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The Stanford Health Assessment Questionnaire: A Review of Its History, Issues, Progress, and Documentation

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ABSTRACT. Over the last 2 decades, assessment of patient health status has undergone a dramatic paradigm shift, evolving from a predominant reliance on biochemical and physical measurements to an emphasis upon health outcomes based on the patient's personal appreciation of their illness. The Health Assessment Questionnaire (HAQ), published in 1980, was among the first instruments based on patient centered dimensions. The HAQ was designed to represent a model of patient oriented outcome assessment and has played a major role in diverse areas such as prediction of successful aging, inversion of the therapeutic pyramid in rheumatoid arthritis (RA), quantification of nonsteroidal antiinflammatory drug gastropathy, development of risk factor models for osteoarthrosis, and examination of mortality risks in RA. The HAQ has established itself as a valuable, effective, and sensitive tool for measurement of health status. It has increased the credibility and use of validated self-report measurement techniques as a quantifiable set of hard data endpoints and has contributed to a new appreciation of outcome assessment. We review the development, content, and dissemination of the HAQ and provide reference sources for its uses, translations, and validations. We discuss contemporary issues regarding outcome assessment instruments relative to the HAQ's identity and utility. These include: (1) the issue of labeling instruments as generic versus disease-specific; (2) floor and ceiling effects in scales such as "disability"; (3) distances between values on scales; and (4) the continuing introduction of new measurement instruments and their potential effects. (J Rheumatol 2003;30:167–78)

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STANFORD HEALTH ASSESSMENT QUESTIONNAIRE HAQ DISABILITY INDEX

The impact of chronic illness is a function of illness severity, the individual patient, and time. Further, it is affected by factors such as age, sex, lifestyle, motivation, priorities, and aspirations. Over the past 2 decades, assessment of patient health status has undergone a dramatic paradigm shift, evolving from a predominant reliance on biochemical and physical measurements, such as erythrocyte sedimentation rate, lipid profiles, or radiographs, to an emphasis upon health outcomes based on the patient's personal assessment of their health status. The shift to inclusion of patient centered values permits longterm, cumulative assessment of outcomes that are relevant to the patient.

The Health Assessment Questionnaire (HAQ) has played an influential role in constructing this new paradigm and in establishing health outcome assessment as a quantifiable set of hard data endpoints that are reliable, valid, and sensitive to change. Its intellectual roots included work by Donabedian[1], Katz[2], Steinbrocker[3], Convery[4], and others. This is a review of the HAQ; it is not a review of outcome assessment or a comparison of the HAQ with other instruments. It describes the HAQ in detail, provides an overview of a substantial part of the HAQ literature, and discusses our view of associated issues. We also provide references for relevant HAQ publications[1-183] since the last review by Ramey and Fries in 1996[135] and information to access translations and adaptations. The HAQ instrument, scoring directions, and additional resources may be accessed at the ARAMIS website, http://aramis.stanford.edu.

UNDERLYING PRINCIPLES OF THE HAQ

Dimensions of health outcomes. What are health outcomes? Why are they important? Are they best based on physician, societal, or patient values? We have argued that these 3 value systems should converge with a service oriented medical profession and a benevolent society, but that the patient's values in particular must be preserved and protected. Studies of patient centered health values have tended to yield 5 generic outcome dimensions, the "5 D's." When queried, patients report that they want: (1) to postpone death, (2) to avoid disability, (3) to be free of pain and discomfort, (4) to avoid

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adverse effects of treatment, such as drug side effects, and (5) to keep dollar costs of treatment low[54,60,104,130]. As an aggregate, they define health outcome in patient terms and can be partitioned into the 5 dimensions along with subcomponents to form a hierarchy.

On the apex of this hierarchy is the global entity of health outcome, which is a function of the underlying 5 patient centered dimensions (death, disability, discomfort, drug toxicity, and dollar costs). However, it is not possible to compute a value for health outcome directly from scores on the 5 dimensions without assuming idiomatic patient tradeoffs. For example, how many dollars saved would a patient consider that his or her life is worth? How much pain would a patient endure for how much disability? To operationalize a health dimension, there are lesser assumptions that must be made by "rolling up" values from lower in the hierarchy (e.g., Is disability in walking more or less important than disability in dressing?), but these may seem to be more defensible assumptions than dimensional death/disability or disability/side effect tradeoffs. For these reasons, we have argued for collection of data for each dimension, but have discouraged further aggregation.

