Quality of Well Being

Self-Administered (QWB-SA) Scale

User's Manual

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I. Introduction

Measuring health outcomes has become an important objective for health care professionals in research, clinical care, health care finance, and public policy. One of the main purposes of measuring health outcomes is to document levels and changes in a patients' health status over time. Depending on the need of the assessor, health status can be measured in many ways. It can be assessed by using endpoints of mortality, disease diagnosis, or by using intermediate outcomes such as blood pressure, cholesterol, or Body Mass Index. Intermediate outcomes are often easier to measure and do not rely upon patient self-report, but may not directly affect health care consumers. Outcomes can be disease-specific or generic. One can attempt to measure outcomes such as symptoms, function, and mortality, which more directly affect the quality of life of health care consumers.

Another issue in the assessment of health is whether to use a disease-specific instrument or a more comprehensive measure of health-related quality of life (HRQoL). Disease-specific measures are often perceived as being more sensitive to subtle changes in the disease of interest, but may miss changes in other areas of health or functioning. Given the unpredictable impact interventions can have on multiple body systems, it is essential to assess health in ways that can capture a patient's overall functioning and well-being.

Health-related quality of life (HRQoL) is a concept used to describe a comprehensive picture of how a person's health affects their overall well-being. The Quality-Adjusted Life Year (QALY) has become a standard measure of HRQoL in medical cost-effectiveness research (Gold et al., 1996). QALYs integrate HRQoL with the duration of life to provide a single comprehensive expression of health outcome.

The Quality of Well-Being (QWB) scale was developed in the 1970's as a comprehensive measure of health-related quality of life (Kaplan, Bush, & Berry, 1975). The QWB is one of the few instruments that can help calculate QALYs as an expression of health outcome. It has been extensively validated and its psychometric properties are well established (Kaplan, Anderson, and Ganiats, 1993). The widespread use of this instrument has been low in part due to length and difficulty in its administration. The Quality of Well-Being Scale-Self Administered (QWB-SA) was developed in response to previously identified limitations of the QWB (Kaplan, Ganiats, and Sieber, 1996). It is easier to administer in most research and clinical assessment protocols than the interviewer-administered QWB.

This manual is designed to serve as a guide to the administration, scoring, and interpretation of the QWB-SA. Psychometric properties are reported and validation studies are described. Initial normative data are provided to assist the user of the QWB-SA in interpreting scores. References are also provided.

II. The General Health Policy Model and The Quality of Well-Being Scale (QWB)

The assessment of health-related quality of life has developed significantly since the 1970's. Among the instruments that assess overall HRQoL, only a few can be used for cost-utility analysis. Cost-utility analysis is defined as cost-effectiveness analysis (CEA) that uses QALYs as the outcome. QALYs have been identified as the preferred outcome metric by Gold et al. (1996) in hopes of standardizing CEAs in medicine and healthcare. QALYs incorporate both quality of life and mortality into one score which allows for comparisons across diseases and populations. In the past, CEAs have used a variety of outcomes, making comparisons difficult. Standardization of outcomes, definitions, and methods of CEA is an important step for integrating findings.

The Quality of Well-being (QWB) scale was the first instrument specifically designed to measure quality of life for the estimation of QALYs. The QWB is a preference-weighted measure combining three scales of functioning with a measure of symptoms and problems to produce a point-in-time expression of well-being that runs from 0 (for death) to 1.0 (for asymptomatic full function). Most HRQoL measures focus on functioning; the QWB and QWB-SA have a functioning component complemented by a strong symptom component. Prior work by our group demonstrated that on any particular day, nearly 80% of the general population is optimally functional. However, fewer than half of the population experience no symptoms. Symptoms or problems may be severe such as serious joint pain, or minor such as taking medication or following a prescribed diet for health reasons.

