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Concepts and Methods in the Development of the ADRQL: An Instrument for Assessing Health-Related Quality of Life in Persons With Alzheimer's Disease

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This paper describes the conceptual framework and development of the ADRQL (Alzheimer's Disease-Related Quality of Life), a new instrument for assessing Health-Related Quality of Life (HRQoL) in Alzheimer disease (AD). The ADRQL is compared to other well-established HRQoL instruments in terms of conceptual framework and domains. The methodology used in instrument development, which relied heavily on caregivers and AD experts to shape content rather than adopting existing classifications, is discussed, as are special challenges in developing an HRQoL instrument for AD. The ADRQL has domains in common with other HRQoL instruments, but as a disease-specific instrument has unique areas of content. Compared to other measures used in AD assessment, the ADRQL is the first instrument to evaluate multiple domains of HRQoL, as opposed to single components of experience. The ADRQL has been conceptualized and developed using current HRQoL theory and methodology. The objective was to develop an instrument for use in evaluations of treatment interventions in AD. Future stages of development will include psychometric analysis and the establishment of validity and responsiveness to change.

Health-related quality of life is recognized as an essential component in the overall evaluation of health, and is used increasingly to reflect patients' perspectives in studies of medical treatment effectiveness and outcomes (Ware, 1995). There are proponents of both generic and disease-specific measures (Wiklund & Karlberg,1991), and both have important uses (Guyatt, Feeny, & Patrick, 1993). Health-related quality of life

measures, whether generic or not, have a shared objective: to provide information about the effects of treatment beyond the traditional focus on mortality and clinical indicators. Determining whether people are "better off" as a result of medical intervention has become increasingly salient as clinicians and patients face choices among alternative treatments or therapies, and payers and policy makers try to determine which alternatives are most cost-effective.

Research definitions of quality of life are usually quite broad, e.g., "those aspects of life and human function considered essential for living fully" (Mor, 1987), and build upon an extensive social science literature concerning quality of life and associated concepts such as well-being and life satisfaction (Andrews & Withey, 1976; Andrews & Inglehart, 1979; Diener, 1984; Lawton, 1984). Health-related quality of life (HRQoL) focuses more narrowly on the "value assigned to the duration of survival as modified by impairments, functional states, perceptions, and social opportunities influenced by disease, injury, treatment, or policy" (Patrick & Erickson, 1993). HRQoL is intended to concentrate attention on those areas of life directly influenced by health; although, as noted elsewhere, "when a patient is ill or diseased, almost all aspects of life can become health-related" (Guyatt et al., 1993).

Although health-related quality of life measures have been developed for many specific diseases, e.g., asthma (Juniper, Guyatt, Ferrie, & Griffith, 1993) and HIV (Wu et al., 1991), only recently has HRQoL begun to receive attention for Alzheimer disease (AD) and other dementias. One reason may be the expectation that assessment of HRQoL must be obtained through self-report which is not feasible for many AD patients. As Lawton, one of several researchers arguing for the need to consider quality of life for patients with Alzheimer's observes, "most cognitively impaired patients do not introspect, or at least do not report reliably on interior phenomena" (Lawton, 1994). Many patients with dementia either are unaware of their impairments and disabilities or are unable to communicate them, having lost the capacity to verbalize and the ability to remember information necessary to assess their own status. The fact that many individuals with dementia reside in nursing homes also may have discouraged application of HRQoL methodologies, since measures would need to be applicable to institutional settings as well as community-living environments. This is a crucial issue since the influence of environment on functioning and opportunities for social interaction, often reflected in HRQoL instruments, may differ considerably across these settings.