These 5 dimensions of health outcome can be further subdivided into more discrete components that appear lower in this hierarchy and help to provide substance. For example, the measurement of disability can include activities that involve upper extremities, lower extremities, or both. Discomfort may include physical and/or psychological origins. Drug side effects or toxicity may encompass consequences of medical treatment or surgery. Dollar costs, or economic impact, can comprise direct (actual expenses) and indirect (loss of productivity) costs. The fact of death includes specific notation of time to death and cause of death. These components are themselves calculable from specific questions at a lower level. Hence, this hierarchical model creates a structure for the macrocosm of measures relevant to outcome and those that are indispensable for comprehensive patient assessment.

An abbreviated alternative to using the 5 dimensions in a hierarchical structure to capture health status is to employ a single global outcome question that can be asked directly using an analog scale, although, of course, with loss of precision and sensitivity to change. Such a question captures, in part, the patient's tradeoffs between the different outcome dimensions and is also a broader perspective that may include idiomatic values such as spirituality, disability-friendly environments, and family support. Instruments that use a single-item global health visual analog scale (VAS) have been recommended as representing meaningful outcomes and internationally as one of the 6 core outcomes (i.e., disability, pain, patient global, physician global, swollen joint count, and tender joint count) to be measured in clinical studies of rheumatoid arthritis (RA)[18,46,121]. The HAQ and other instruments[65,95,111] contain such a scale.

Longitudinal data collection. Just as collection of patient centered data is a requisite for proper assessment of health outcomes, cumulative effects of a patient's chronic illness collected over time must also be considered. For evaluation of health outcome, aggregated measures captured longitudinally are superior to cross sectional assessments, since they capture the entire effect of a longterm illness and are a sensitive indicator of treatment effect over time[58]. Cross sectional data provide only a vertical slice of the patient's experience at a particular point in time. For example, patient outcomes estimated solely from cross sectional measurements are unable to distinguish early development of disability from late, since cumulative disability in a patient may be vastly different than disability experienced between only 2 discrete assessment periods. Thus, reliance on a patient's final measurement or on a first and last value may provide a biased view of the disease or treatment impact. Sequential health status measurements obtained at regular intervals permit comparison of the impact by allowing approximation of the area under the curve[169]. Longitudinal data should be an inherent component of patient outcome measurement assessment. A single point in time assesses health status at that point; a series of assessments permit cumulative outcome assessment.

A psychometrically sound instrument. Assessment of health outcomes requires an instrument with excellent psychometric properties of reliability, validity, and sensitivity[70]. Reliability, the ability of an instrument to produce results repeatedly, is affected by factors such as clarity and precision of language. Validity is established by assessing the degree to which the instrument measures what it is intended to measure. Sensitivity identifies the degree of an instrument's ability to detect change over time. Measuring sensitivity to change requires graded responses (e.g., not walk versus can't walk) and indices that have a continuous or nearly continuous scale. From these basic principles (a focus on patient centered values, use of a multidimensional instrument with established psychometric properties, and the aim of collecting data longitudinally), the HAQ was intended to assess patient outcome both comprehensively and cumulatively.

THE "FULL" AND "SHORT" OR 2-PAGE VERSIONS OF THE HAQ

The HAQ has been one of the most cited and employed instruments, particularly but not exclusively in the rheumatic disease literature. However, there has been some confusion relative to what the term "HAQ" refers: typically, it is used to refer to one of 2 versions of the HAQ. The full HAQ assesses 5 dimensions of health outcome (Table 1), while the version that has received the widest attention and most frequent use, and that is commonly referred to in the literature as "the HAQ," is the "short" or 2-page HAQ. The short HAQ contains the HAQ Disability Index (HAQ-DI), the VAS Pain Scale, and the VAS Patient Global in a 2-page format, permitting convenient assessment of 3 of the 6 American College of Rheumatology (ACR) outcome measures for RA[44]. Further, the HAQ-DI is often used by itself.

Table 1. Structural dimensions of the 2-page or Short HAQ (Items 1 and 2) and the Full HAQ (Items 1–5).