The QWB was developed using theory from the General Health Policy Model (Kaplan, 1993b, 1993c; Kaplan & Anderson, 1996; Kaplan, Anderson & Ganiats, 1993). This model includes several components, such as mortality (death) and morbidity (health-related quality of

life). Kaplan and colleagues have suggested that diseases and disabilities are important for two reasons: illness may cause life expectancy to be shortened, and illness may make life less desirable at times prior to death. In assessing the impact of a health intervention, one must measure both a possible decrease in mortality and an improvement in health. In addition to mortality and morbidity, the General Health Policy Model incorporates preference for observed health states (utility) (and duration of stay in health states prognosis).

Utility studies looking at how people value health have been conducted to place the observable states of health and functioning onto a preference continuum for the desirability of various conditions, giving a "quality" rating between 0 for death and 1.0 for completely well. A Quality-Adjusted Life Year (QALY) is defined as the equivalent of a completely well year of life, or a year of life free of any symptoms, problems, or health-related disabilities. Consider, a person who has a set of symptoms and is in a state of functioning that is rated by community peers as 0.5 on a 0.0 to 1.0 scale. If the person remains in that state for one year, he or she would have lost the equivalent of 1/2 of one year of life. A person who has the flu may also be rated as 0.50. In this case, the illness might only last three days and the total loss in QALYs might be 3/365 X 0.50 which is equal to 0.004 QALYs. This may not appear as significant an outcome as the person whose symptoms persist for one year. But suppose that 5,000 people in a community get the flu. The well years lost would then be 5,000 x .004 which is equal to 20 years of perfect health in one person. The quality-adjusted life expectancy is the current life expectancy adjusted for diminished quality of life associated with dysfunctional states and the duration of stay in each state.

By administering the QWB before and after a treatment or intervention program, the intervention can be described in terms of the quality adjusted life years that it produces or saves. When costs are examined (using standardized methods), every intervention can be given a

cost/QALY value. This value delineates how much it costs, on average, to produce an extra QALY for each subject in a given study.

Several studies have demonstrated that the QWB is responsive to clinical change in a variety of patient populations. For example, QWB scores have been shown to be associated with health improvements in patients with cystic fibrosis (Orenstein et al, 1989), chronic sinusitis (Hodgkin, 1994), and cochlear implant (Harris, et al., 1995). In addition, the QWB is responsive to medications expected to have a minor effect such as oral gold treatment for patients with arthritis (Bombardier, et al., 1986) or medications that have a larger effect such as AZT for patients with HIV infection (Kaplan, Anderson, Wu, et al., 1989). Other applications of the QWB include chronic obstructive pulmonary disease (Kaplan, et al., 1984), AIDS (Kaplan, et al., 1989), diabetes mellitus (Kaplan, et al., 1987), atrial fibrillation (Ganiats, et al., 1992), lung transplantation (Squier, et al., 1994), cancer (Kaplan, 1993a), depression (Kaplan, 1997), schizophrenia (Patterson et al, 1996), fibromyalgia (Kaplan, Schmidt, and Cronan, 2000), osteoarthritis (Groessl, Kaplan, and Cronan, 2000), and several other conditions (Kaplan, 1993b). Further, the method has been used for health resource allocation modeling and served as the basis for the innovative experiment on rationing of health care by the state of Oregon (Kaplan 1993b, 1993c).

III. The Quality of Well-Being Scale Self-Administered (QWB-SA)

A. Development of the questionnaire

The demand for rapid health status assessment is exemplified by the current widespread use of the SF-36, though the SF-36 cannot be used to produce QALYs. What is needed is a clinically useful, self-administered instrument that is sensitive to changes at the higher levels of functioning, and that produces QALYs for important cost-effectiveness analyses. A self-administered version of the QWB, known as the QWB-SA, was developed to meet this need.

There are several improvements from the original QWB seen in the QWB-SA. First, several items assessing mental health are now included. Second, the assessment of symptoms follows a clinically useful Review of Systems model, rather than clustering symptoms based on preference weights. Third, additional symptoms not included in the interview format of the QWB are in the symptom assessment portion of the QWB-SA. Finally, the administration of the questionnaire no longer requires a trained interviewer and can be completed in less than 10 minutes.