In spite of these obstacles, several arguments support the development of a measure of quality of life in individuals with dementia. First and foremost is the observation that many individuals with dementia improve with therapeutic intervention (Rabins, 1994). Treatments can have desirable and undesirable outcomes. Since these are observed by family members and clinicians, they should be accessible to measurement. In this regard, measures of quality of life are similar to other phenomena such as physical function, cognitive function, activities of daily living and behavior disorder, all of which are commonly used as outcome measures. Second, while the view is sometimes expressed that the life of a person with dementia is by definition of negligible quality, this is inconsistent with both clinical experience and other research. Onset of serious, disabling disease or terminal illness does not eliminate variation in quality of life or well-being among those afflicted (Tsevat et al., 1998), although the metric on which these are measured is often different from what would be applicable to a broad segment of the population. Positive quality of life has been identified in many groups of patients with severe illness, including those with end-stage renal disease (Churchill, Wallace,

Ludwin, Beecroft, & Taylor, 1991), terminal cancer (Mor, 1987), and HIV-infection (Hays & Shapiro, 1992). Health-related quality of life also has been measured successfully in persons with severe mental illness (Lehman, 1988). People with dementia, like others with a serious debilitating disease, still have quality in their lives, even though it may be difficult for persons *not* in this state to see it. An underlying assumption of our work on HRQoL in AD is that all human life has quality and that it can be quantitated.

A necessary first step in developing an instrument to evaluate health-related quality of life is to determine the basic areas or domains that are to be assessed. For populations who cannot communicate for themselves, which include young children and individuals with disease-related impairments in communication, there are two alternative approaches, (1) to define the domains *a priori* or, (2) to use proxy respondents to identify domains of importance. As described below, we took the second approach, using caregivers and AD experts to shape the content of the instrument (a process described in more detail below) rather than adopting existing classifications from other instruments already in use. This method yielded some domains that are equivalent to those in other HRQoL instruments and some domains that appear distinct in concept, definition, or both.

This paper describes the development of the ADRQL, a health-related quality-of-life instrument for use in patients with Alzheimer's disease. The conceptual framework for the instrument and its relationship to other established instruments measuring HRQoL are described, as are the unique challenges of assessing HRQoL in persons with dementia. Other stages of the instrument development process are described as well. The ADRQL was specifically designed to contain concepts and domains most important to caregivers and providers of care for people with AD and to detect change in health-related quality of life in response to treatment interventions. As such, it is disorder-specific and incorporates the unique characteristics of the daily life of persons with dementia.

The potential uses for this instrument include evaluations of behavioral interventions, environmental settings, and drug treatments in AD patients. Instruments intended for evaluations of medical effectiveness of treatment interventions must demonstrate several key measurement properties including a strong conceptual foundation, content validity, and responsiveness to change (Guyatt et al., 1993).

CONCEPTUAL DEVELOPMENT OF THE ADRQL

The ADRQL was developed to produce a multidimensional disease-specific HRQoL instrument for use with people with AD. The conceptual process was guided by two objectives:

— to develop an instrument that would be consistent, both conceptually and methodologically, with previous approaches used in measuring health-related quality of life

— to develop an instrument that would detect change and yield a quantitative assessment of health-related quality of life, making it suitable for clinical trials and medical effectiveness studies.

Table 1 provides a comparison of the content of the ADRQL with that of other HRQoL instruments, both generic and disease-specific. This comparison provides a basis for evaluating the ADRQL in the broader context of HRQoL instrumentation. Two of the instruments selected for comparison, the Short-Form 36 (SF-36)(Ware & Sherbourne,

TABLE 1. Comparison of Health-Related Quality of Life Domains in the ADRQL With Other Generic and Disease Specific Measures

	Generic			Disease-Specific	
Alzheimer Disease Related Quality of Life (ADRQL)	**Short Form 36 (SF-36)[1]**	**Quality of Well-Being Scale (QWB)[2]**	**Core Concepts of Quality of Life (Patrick & Eriskson)[3]**	**Arthritis Impact Measurement Scale 2 (AIMS2)[4]**	**Quality of Life in Alzheimer Disease (Lawton)[5]**
Social Interaction	Social funtioning	Social activity	Social contact	Social activities Suppprt from family and friends	Socially appropriate behavior
Awarness of Self	Role-Limitations due to physical problems	Social activity	Limitations in usual role	Work	
	Role-Limitations due to emotional problems				
Feelings and Mood	General mental health		Affective functioning	Mood Level of tension	Psychological well-being Presence of positive/ negative affect states
Enjoyment of Activities		Symptom/ problem list	Social integration		Engagement in positive activities
Response to Surroundings					

[1]From Table 1, Information about SF-36 Health Status Scales and the Interpretation of Low and High Scores (Lehman, 1988).
[2]From Table 1, The QWB Scale, Showing the Combinations of Mobility, Physical Activity and Social Activity Items and Associated Social Preference Weights (Kaplan & Bush, 1982).
[3]From Table 4.1, Core Concepts and Domains of Health-related Quality of Life (Patrick & Erickson, 1993).
[4]From Table 1, AIMS 2 Scale Scores in Rheumatoid Arthritis and Osteoarthritis Subject Groups (Ware, 1993).
[5]Quality of Life in Alzheimer Disease (Lawton, 1994).