1. Disability; these 8 categories make up the "Disability Index" (HAQ-DI):		
Dressing	Walking	
Arising	Reach	
Eating	Grip	
Hygiene	Outside activity	
2. Discomfort		
HAQ VAS pain scale	Patient Global VAS	
Supplemental dimensions also included in the Full HAQ (tailored to specific hypotheses or research questions)		
3. Drug side effects		
Medical	Toxicity Index	Surgical
4. Dollar costs		
Direct costs: Medical/surgical costs		
Medications	Paramedical visits	
Laboratory tests	Devices	
Radiographs	Hospitalizations	
Physician visits	Surgeries	
Indirect costs: Loss of productivity		
5. Death		
Time to death		
Cause of death		

The full HAQ was developed originally for use in multiple illnesses so that the effects of different disease processes could be compared, even though much of its early work emanated from the rheumatology field. For example, in osteoarthritis (OA), pain is dominant and typically increases over the years; in RA, disability is dominant, in HIV-AIDS both of these may predominate, but in almost all diseases, patients will be affected by personal issues involving the 5 patient centered dimensions. These generic objectives drove the design and development of the HAQ. As such, the full HAQ includes sections on drug side effects and medical costs, as well as supplemental sections on demographics, lifestyle, and health behaviors. As with any instrument, the HAQ has limitations, and as generally used, does not capture disability associated with sensory organ dysfunction or psychiatric dysfunction and does not directly measure patient satisfaction or social networking. Yet these variables, or other variables of interest to the user, can be readily appended as separate instruments.

The full HAQ was one of the first instruments deliberately designed to capture prospectively and by protocol the longterm influence of chronic illness. It was immediately adopted in 1980 by the Arthritis, Rheumatism, and Aging Medical Information System. It was designed to be efficient, structured for practical application during clinic visits, and to be compatible with high return rates when administered by mail or telephone. In its early development, the full HAQ was titled the "Arthritis Assessment Questionnaire" or "AAQ." However, after it was recognized that the 5 outcome dimensions (disability, discomfort, drug toxicity, dollar costs, and death) conceptualized in the HAQ represented general concepts, and were not restricted to any single specific disease area, the current HAQ name was adopted.

Both the short HAQ and the full HAQ are copyrighted for the purpose of insuring that it will be used unmodified to preserve the validity of its results and contribute to standardization of assessment across studies. However, the HAQ is considered to be in the public domain, and permission for its use is given routinely without charge. A "HAQ-PAK" containing the full HAQ and scoring directions is available on the internet at http://aramis.stanford.edu. Changes may sometimes be made by vendors to maintain language or cultural adaptations.

Use of the HAQ has spanned multiple and diverse settings. The full HAQ has been used by ARAMIS more than 100,000 times to assess clinical status, evaluate effectiveness in clinical and observational trials, and to define health outcomes[56]. Studies using the HAQ have been conducted in patients with HIV-AIDS, normal aging populations, adults and children with rheumatic diseases, and in disabled workers[26,56,57,106,135]. It has been employed in population based studies, including the followup to the National Health and Nutrition Examination Survey (NHANES)[86]. It has been applied to a variety of diseases and conditions, including OA, juvenile RA, systemic lupus erythematosus, ankylosing spondylitis, fibromyalgia, psoriatic arthritis, and systemic sclerosis. Extensively implemented internationally, the HAQ-DI has been translated and culturally validated into more than 60 languages (Table 2).

The components of the "short" HAQ have retained their original content and format since the early 1980s, while the additional dimensions in the full HAQ, drug side effects and dollar costs and other items, are periodically tailored and supplemented with additional questions when contemporary issues arise for specific hypotheses or research questions by ARAMIS or other investigators. The dimension of mortality is assessed by specific ARAMIS protocols.

DEVELOPMENT OF THE HAQ-DI

The HAQ-DI, initially developed in the late 1970s under the auspices of the Stanford Arthritis Center, was the original HAQ section to be developed and validated. The HAQ-DI was developed by parsing questions and components from a variety of instruments[59]. It recognized the importance of the original American Rheumatism Association (ARA) functional class measure[3] and also the lack of sensitivity to change of that 4 category measure. It evolved over numerous iterations through a series of subjective and objective assessments via statistical evaluation, physician appraisal, and patient feedback[58,59]. Associations with clinical variables such as sedimentation rate or tender joint counts were tested, where we sought to achieve equal or better measurement characteristics with more patient outcome related dependent variables.