The period assessed by the QWB-SA is shorter than in the QWB. The QWB asked patients about symptoms and function "over the past 6 days" prior to the day of administration, whereas the QWB-SA questions refer to the 3 days prior to the day of administration. This change was designed to reduce respondents' recall bias without decreasing the instrument's ability to assess over a period of time. In addition, assessing 3 days rather than 6 days results in a more rapid administration. The impact on the overall quality of life score of using only the last 3 days was examined by dropping information from Day 4, 5, 6 and recalculating QWB scores based only on the past 3 days. No significant differences in scores were found.

The development of the QWB-SA has gone through several stages. First, a list of symptoms and health-related problems was developed. The current version of the interviewer-administered QWB uses a list of 26 symptom clusters; these clusters are based on the preference weights assigned to each symptom. Despite having similar preference weights, some of the symptoms within a given group were clinically heterogeneous or unrelated. The endorsement of a symptom cluster did not specifically identify the health problem experienced; the endorsement of an item on the QWB-SA does suggest symptoms that are clinically related.

The symptom checklist of the QWB-SA was expanded to 58 symptom complexes including at least 12 symptoms that are typically considered "psychological." Most items focus on one problem related to one body system.

The expansion of the symptom checklist for the QWB-SA involved conducting several focus groups comprised of physicians. Input on which symptoms would be important to be aware of led to structuring symptoms along a medical Review of Systems. The different symptoms selected reflect different important aspects of health, are understood by physicians as distinct signs/predictors of various disease conditions, and cover different degrees of severity. A total of 58 different symptoms emerged. The QWB-SA reflects a broad array of symptoms, and has been organized to closely resemble how a clinician might conduct an assessment of a patient's symptoms, again potentially increasing the clinical utility of the QWB-SA.

The format for the QWB-SA includes five sections. The first part assesses the presence/absence of 19 chronic symptoms or problems (e.g., blindness, speech problems). The question format does not assess each of the previous 3 days (as in the rest of the questionnaire) with the expectation that these chronic conditions do not vary much over the 3-day assessment period. These chronic symptoms are followed by 25 acute (or more transient) physical symptoms (e.g. headache, coughing, pain), and 14 mental health symptoms and behaviors (e.g., sadness,

anxiety, irritation). The remaining sections of the QWB-SA are similar to the QWB and include assessment of a person's mobility (including use of transportation), physical activity (e.g., walking and bending over), and social activity including completion of role expectations (e.g., work, school, or home).

B. Derivation of preference weights

A unique aspect of the QWB-SA is that a person's score reflects a societal perspective on the value of that person's level of functioning and well-being. Preference weights (i.e., societal value of various health states) used with the QWB-SA were derived from a community sample. Preference weights have been found to be quite consistent across groups (Balaban, et al. 1986; EuroQol Group, 1990; Froberg and Kane, 1989c). While the community sample used for the development of the QWB-SA preference weights was geographically homogeneous, the age and gender distributions were similar to the census statistics for the U.S. population in 1990.
A total of 435 English-speaking adults were drawn from several primary care clinics as well as two college campuses in San Diego. The final sample included 239 females (56%) and 191 males between the ages of 18 and 85 (mean age = 38 years). Distribution by age, gender, and ethnicity approximated those reported in the 1990 U.S. census.

Each item included on the QWB-SA was described as a health state to be rated on a 0 to 100 scale. Subjects were asked to use "0" as an anchor for death/worst possible health state and "100" for optimum health (no dysfunction or symptoms). Subjects were provided two examples to assess their understanding of the task: one that described the maximum dysfunction in the areas of mobility, physical activity, social role activity, while the other example listed no dysfunction or symptoms. Due to the very large number of items to be rated and the burden created by having each subject rate each possible health state, each subject completed a randomly

selected subsample of 12 items. Ratings for QWB-SA items included one symptom and a level of impairment for a mobility, physical activity, or social activity item. Subjects rated each symptom separately and in combination with multiple levels of one of the functional scales (i.e., mobility, physical activity, social activity). Once all subjects provided ratings, preference weights were estimated using an adaptation of Multiattribute Utility Scaling method (Anderson and Zelinski, 1990). The method assumes an additive model, such that an item's weight is calculated with the following formula:

item weight = 1.0 – (mean rating/100)