1992) and the Quality of Well-Being scale (QWB) (Kaplan & Bush, 1982; McDowell & Newell, 1996), are global or general instruments that are intended for use in assessing individuals and populations regardless of health levels or type of disease. As defined by Ware (1993), generic measures assess health concepts that "represent basic human values that are relevant to everyone's functional status and well-being" and are not "age, disease, or treatment specific." Also included is Patrick and Erickson's (1993) general framework of core concepts and domains of health-related quality of life. Although not an instrument, this comprehensive listing serves as a useful guide for assessing any HRQoL instrument. The two disease-specific comparisons are the Arthritis Impact Measurement Scales 2 (AIMS2) (Meenan, Mason, Anderson, Guccione, & Kazis, 1992) and Lawton's formulation of quality of life issues in AD (Lawton, 1994). The AIMS2 is designed for use in a particular age group, elderly people suffering from arthritis. Similarly, Lawton frames the domains of importance in measuring HRQoL in Alzheimer's disease and identifies methods that could be used for assessment (Lawton, 1994).

All health-related quality of life instruments share a common goal, to quantify individual subjective feelings about day-to-day living experiences as they are affected by health and illness. Operationally, these experiences are conceptualized as major domains in which the effects of health and illness on individuals are expressed. HRQoL instruments are characterized by multiple domains as well, since it is generally acknowledged that the effects of illness or treatment can vary across domains. The process of developing and defining domains for a particular instrument nonetheless leads to considerable differences across instruments. These include varying numbers and types of domains, as well as differences in definition even when measuring a similar concept.

Similarities and differences in content and structure among existing HRQoL instruments are apparent in Table 1. The ADRQL, which is the focus of these comparisons, consists of 5 domains: Social Interaction, Awareness of Self, Feelings and Mood, Enjoyment of Activities, and Response to Surroundings. The SF-36, by contrast, assesses 8 areas (physical functioning, social functioning, general health, bodily pain, mental health, vitality, role—physical, role—emotional; not all are shown in Table 1); the QWB assesses 3 areas (mobility, physical activity, social activity); and the AIMS2 consists of 12 areas (among these are arthritis pain, work, mood, hand and finger function, self-care; not all are shown in Table 1). A major difference between these instruments and the 2 instruments developed for Alzheimer's disease, is the inclusion of domains reflecting physical activity (discussed in more detail below). All five domains of the ADRQL fall within the concepts of social and psychological functioning as described by Patrick and Erickson (1993). Only domains related to these concepts are included for the other instruments shown in Table 1, since the main objective is comparison of these instruments with the ADRQL.

Four areas of social functioning are identified by Patrick and Erickson (1993), 2 of which appear in the ADRQL as well as in the other four instruments shown in Table 1. These are interaction with others (talking to or seeing family and friends) and role performance (in work or school, as a spouse or child). Interaction or involvement with other people is characterized in the ADRQL as Social Interaction. Lawton's framework, which is concerned with Alzheimer's disease specifically, evaluates "socially appropriate behavior" (1993), while the AIMS2 includes domains on "social activities" and "support from family and friends." The SF-36 assesses "social functioning," and the QWB includes contact with family and friends under social activity.

Role performance is included in both generic instruments. The SF-36 distinguishes between role limitations due to physical impairments and those due to emotional problems, while the QWB assesses presence/absence of limitations in work, school, housework (again under the social activity dimension). In the AIMS2, the only role-related domain is work. Ability to perform one's role in a work or family setting is inevitably affected by the progression and severity of Alzheimer disease. Lawton, for example, does not suggest any assessment in role-related activities as a component of quality of life in Alzheimer (1994). The ADRQL domain that most closely approximates role functioning is Awareness of Self. Unlike the domains that focus on limitations in role performance, however, this domain of the ADRQL is intended to reflect whether a "continued connection" to these roles is observed in the subject's behavior.