A comprehensive validation of each item set was performed to yield the final instrument. Correlation matrices were constructed, and intercorrelations, item-total correla-

tions, correlations with extant "gold standards" such as performance of activities of daily living, physiological and biochemical measures, and chart reviews were evaluated. When 2 items had correlations of ≥ 0.90, indicating redundancy, one was eliminated, as were items with correlations of ≤ 0.50 since such items did not accurately measure the dimension represented by the other items in the index or had ambiguous, inconsistent, or incomplete responses. Details of HAQ development are described in Fries, *et al* (1980)[58] and Fries, *et al* (1982)[59].

RELIABILITY AND VALIDITY OF THE HAQ-DI

The HAQ-DI has been repeatedly validated as a reliable measurement instrument for self-assessment by mail, in the office, by telephone, and by comparison with paraprofessional and physician judgments[58]. Evaluations of the psychometric properties of the HAQ-DI have provided consistent and substantial evidence of both its reliability and validity across many applications and in different patient populations and are reported in detail with related publications in the 1996 HAQ review by Ramey and Fries[135]. The HAQ has since become one of the most frequently used instruments for evaluation of functional status, one of the instruments recommended for use in clinical trials in RA[46], and has de facto become a required dependent variable for trials in RA.

Test-retest correlations confirming reproducibility have ranged from 0.87 to 0.99, and correlations between interview and questionnaire formats have ranged from 0.85 to 0.95. Validity has been confirmed in numerous studies. There is consensus that the HAQ-DI possesses face and content validity, and correlations between questionnaire or interview scores and task performance have ranged from 0.71 to 0.95, indicating criterion validity. The construct/convergent validity, predictive validity, and sensitivity to change have also been established in numerous observational studies and clinical trials[135]. Recently, it was compared with the Western Ontario-McMaster Universities OA Index (WOMAC) and was found to be similarly and significantly correlated (HAQ R = 0.67, $p < 0.0001$)[136], and when compared with the modified HAQ (MHAQ) and the RA-HAQ (both shortened versions of the HAQ-DI), it was found to be more efficient at detecting change and assessing functional ability than either of the 2 comparators[180].

OVERVIEW: THE FULL HAQ

1. Disability. The disability assessment component of the full HAQ, the HAQ-DI, assesses a patient's level of functional ability and includes questions of fine movements of the upper extremity, locomotor activities of the lower extremity, and activities that involve both upper and lower extremities. It can be self-administered in 5 minutes and scored in less than one minute. Standard scoring takes into account use of aids and devices or assistance from another person. There are 20 questions in 8 categories of functioning that represent a comprehensive set of functional activities — dressing, rising, eating, walking, hygiene, reach, grip, and usual activities. The stem of each item asks over the past week "Are you able to..." perform a particular task. Each category contains at least 2 specific component questions. For example, under the category of arising, the patient is asked about their ability to stand up from a straight chair and to get in and out of bed.

Scoring is patterned after the ARA/ACR functional class[3,80]. For each item, there is a 4 level difficulty scale that is scored from zero to 3, representing normal (no difficulty) (0), some difficulty (1), much difficulty (2), and unable to do (3). The highest component score in each category determines the score for the category, unless aids or devices are required. Dependence on equipment or physical assistance increases a lower score to the level of 2 to more accurately represent underlying disability. A complementary scoring method ignores scores for aids and devices when computing the category scores and represents residual disability after compensatory efforts. The 8 category scores are averaged into an overall HAQ-DI score on a scale from zero to 3, zero indicating no disability, 3 indicating complete disability. The scale is not truly continuous but has 25 possible values (i.e., 0, 0.125, 0.250, 0.375 ... 3). The HAQ-DI score is not computed when the patient provides answers in fewer than 6 categories. When the HAQ-DI is used to assess disability in a specific disease or condition, usually a single-word change is made in the stem to identify the condition[13,66]. Disability repeatedly has been correlated to mortality rates, progression of aging, and health care resource utilization[25,57,135,181].

