved clinical practice, assessment of risk, cost, and health care policy?

The use of HRQL measures has become more prevalent during the past decade. All indications suggest this trend will continue, and health care practice as well as policy will be influenced by data that attempt to address questions of values as they relate to health.

In addition to its application in clinical trials, quantitative measures of HRQL provide both clinicians and
researchers with important information to aid in assessing the total impact of disease on their patients’ lives. Quantitative assessment allows us to weigh the relative impact of a specific disease on a patient’s daily activities to evaluate the impact of a specific treatment strategy on a patient’s HRQL. For instance, the ability of a patient to maintain a personally desired level of HRQL with palliative care despite having metastatic cancer may provide important information to clinicians. Such a patient and his/her clinician may need to weigh treatment options that severely impact overall quality of life for some gain in lifespan, against maintaining a comparably better HRQL with a plan of care that does not offer as good outcomes in terms of survivability. Health-related quality of life can help guide clinical decision making for physicians and the medical decisions of patients.

**SUMMARY QUESTIONS**

1. Define function and health-related quality of life
   a. Function is a term that refers to an individual’s ability to perform needed/desirable activity. True or False?
   b. Health related quality of life measures:
      a. morbidity
      b. disease activity
      c. health status

2. Name a valid, reliable measure of function and HRQL
   a. Select a reliable functional measure:
      a. creatinine
      b. FIM
      c. mini-mental status (FIM)
   b. Select a reliable HRQL measure:
      a. SF36
      b. Beck depression index
      c. Brief pain inventory

3. The World Health Organization defines health as the absence of fatigue. True or False?
4. What is the intent of the international Classification of Function, Disability and Health? Give an example of how it might be used.
   a. The International Classification of Function can be used to classify functional status. True or False?
   b. The ICF can help diagnose disease. True or False?

**REFERENCES**