In addition to social functioning, the other domain consistently represented across HRQoL instruments is an appraisal of perceived emotional well-being or distress. Patrick and Erickson identify two areas of psychological function, affective and cognitive (1993). The first includes "distress and well-being," while the second reflects attributes such as alertness and problems in reasoning. The instruments in Table 1 focus on domains that reflect affective functioning; none includes cognitive functioning as a domain. Clearly, changes in cognitive functioning are an important outcome in treatment interventions for AD. There is little precedent for including it in an HRQoL instrument, however, perhaps because, as Patrick and Erickson note, the relationship of cognitive functioning to psychological well-being or social functioning is not well understood (1993). The affective component of psychological function is captured in the ADRQL under Feelings and Mood, and is most similar to the two disease-specific instruments which assess "psychological well-being" and "presence of positive/negative affect states" (Lawton, 1994) and "mood" and "level of tension" (Meenan, Mason, Anderson, Guccione & Kazis 1992). The SF-36 deals with psychological functioning by characterizing general mental health in four areas—anxiety, depression, loss of behavioral/emotional control, and psychological well-being. The QWB focuses on the functional end result of disease expressed in mobility and social/physical activity limitations, and does not provide a means of evaluating psychological well-being or mental health.

The last two domains of the ADRQL, Enjoyment of Activity and Response to Surroundings, have few counterparts in the other instruments. They are salient for persons with dementia in the eyes of caregivers and providers, however. Lawton notes that most contemporary QoL assessment methodologies focus on limitations and disabilities, paying little attention to positive behaviors (Lawton, 1994). Given the severe impairments in social behavior and activity that result from Alzheimer's disease, he argues the need for understanding "which behaviors can survive dementia." The Enjoyment of Activity domain in the ADRQL is intended to evaluate this type of behavior in AD and is similar to "enjoyment of positive activities" suggested by Lawton (1994). Patrick and Erickson's (1993) "social integration" concept which is directed at participation in community life and the social ties that result, has some common ground with Enjoyment of Activity as well. The level and types of participation in activities among persons with dementia, however, will necessarily be quite different from what would be viewed as appropriate in individuals without cognitive impairment. Social integration,

leisure behavior and activities or, in Lawton's terminology, "lifestyles outside the work domain," (Lawton, 1994) are not reflected in either of the generic measures (QWB and SF-36). These focus instead on role performance and ability to engage in more instrumental task-oriented activities (e.g., activities of daily living, household tasks, work).

Response to Surroundings has no counterpart in the other instruments shown in Table 1. Just as "arm function" is unique to the AIMS2, Response to Surroundings is unique to the ADRQL. This domain is intended to address both positive and negative interactions with one's physical environment. The design and configuration of physical environments (both community and nursing homes) is seen as potentially important in AD treatment (Cohen & Weisman, 1991) and is a field in which considerable advances may occur in the near future. In the general population, this dimension has not been considered relevant to health-related quality of life, perhaps because the physical environment has not been viewed as having an impact on health-related quality of life except indirectly through enhancing or limiting physical functioning.

While the ADRQL draws on concepts that have been included in many other efforts to assess health-related quality of life, the specific items or indicators for each domain will differ from what would be used in a general population. A generic instrument, such as the SF-36, includes indicators of social interaction that reflect the impact of physical or emotional health on normal social activities. However, use of these indicators in an AD population would result in a "floor" effect, whereby virtually all individuals would be grouped at the worst scores. Since the items within each domain must discriminate among individuals, an instrument designed for use in persons with AD must reflect the range of scores (and functioning) possible among these individuals, rather than the much higher levels of functioning that would be expected in nonaffected individuals. Items that discriminate within an AD population, on the other hand, will not be suitable for discriminating among individuals without dementing diseases, since virtually all of these individuals will be capable of performing at the highest level.