Once preference weights were calculated for all symptom items, weights for mobility, physical activity, and social activity were calculated by subtraction. That is, once the weight for a symptom (i.e., shortness of breath) was established, the mean rating for a health state with both a symptom and a functional item (e.g., confined to bed) was subtracted from the symptom alone to determine the preference weight assigned each item from the functional scale. In this manner, new preference weights were derived for the QWB-SA and are presented in Appendix A. Item preference weights are higher on the QWB-SA than weights originally calculated for the QWB more than 20 years ago (Kaplan et al, 1978). Thus, the lowest total score for a living subject on the QWB-SA is .09, whereas for the QWB, it is .33. This results in a greater distribution of scores that approaches a normal curve as compared to the truncated distribution evident with the QWB. The distribution of QWB-SA scores approaches normality to a greater degree than the HUI and EuroQoL and has fewer ceiling effects (Ganiats, Barrett-Connor, Sieber, 1999 Barcelona ISQoL).

IV. Psychometric Properties of the QWB-SA

The initial published report of the psychometric properties of the QWB-SA included a test of the impact of mode of administration on overall scores as well as test-retest reliability (Kaplan, Sieber, and Ganiats, 1997). *Using the same preference weights in the scoring algorithm for both the interviewer-administered QWB and the QWB-SA*, a 2 x 2 (Mode x Time) factorial design allowed for two types of comparison: to detect differences between the two modes of administration using the same scoring algorithm, and to assess the stability of scores on each instrument over a 4 week time period. Each of 218 English-speaking adults recruited from primary care clinics was assigned to one of four groups that differed in mode of administration at each time point: 1) interviewer-interviewer, 2) interviewer-SA, 3) SA-SA and 4) SA-interviewer. Table 1 suggests the two measures yielded nearly identical scores at both the baseline and the one-month evaluations (with all main effects and interactions in the model being non-significant). This implies that the different modes of administration produce equivalent results. These results also demonstrate that both the QWB and QWB-SA scores remain stable over a one-month time period for relatively healthy adults not under-going any health intervention or change: r = .60 for the QWB, and r = .77 for the QWB-SA.

Table 1. Means and Standard Deviations for QWB by Mode of Administration

Mode	Baseline	1 Month
QWB	.708 (.119)	.707 (.108)
QWB-SA	.701 (.101)	.700 (.110)

The same analysis was then performed on the QWB-SA using the new preference weights derived specifically for the QWB-SA. **(*Note: All QWB-SA scores reported in this manual hereafter reflect the use of the preference weights to be used in future administrations of the QWB-SA.)*** The same data from respondents reported in Kaplan, Sieber, and Ganiats, (1997) was used, though the QWB-SA total scores were calculated using the newly constructed preference weights (Appendix A). A total of 118 females (54%) and 100 males between the ages of 18 and 85 (mean age = 50 years) completed one of the two instruments at both time points.

Data were analyzed by comparing both instruments' total scores at both the baseline and one-month evaluations (See Table 2). (Interviewer-administered QWB scores are presented in the following tables for comparison.) Test-retest correlations were computed for each instrument and showed greater temporal stability for the QWB-SA (r=.80) than for the QWB (.60; both $p<001$). Results did show that QWB-SA scores were significantly lower than the QWB scores at baseline ($F(1,217)=18.06$; $p<001$) and at one month follow-up ($F(1,217)=4.00$, $p<05$).