2. Discomfort. Pain is one of the most complex dimensions to measure, since it is a subjective composite of physiological, psychological, and social dimensions[19]. In the early years, the ARAMIS group conducted extensive testing to develop a valid pain measurement instrument and had attempted to elaborate pain activity by where the patient feels pain, when it occurs, and by its severity. However, this failed to yield an index that outperformed a simple VAS in terms of reliability, validity, and sensitivity to change[55,135]. As a result, the HAQ retains the basic tenet that "pain is what the patient says it is." The HAQ Pain Scale consists of a double anchored horizontal VAS that is scored from zero (no pain) to 3 (severe pain) — or alternatively from 0 (no pain) to 100 (severe pain). The VAS for pain has been used widely in experimental, observational, and clinical settings[17,89,94,119,135,164].

3. Drug side effects. Evaluation of drug therapy requires assessment of both effectiveness and toxicity. Toxicity data collected by the full HAQ include: the offending drug, dosage, time taking drug, specific side effects, degree of severity, the importance to the patient, and subsequent drug course, i.e., whether the drug was discontinued due to the side effect. Several publications have reported outcomes using HAQ drug side effect data[135,152,154]. In addition, HAQ-derived drug side effect data permitted the develop-

ment of a summary toxicity index (TI) that quantifies the magnitude of adverse effects (toxicity) associated with specific medications[135,173]. The TI is a first attempt to quantitatively describe the overall toxicity of medication; prior adverse effect assessments had used variables comprised of the percentage of patients discontinuing the drug because of side effects or had presented comparative frequencies of selected individual side effects. The TI comprises HAQ side effect data, laboratory abnormalities, and hospitalizations. To obtain the TI, standardized rules are applied to attribute particular events to particular therapies based on known toxicities of particular drugs as reported in the literature [e.g., a patient was hospitalized for gastrointestinal bleeding after taking nonsteroidal antiinflammatory drugs (NSAID)]. Weights established for different side effects, resulting from ratings by physicians, patients, and health professionals, are then assigned. The TI has been shown to be valid and sensitive for differing weights and found to be stable[135,152]. Since development of the TI, comparison of adverse events between NSAID has documented 2- to 4-fold differences in side effects, in contrast to conventional assumptions of their equivalence[61], and TI scores of disease modifying antirheumatic drugs (DMARD) have been found to be variable and sometimes to be less toxic than NSAID[62].

4. Dollar costs. Information for computing and adjusting direct medical costs and indirect costs due to loss of productivity are captured by the full HAQ. Direct cost data include physician visits, hospital days, laboratory costs, radiographs, medications, and other medical costs including use of alternative treatments and procedures. All major cost items such as hospitalizations, surgeries, and procedures are audited and source documentation obtained. Direct costs are measured in terms of units of service that are then assigned dollar values, allowing automatic adjustment for inflation and for different pricing structures in different regions. Standard costs for each service are developed from multiple sources (e.g., Physicians' Fee Reference, Medicare reimbursements, surveys of providers, insurance company data, American Hospital Association data, and pharmaceutical industry sources) and applied to computations that cumulate such variables as doctor visits, hospital days, and medication costs into a direct cost figure. While actual charges are sometimes used for validation, differences between costs and charges confound such data and decrease its overall utility. Indirect costs are derived from patient report of days lost from paid employment due to the patient's illness. A number of major studies have used HAQ cost data[24,25,67,135,181].

5. Death. In this HAQ dimension, verification and cause of death are obtained by ARAMIS protocols that describe procedures for identifying deaths, time to death, and causes of death for patients lost to followup. The National Death Index is searched annually to identify whether patients lost to followup have died. A number of mortality studies have been published using data from these sources and have included correlations with morbidity and costs[108,135,181].

GLOBAL HEALTH

Both the short and full HAQ contain the HAQ's patient Global Health Analog Scale. It is among the common VAS instruments that include the Torrance "feeling thermometer" in the EuroQol instrument and the VAS in the Arthritis Impact Measurement Scales (AIMS), which are used to measure quality of life. The HAQ Global is a 15 cm double anchored horizontal VAS that runs from zero, representing "very well," to 100, "very poor," and has been validated as a measure of quality of life[22]. Fries and Ramey[55] compared the HAQ Global to the Torrance quality-of-life "feeling thermometer" and found the 2 scales to be highly correlated ($r = -0.676$, $p < 0.001$), indicating that both instruments are measuring similar quality of life constructs.