One major difference between the ADRQL and many other instruments assessing quality of life is the absence of a domain reflecting physical functioning. Cognitive functioning, as already noted, is rarely included in HRQoL instruments, even though Patrick and Erickson list it as a domain of psychological functioning (1993). Both physical functioning and cognitive functioning are important components of the full battery of assessments that are needed to evaluate treatment interventions for Alzheimer disease. Cognitive functioning is critical, of course, because it is impaired in all individuals affected with the disease. For both cognitive and physical functioning, however, several well-established scales exist. The ADL (Katz, Ford, Moskowitz, Jackson, & Jaffe, 1963) and IADL (Lawton & Brody, 1969) are extensively used to evaluate the impact on functional performance of physical limitations in basic and complex areas of task functioning. There also are valid and reliable measures of cognitive functioning that have been used extensively in studies of the Alzheimer population (Folstein, Folstein, & McHugh, 1975; Rosen, Mohs & Davis, 1984). There are additional reasons, however, for not incorporating these domains in an HRQoL instrument for persons with AD.

First, declines in cognitive function are a necessary component in diagnosing Alzheimer disease. Furthermore, progressive and ultimately overwhelming physical deterioration accompanies dementing illness such as AD. Because cognitive and

physical decline are closely aligned with disease progression or severity, inclusion of these domains in an HRQoL instrument runs the risk of building into the measurement process a strong correlation between a decline in functioning and a decline in quality of life. How change in physical and cognitive functioning resonate in other aspects of life is far from clear. Excluding physical functioning and cognitive functioning as domains in the ADRQL allows hypotheses to be tested concerning the relationship of changes in quality of life to changes in physical and cognitive functioning.

Another reason for excluding cognitive and physical functioning is the strong likelihood that these would dominate the assessment of health-related quality of life in Alzheimer patients, and render the instrument less sensitive to changes in other domains. Mor (1987), for example, in using the Spitzer Quality of Life Index, noted that its central organizing principle was physical functioning and that "if the index serves only as a physiological marker, it is probably not sufficiently sensitive for use as an outcome variable in studies evaluating the effect of a medical or health care system intervention on patients' lives." Ideally, HRQoL measures, which are inherently subjective, should be sensitive to changes that may not be reflected in measures of physical or cognitive functioning. Small improvements in cognitive functioning, for example, may have little or no impact on quality of life domains, while interventions that do not measurably affect cognitive functioning may show improvement in quality of life. It is critical to evaluate the impact of treatment interventions in the areas of cognition, physical function, *and* HRQoL and to do so with measures that do not assume that a change in one evokes a change, or a change of equal magnitude, in another.

Lawton has proposed conceptualizing quality of life across 4 sectors—psychological well-being, perceived quality of life, behavioral competence (social, physical, cognitive), and objective environment (1994). The ADRQL has domains and indicators that have a common ground with three of the four qualities (psychological well-being, perceived quality of life, and the social component of behavioral competence). With the addition of instruments that evaluate physical and cognitive functioning, and measures of the external environment (e.g., quality of care), an evaluation of Lawton's broad concept of quality of life could be achieved. Such a battery could also form the basis for evaluating the impact of AD treatments in both functioning and health-related quality of life.

INSTRUMENT DEVELOPMENT

Given the inability of those with the disease to make such assessments, caregivers and health care professionals were viewed as best suited to identify health-related quality of life issues in Alzheimer disease. Caregivers, most often close family, are well informed concerning the day-to-day activities and behavior of people with Alzheimer disease, although their views may be influenced by their own experience. Health care professionals offer a clinical perspective and, based on experiences with many patients, are in a position to identify behaviors that appear common to persons with AD. Both groups were used in the iterative process of identifying domains of HRQoL in AD and in developing and selecting items.

Initially, the authors developed an item pool based on objectives for the instrument, knowledge of other health-related quality of life measures, and clinical and research experience with Alzheimer's disease. Next, a local expert panel of

health care professionals was convened. It consisted of nurses working in long-term care and outpatient dementia assessment centers, physicians working in outpatient and inpatient psychiatric and long-term-care facilities that specialize in treating persons with dementia, an activity therapist, a social worker and a representative of the local Alzheimer Association. After being presented with the objectives of the instrument, these individuals were asked to develop a list of potential items, and then to review the items developed previously by the authors. Finally, the group was asked to develop a list of major life domains.