Table 2. Means (and standard deviations) for QWB by Mode of Administration & Time

Mode	Baseline	1 Month
QWB	.709 (.112)	.699 (.112)
QWB-SA	.634 (.159)	.663 (.149)

QWB-SA scores were compared between groups based on gender, ethnicity, and education. Substantial literature suggests that women live longer than men, yet report greater morbidity (Wingard, 1984). A sensitive health status measure should capture these differences in function and symptom reporting. Current results reflect such differences on the QWB-SA. Significant negative correlations were found between age and the QWB-SA ($r = -.23$) and QWB ($r = -.20$; both r's $p<05$). Given that men in this sample were older (mean age 52.7) than women (mean age was 45; $F(1, 217) = 22.4$, $p<001$), ANCOVAs were performed to examine gender differences on each measure with age as a covariate. Table 3 shows the age-adjusted means for men and women on both instruments; no differences were found by gender on the interviewer version of the QWB, though women did score lower than men on the QWB -SA ($F(1,217)= 13.96$, $p< 001$).

Table 3. Age-adjusted Means (Standard Error of Measurement) by instrument and gender

Mode	Males	Females	p <
QWB	.716 (.011)	.697 (.009)	ns
QWB-SA	.692 (.016)	.614 (.014)	0.001

Finally, differences in scores between ethnic groups were examined for each instrument. Given the low number of minority subjects who participated in this validation study, scores for all non-Hispanic Caucasians were compared to the mean for all other subjects combined. The age- and gender-adjusted means in Table 4 show no differences between these two groups on either the QWB or QWB-SA, though this analysis has limited power due to a small sample size.

Table 4. Age-adjusted means (Standard Error of Measurement) by instrument and ethnicity

Mode	Caucasian N=169	Non-Caucasian N=45	p <
QWB	.724 (.015)	.695 (0.26)	ns
QWB-SA	.641 (.017)	.614 (.033)	ns

Similar analyses on QWB-SA scores showed no statistically significant differences by educational level (adjusted by age and gender; see Table 5). The limited sample size in this study may have limited the statistical power to detect differences seen in Tables 4 & 5. More research is clearly needed to understand the possible influence these socio-demographic variables have on QWB-SA scores.

Table 5. Age-adjusted means (Standard Error of Measurement) by instrument and education

Education	n	QWB-SA total
HS graduate or less	17	.590 (.038)
some college	46	.661 (.021)
college degree	19	.635 (.033)
some graduate school or graduate degree	19	.638 (.035)

Finally, each subject rated his/her overall health (i.e., 5-point scale from "poor" to "excellent") at the end of each administration of the QWB-SA. This rating was used as the independent variable in a one way ANOVA with linear contrasts. QWB-SA scores served as the dependent variable. Table 6 shows the significant linear trend that emerged ($F(1, 152)=62$; $p<.001$), thus providing convergent validity for overall QWB-SA score and self-rating of health status.

Table 6. QWB-SA and (SEM) score by self-rating of health

Self-rated health	n	QWB-SA total
Poor	11	.448 (.032)
Fair	32	.536 (.017)
Good	33	.639 (.020)
Very good	54	.696 (.025)
Excellent	23	.758 (.032)

Research has demonstrated sensitivity of the QWB-SA to headache status in migraineurs (Sieber, David, Adams, Kaplan, and Ganiats, 2000), depression severity (Pyne, Sieber, David, Kaplan, Rapaport, and Williams, 2001), expected differences in a variety of medical conditions (Frosch, Sieber, Wiesman, Kaplan, 2000) and responsiveness to cataract surgery (Kaplan, Rosen, and Sieber , 2000). Additional studies that have reported on the use of the QWB-SA can be found in Appendix B.

It must be noted that the studies listed in Appendix B do not constitute a normative database. The studies were selected based on the overall quality of the study design, sample size, and generalizability of the study participants to other populations. There are many more research projects using the QWB-SA than are listed in Appendix B; however, the QWB-SA data reported is done with the hope that researchers can better estimate sample size for their study and to place their own participants' scores within a broader context.

V. Use of the QWB-SA

A. Modes of Administration

The QWB-SA is designed to be self-administered. The instructions below pertain to the scannable form used by UCSD and can be accessed by researchers for a nominal fee.