CORRELATIONS OF HAQ-DI WITH OTHER HEALTH STATUS MEASURES

The HAQ-DI has been significantly correlated with a wide variety of health status measures, including self-report measures, biochemical and clinical studies, assessment of morbidity, evaluation of health care resource utilization and cost estimations, and studies of mortality[135]. Among the self-report measures that have been correlated with the HAQ-DI since the review by Ramey and Fries in 1996 are the AIMS[161], AIMS2[9], global health status[98,123], VAS pain scale[98,165], Beck Depression Scale[156], Carstairs Index[109], Danish Nottingham Health Profile[163], Disease Activity Score[84,156,165], Dutch AIMS[165], EuroQol[22], Hollingshead Index[105], Life Event Interview[102], London Handicap Scale[74], Nottingham Health Profile[83], Medical Outcome Study Short Form-36 (SF-36)[22,88,162], Social Network Delineation Questionnaire[63], Trait Anxiety[133], and the WOMAC[22,136,179]. Correlations with clinical measures have included the areas of joint and muscle activity[27,33,82,98,105,119,123,126,156,159,165,176], bone health and radiographs[27,53,92,155,161], body fat[92,116,155], and health behaviors[93,144]. Biochemical assessments have included C-reactive protein[31,89,177] and human leukocyte antigen (HLA) typing[76,141,146].

In addition, the HAQ-DI has been utilized as a predictor variable in investigations of productivity, morbidity, health care utilization, health care costs, and death. Functional status evaluated by the HAQ-DI has been significantly correlated with work related measures like work capacity, household work performance, work task performance, work disability, occupation, and ability to live independently[13,49,66,90,128,135,157,175,178]. In investigations related to health care, the HAQ-DI has been correlated with myriad assessments of health care such as direct costs[25,135,153,183,184], hospital admissions, length of hospital stay, postsurgery delirium, use of aids and devices, health care resource utilization, health care system performance, in miscellaneous other areas like specialty care and patient satisfaction with

health care workers, in post-total knee replacement surgery, and predictors of mortality[29,135,170,171].

CHILDHOOD HEALTH ASSESSMENT QUESTIONNAIRE (CHAQ)

The HAQ-DI was used as a template by Singh and colleagues[151] to develop the CHAQ, which is a parent and/or self-administered questionnaire designed to measure health status in children as young as one year of age. These investigators added several new questions and modified existing ones, so that for each functional area there is at least one question that is relevant to children of all ages. The CHAQ has been validated in patients with juvenile RA[50,69,103,115] and dermatomyositis[45], and has been administered in studies of children with spina bifida[5], polyarticular juvenile chronic arthritis[140], juvenile arthritis[174], and oligoarticular juvenile chronic arthritis[142]. Since its inception and the last HAQ review in 1995[135], the CHAQ has continued to show excellent psychometric properties[43,45,50,51,85,113,140,142,167,174] and has been translated into more than a dozen languages (Table 2).

LANGUAGE AND CULTURAL ADAPTATIONS

The HAQ-DI was originally developed and validated for English speaking populations in the United States and Canada, and has since been translated or culturally adapted into more than 60 different languages or dialects, often with only minor changes. Table 2 lists translations for HAQ-DI since the last review[135] and includes translations for the CHAQ. Translations and cultural adaptations of the HAQ-DI are usually carried out by administering investigators. Many have also been performed by the MAPI Research Institute in Lyon, France, and the Health Outcomes Group in Palo Alto, California, both of which have had extensive experience in translating and culturally validating the HAQ-DI; fees are sometimes charged by these vendors.

Translated HAQ-DI have generally been fully validated, using methods such as test-retest reliability, item-total correlations, convergent validity, interviewer versus self-administered formats, and factor analyses. To date, culturally adapted HAQ-DI instruments have proved to be as reliable and valid as their parent. To adapt the HAQ-DI culturally, modifications of individual items have sometimes been necessary. The types of items most frequently in need of adaptation have included colloquial expressions or those for which names or types of items or utensils are culturally idiosyncratic. For example, some Asian cultures do not consume milk in cartons; thus, an appropriate substitution in keeping with the original intent of the item is made. In some European countries a bathtub is much more commonly used than a shower, requiring question modification.

Table 2. Translations and cultural adaptations of the adult Health Assessment Questionnaire (HAQ) and the Childhood Health Assessment Questionnaire (CHAQ).