After including the panel's recommendations, the draft instrument contained 9 domains of 4 or more items in each. This list of items and domains was mailed to 12 experts with national reputations in research or treatment of AD. Among them were individuals with clinical (psychology, psychiatry, nursing) expertise, research experience, or both. The national expert panel was asked to review the draft instrument and to identify items for inclusion or deletion among both items and domains. Once responses were obtained from this external panel (11 out of 12 responded), a revised instrument was constructed that reflected the modifications contributed by the local and national expert panels. Decisions concerning modifications were based on consistency with the initial conceptual framework, inclusion of items and domains that had not been considered, and the elimination of redundancy.

The instrument was then presented to a focus group of 12 family caregivers of persons with Alzheimer's disease. Among them were spouse and adult child caregivers, men and women, and African American and White individuals. Participants were asked to consider what behaviors or observable indicators they would use to evaluate a good or poor quality of life for someone with AD. Subsequent to this discussion, they were asked to examine the draft instrument, to comment on existing items and domains and to add or change any items they felt were missing or inadequately represented. Modifications suggested in the caregiver focus group were incorporated into another draft of the instrument and reviewed a final time by the local expert panel. Useful modifications were made at each stage of this process, but at no point was there serious disagreement about the key domains for assessing HRQoL in AD.

The final stage in the development process involved efforts to verify the placement of items within domains and the ability of caregivers to comprehend content. For the first, 5 researchers in gerontology and health services research were given the titles of the domains and asked to sort the pool of items into them. For 80% of the items, at least 4 participants sorted them into the expected domain. Two items out of 48 were sorted incorrectly by all participants; these had been placed in the Feelings and Mood domain but were sorted into Social Interaction because the presence of other people was mentioned in the items. All missorted items were reviewed by the investigators. Minor modifications were made including placing one item in a different domain and slightly rewording others.

The final step was an additional effort to ensure that the items and definitions used in the instrument would be clearly understood by caregivers. Three cognitive interviews were conducted with current caregivers who were chosen to reflect diverse demographic backgrounds (one White male spouse, one Black female spouse, one Black adult child caregiver). Cognitive interviews provide a means of identifying words or phrases that are confusing or difficult to understand, and are used to explore the thought processes respondents use in deciding on answers to questions (Fowler, 1992; Willis,

Royston, & Bercini, 1989). No changes were made to content based on these interviews, but instructions were shortened and simplified, and wording complexity was reduced.

Table 2 reflects the final conceptual domains of the ADRQL and their definitions. Representative items, both positive and negative, are also shown. It is important to note that items rely primarily on observable behaviors and actions such as physical gestures, speech and facial expression, although some, e.g.,"shows sense of humor," call for a more subjective assessment.

Concomitant with the focus group and mail survey, a review of the literature was undertaken with particular attention to instruments addressing (1) aspects of well-being or health-related quality of life in Alzheimer's disease, and (2) assessment of patient characteristics or attributes through observable behavior. Table 3 compares 4 instruments described in the literature that address health-related quality of life in Alzheimer's disease. The instruments included were developed to measure well-being or distress in persons with AD. All use a proxy respondent to evaluate the subject's status. Caregivers are used in the Progressive Deterioration Scale (PDS) (DeJong, Osterlund, & Roy, 1989), the Pleasant Events Scale (PES-AD) (Logsdon & Teri, 1997), and the ADRQL, while observer/raters, either clinicians or other trained observers, are used in the Discomfort Scale for Persons with Dementia of the Alzheimer Type (DS-DAT)