Independent translations and adaptations: Arabic[149], Australian[28,77], Austrian[150], Austrian CHAQ[87], Bulgarian CHAQ[112], Chinese[97], Croatian CHAQ[73], Danish CHAQ[117], Dutch CHAQ[182], Czechoslovakian CHAQ[32], English (British) CHAQ[120], Finnish[72], Finnish CHAQ[127], Flemish CHAQ[91], French (France)[71], French CHAQ[131], Georgian CHAQ[125], German[101], German CHAQ[52], Greek CHAQ[132], Hebrew CHAQ[75], Hungarian CHAQ[122], Italian[137,145], Italian CHAQ[44,143], Latvian CHAQ[139], Korean[11], Korean CHAQ[12], The Netherlands[78,79,166], Norwegian[51,96], Norwegian CHAQ[50,147], Polish[138], Portuguese (Brazil)[47,48], Portugal[47], Portuguese CHAQ[107,110], Russian CHAQ[118], Scandinavian (multiple languages)[20], Scottish[100,129], Serbian CHAQ[160], Slovak CHAQ[168], Spanish (Mexico)[23], Spanish[42,68], Spanish CHAQ[34], Chilean[30,114], Costa Rican[10,64,69,115], Argentinian[115], Swedish[7,15,16,21,35-41,158], Swedish CHAQ[7,8,81], Swiss German and Swiss French[174], Thai[123], Turkish[99,148], Turkish CHAQ[124].

Translations/adaptations available through the Health Outcomes Group (E-mail: HOG_USA@Compuserve.com): Australian, Austrian, Belgian Dutch (Flemish), Belgian French, Canadian French, Chinese (Cantonese, Hong Kong), Croatian, Danish, English (Canadian, United Kingdom), Finnish, French (France), German (Germany, Switzerland), Greek, Israel (English), Hebrew, Italian, Lithuanian, Portuguese (Brazil, Portugal), Romanian, Singapore (English, Malay, Mandarin), Slovenian, South Africa (Afrikaans, English), Spanish (Argentina, Chile, Colombia, Costa Rica, Guatemala, Peru, Spain, United States, Venezuela), Swedish, Turkish

Translations/adaptations available through the MAPI Institute (http://www.mapi-research-inst.com): Australian, Austrian (German), Belgian Dutch (Flemish), Belgian French (Walloon), Canadian French, Czech Republic, Danish, Dutch, English (Canadian, India, New Zealand, United Kingdom), Finnish, French (France), German, Greek, Hebrew, Hungarian, Israel, Italian, Japanese, Norwegian, Polish, Portuguese (Brazil), Russian, Slovak Republic, South Africa (Afrikaans, English), Spanish (Argentina, Costa Rica, Guatemala, Mexico, Spain, Venezuela), Swedish

CONCEPTUAL ISSUES IN MEASUREMENT

The importance of assessing health outcomes in chronic disease has become recognized and appreciated and is a significant component of study design. As a result, there has been escalating interest in issues regarding measurement properties and instrument development.

Generic versus disease-specific instruments. A "generic" (suitable for many diseases and conditions) or a "disease-specific" (limited to use in one or a few disease conditions) distinction has been made for several instruments in assessing patient outcomes. For example, the WOMAC and AIMS were designed for and are correctly labeled as disease-specific assessment tools for OA and arthritis, respectively[14,185]. They have not been used in other conditions. The SF-36[172] has long been established as a generic instrument for measuring dimensions of patient outcomes in numerous types of conditions. Because the full HAQ originated from the rheumatology field, it sometimes has been characterized as a disease-specific instrument rather than having been adjudicated on the basis of its structure, content, and history of use. The HAQ has been and can be administered across diverse disciplines and in different cultures. The "5 Ds" of disability, discomfort, drug toxicity, dollars, and death are generic.

The HAQ has proved itself as a generic tool from its generic, largely universal patient centered foundations and its numerous demonstrated applications in a variety of popula-

tions, ranging from normal populations to aging populations to patients with HIV-AIDS, as well as in children and adults with diverse rheumatic conditions. Functional sections of other generic instruments, such as the SF-36 and the Sickness Impact Profile, have been significantly correlated with the HAQ-DI and measure similar constructs[15,22,78,88,162], although the HAQ also includes additional items that assess dollar costs, drug side effects, and death that are not part of these instruments. None of these instruments, including the HAQ, is entirely complete, and there does not appear to exist an instrument that can be considered the "ideal" generic instrument: supplementary questions or instruments will probably always be required for some specific studies.

Floor and ceiling effects. Some investigators have suggested that many outcome instruments, including the HAQ-DI, are not sensitive to change at the ends of the spectrum, e.g., a person with a HAQ-DI of zero (not disabled) cannot get better, while the individual could perhaps become more fit, and a person with a HAQ-DI of 3 (completely disabled) seemingly cannot become more disabled, although perhaps the patient could worsen. However, this issue can be interpreted alternatively. If 10% of a sample of patients with RA have a HAQ-DI score of zero, this may not be a "ceiling effect." It can instead be interpreted to mean that if 10% of patients report no difficulties with any of their activities of daily living, then 10% of patients with RA have no disability. That none of these patients might be able to run a mile in 8 minutes is neither relevant nor useful to estimation of their level of disability. If we proposed a "fitness" index, the index would have to accurately represent "fitness." A disability index must represent disability. If a patient is completely unable to perform any activity of daily living and has a HAQ-DI score of 3, then they are in essence totally disabled. In the disability context, you cannot be more than totally disabled, although as a patient you might get worse in other areas, such as pain and cognition. Normal, healthy individuals consistently score zero on the HAQ-DI. In our view, this is not a ceiling effect; it is a characterization of the disability status of the patient. In this sense, "floor" and "ceiling" effects define the limits of the concept of disability and may be considered a strength and not a weakness.

Distances between values. The comparison of outcomes relative to differences in scores at different ranges on a scale is a significant issue. For example, the HAQ-DI has category ranks for each variable, where zero equals "without any difficulty," 1 "with some difficulty," 2 "with much disability," and 3 represents "unable to do." The question is whether we know if the "disability distance" between zero and 1 is the same as between 1 and 2 or between 2 and 3. This is a provocative question, to which the answer is probably "no," and one that is being studied. In practice, the problem is less than might be expected, since most patients progress irregularly across the HAQ-DI's 8 categories, averaging out distance effects, if any. Thus, the HAQ-DI appears to behave smoothly over time, with progression rates and treatment effects reasonably similar regardless of initial HAQ-DI level.

Proliferation of instruments. In recent years there has been introduction of several new assessment tools that conceptually or in content are similar to established instruments. The best studied and most widely used instruments share several criteria: they are based on a coherent conceptual model; they have demonstrated reliability, validity, and sensitivity to change; they have been widely used in diverse settings and have good norms; they are available in multiple languages and have been stable for a sufficient length of time that longitudinal studies are possible. Although no existing instrument is ideal, and a new instrument might contain improvements, if the improvements are not substantial, the instrument will not likely make an enduring contribution. Lack of multiple validations and assessments and difficulty in relating results to the literature are disadvantages. Given their histories, we believe that the HAQ, which has evolved de facto into the standard instrument in many areas, and the SF-36 (or SF-12), which has the largest overall use and a long history, are viable choices for use as standard instruments, with additional question sets added to meet the needs of particular studies. We must be able to compare results across studies and across diseases, and this cannot occur without an essentially common vocabulary. A few standard instruments, meeting the above criteria, and to which disease-specific questions may be added as required would appear to have substantial advantages over a proliferation of additional variations on a theme.

CONCLUSIONS

A full understanding of the natural history of disease or clinical treatment requires consideration of a comprehensive set of patient centered health outcome variables that are collected longitudinally. Outcome measurement is rapidly increasing in use, and we anticipate increased focus on a smaller number of instruments with supplemental questions used for disease or study-specific queries. Such instruments will have extensive validations and good psychometric properties, and will be available in many languages. We believe the HAQ has appropriate attributes to be among those considered for use as standard instruments. New applications may be to guide use of therapeutic choices and as justification for the use of powerful, but expensive, new therapeutic agents.

Collection of longitudinal patient outcome data, based on the 5 patient centered dimensions, is increasingly standard in clinical trials, epidemiologic studies, and in patient care, representing a major paradigm shift over the past 2 decades. The HAQ has increased the credibility and use of comprehensive measurement techniques involving validated patient self-report and has led to a new appreciation of outcome assessment. We hope that this review of the Health Assessment Questionnaire will prove useful as a guide to the literature and to understanding pertinent issues regarding patient outcome assessment.

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