TABLE 2. Conceptual Domains of the ADRQL, Definitions and Representative Items

Domains	Definitions	Examples of Items
Social Interaction	Relates to family members, friends, neighbors or professional caregivers in some observable way though physical gestures, talking or facial expression	Smile of laughs when around other people Becomes upset or angry when approached by other people
Awareness of Self	Awareness of a person's own special personal identity and of his/her major relationships in the family, in friendships or in work or community	Shows interest in event, places or habits from person's past No longer responds to own name
Enjoyment of Activities	Participation and enjoyment in daily life, for example in leisure and recreational activities or hobbies	Enjoys solitary activities such as listening to music or watching T.V. Dozes off or does nothing most or the time
Feelings and Mood	Signs that can be seen or heard by others of how a person often feels. These may be spoken statements, expressions or physical gestures	Shows sense of humor Throws; hits, kicks bangs or objects
Response to Surroundings	How a person responds to their living environment and other places in some observable way though physical gestures, talking, facial expression	Gets enjoyment from or is calmed by possessions or belongings Makes repeated efforts to leave places

(Hurley, Volicer, Hanrahan, House, & Volicer, 1992) and the Affect Rating Scale (Lawton, Van Haitsma, & Klapper, 1996). The PDS and the PES-AD have content that reflects activities characteristic of community residence (helping around the house, ability to safely travel distances alone). The DS-DAT and the Affect Rating Scale, on the other hand, focus on manifestations of a person's emotional and physical state (e.g., noisy breathing, contentment) and were developed using nursing home patients in later stages of the disease.

The ADRQL shares both content and methods with these other instruments. Proxy respondents will be used in administering the ADRQL. Like the PDS and PES-AD, interaction with others and participation in activities or tasks are assessed in the ADRQL (Social Interaction, Awareness of Self, and Enjoyment of Activities Domains). The dimension Feelings and Mood includes items like those in the DS-DAT and Affect Rating Scale that are designed to be "signs that can be seen or heard by others of how a person often feels" (Table 2).

The ADRQL differs in several important respects. It has been conceptualized as an evaluation of HRQoL in AD, whereas the instruments above focus on single components of experience (affect, pleasant activities). The ADRQL was developed through a process that elicited the instrument's content from caregivers and providers, rather than relying on existing classifications of quality of life to generate concepts and items. Unlike the instruments above, the ADRQL will incorporate views of caregivers concerning the contribution of various indicators to HRQoL, which has both advantages and disadvantages described more fully below. Finally, the ADRQL has been designed specifically to evaluate change in HRQoL. Longitudinal analyses will be undertaken to test "responsiveness" of the instrument to change.

APPROACH TO MEASUREMENT IN THE ADRQL

The ADRQL was developed using a methodology that incorporates into the instrument preferences among individual indicators of quality of life. Underlying this approach is the recognition that preferences for various health states vary among individuals and that this variation can be identified, quantified and used to produce individual scores which lend themselves to statistical analysis. The items and domains of the ADRQL have been developed with the view that not every item or domain is equal in what it brings to quality of life. By developing weights for items, these differences can be incorporated into the measurement of HRQoL. A weighted scale of this type has several advantages. Within each domain, there may be some items that are more commonly performed or observed than others. These would always carry greater influence in overall HRQoL were not their importance (preference weight) also considered. Weighting a scale also increases its sensitivity to differences among individuals because it provides a continuous measure rather than a series of discrete yes/no responses. Finally, using a preference-based weighting approach provides opportunities for both single and subscale HRQoL scores for each person.

Once a weighted approach is selected, it is necessary to determine which groups should make judgments about the relative importance of each item to overall HRQoL (i.e., provide the weights). For the ADRQL, family caregivers with major caregiving responsibilities for persons with Alzheimer's disease were selected. Sixty-one caregivers were interviewed and asked to rank, on a scale from 1 to 10, the importance of each

item to good/poor health-related quality of life in persons with Alzheimer's disease (psychometric analyses of the weights resulting from this process are in progress). Information was also obtained about caregivers (race, socioeconomic status, relationship to subject, current health status, caregiver burden, depression) and the person they care for. Final item selection and weighting of the instrument is based on psychometric analyses. The procedures being used followed parallel those used in developing such well-known instruments as the Sickness Impact Profile (Bergner et al., 1976).

USE OF CAREGIVERS TO ASSESS HRQOL IN PERSONS WITH AD

The ADRQL uses caregivers as proxy respondents for persons with AD. As Table 3 indicates, use of proxies for patient assessment in AD is common (DeJong et al., 1989; Lawton et al., 1996; Logsdon & Teri, 1995). Caregivers, health care providers and trained observers are all routinely employed as proxy respondents. In quality of life and health status assessment, however, use of proxy respondents is less common. The SF-36, for example, is structured for self-assessment. Studies of proxy assessment of health status, usually indicators of physical functioning, have yielded mixed results (Epstein, Hall, Tognetti, Son, & Conant, 1989; Rothman, Hedrick, Bulcroft, Hickman, & Rubenstein, 1991; Spranger & Aaronson, 1992). For the most part provider ratings of general health perceptions and changes in health status are only moderately correlated with those of patients (Berlowitz, Du, Kazis, & Lewis, 1995). Some studies of patients' ratings and relatives' ratings of the patient also yield conflicting results. In several studies, greater disability was reported by proxies rather than subjects (Epstein et al., 1989; Magaziner, 1992). Concordance between patient and proxy is greatest, however, when the areas being rated are concrete and observable (Sprangers & Aaronson, 1992).

One major challenge to the validity of caregiver evaluations is the extent to which their assessment may be colored by the effects of the subjects' illness on their own quality of life. Many studies have demonstrated high rates of emotional distress in persons caring for individuals with dementia (Rabins, Mace, & Lucas, 1982; Schultz, Alison, O'Brien, Bookwala, & Fleissner, 1995). Caregiver ratings of "burden" have been found to correlate poorly if at all, however, with measures of disease severity in the person cared for (Fitting, Rabins, Lucas, & Eastham, 1986; George & Gwyther, 1986). Another recent study indicates caregivers are able to act as surrogate reporters of depression in persons with AD (Logsdon & Teri, 1995). The structure of the ADRQL should reduce the influence of caregiver characteristics on responses, since caregivers are not asked to assess how well an individual is functioning in various areas but rather about the occurrence of observable behaviors during a recent period. The relationship of caregiver characteristics to preferences among quality of life indicators is an important issue. Our working hypothesis is that there is no relationship between the two.

An underlying assumption of our choice to develop a rating that can include all persons with AD is that each person with AD has a "personhood," no matter how severe the illness. An extensive discussion of this issue is beyond the scope of this paper (see Post, 1995 and Moody, 1992, for helpful discussions) but we believe our use of a proxy who has some knowledge of the ill person and the choice to measure quality of life in ill persons with AD is the best methodologic solution to the question of how to assure that personhood is appreciated throughout the illness.

TABLE 3. Comparison of the ADRQL With Other Instruments for Assessment of Well-Being in AD Patients

Instrument	Domains of Items	Respondent
ADRQL	Social interaction Awareness of self Enjoyment of activities Feelings and mood Response to surrounding	Caregivers
Progressive Deterioration Scale (PDS) (DeJong et al., 1989)	(Content areas) Extent to which patient can leave immediate neighborhood Ability to safe travel distance alone Confusion in familiar settings Use of familiar household implements Participation/enjoyment of leisure/ cultural activities Extent to which patient does household chores Involvement in family finances, budgeting, etc. Interest in doing household tasks Travel on public transportation Self-care and routine tasks Social function/behavior in social settings	Caregivers
Pleasant Events Schedule - AD (PES - AD) (Logsdon & Teri, 1997)	2 domain, passive-active, social-nonsocial, 20 items examples Listening to music Laughing Helping around the house Recalling and discussing past events	Caregivers or patient/ caregiver teams
Discomfort Scale for Persons with Dementia of the Alzheimer's Type (DS - DAT, Hurley et al., 1992)	Noisy breathing Negative vocalization Content facial expression Sad facial expression Frightened facial expression Frown Relaxed body language Tense body language Fidgeting	Observer/ Rater
Affect Rating Scale (Lawton et al., 1996)	Pleasure Interest Contentment Anger Anxiety/Fear Sadness	Observer/ Rater

CONCLUSIONS

This article describes the concepts and methods underlying development of the ADRQL, an instrument for assessing health-related quality of life in persons with Alzheimer disease. It was developed for use in evaluating the impact that treatment interventions in AD have on health-related quality of life or, in lay terms, whether the intervention makes the patient better off in ways that matter to patients and their families. This paper reports on the conceptual development of the instrument and its place in the broader context of health-related quality of life assessment.

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