A-1 Self-Administered

The following are directions to investigators for instructing participants in self-administration of the QWB-SA.

General Instructions:

- The QWB-SA form (as designed, produced, and distributed by the UCSD Health Services Research Center) can be completed using either a black or blue ball point pen; use of a #2 pencil is discouraged and use of felt tip ink pens are not permissible.
- Circles provided for a patient's response to any item on the QWB-SA should be filled in completely. Putting check marks or lines through the circles is not acceptable.

- The "Today's Date" field should be filled out "Month/Day/Year." For example, February 5, 2001 should be entered in the date field as "02/05/01."
- The "Participant" field (at the bottom of each side) should have the subject's identification number *left justified*.
- The "Protocol Number" field (at the bottom of the back side) is a free field that can be determined by the researcher or data manager. If the questionnaires are to be scanned at any point, entries in the "Protocol Number" field should be *left justified*.

- The "Investigator Number" field (at the bottom of the back side) allows for the opportunity of identifying the person collecting the data or the site from which data is being collected. Entry of such an identifier should be *left justified.*

Specific Instructions:

Questions 1a-1k are a list of chronic symptoms as well as commonly used health aids. For these questions the subject simply fills in the circle corresponding to "Y" (for yes) if s/he currently experiences the symptom or uses the health aid listed, or "N" (for no) if the subject is not currently experiencing the symptom or using the health aid listed.

For questions 2-8, the QWB-SA scale queries subjects on their functional health status, including the presence of certain physical symptoms (Q2), mental health symptoms (Q3), the subject's ability to perform self-care activities (Q5), limitations in mobility (Q6), physical activity (Q7), or usual activities (Q8). These questions refer to a three-day time period that corresponds to the three days directly preceding the day the questionnaire is completed. For example, if a participant were completing the QWB-SA on Thursday, February 5, 2001, s/he would answer questions about Wednesday, 02/04/01 ("Yesterday" on the QWB-SA form), Tuesday, 02/03/01 ("2 Days ago"), and Monday, 02/02/01 ("3 Days ago"). It is important that the subject understand the specific days s/he is being asked about. If the subject did not experience a particular symptom in the past 3 days, s/he would fill in the circle corresponding to "No Days." Symptoms are reported for each of the 3 days separately. For example, if the subject experienced the symptom 2 days ago but not yesterday or three days ago, s/he would fill in only the circle corresponding with 2 days ago; if the subject experienced the symptom on all of the past 3 days s/he would fill in a circles for each of the 3 days separately.

Question 4 asks if the subject had any symptoms that were not mentioned on the QWB-SA. If the subject experienced symptoms that were not mentioned, s/he would fill in the circle corresponding to "Yes" and then write in the particular symptom(s) along with which of the past 3 days s/he experienced them.

Question 8c asks if the subject changed any plans or activities due to their health not already reported. If s/he did have to change plans/activities, s/he should write a description of the limitation(s) in the box provided.

Questions 9a-c instructs the subject to rate their overall health state in 3 different ways. First, on a 5 point scale from "poor" to "excellent." Second, a respondent compares current health to health of one year previous, and third to rate his/her overall health over the past 3 days on a 0 – 100 scale.

Question 10 provides space for the respondent to provide information regarding gender, age, ethnicity, and education level.

A-2. Interviewer

The QWB-SA can be administered by telephone or in a face-to-face interview, though the psychometric properties of the QWB-SA administered by these methods have not been specifically studied. If an investigator finds it necessary to administer a QWB-SA by telephone or via an interviewer, the questions should be read exactly as they appear on the questionnaire.

A-3. Proxy

Assessment by proxy is not recommended for the QWB-SA but may be the only option for a subject who cannot comprehend all of the questions or cannot adequately communicate responses to the questions. For example, this option may be considered with subjects who are

cognitively impaired (e.g., brain injury, dementia). The User is warned, however, that problems abound with data on subjective health states gathered by proxy. Psychometric properties of the QWB-SA administered by proxy have not been evaluated. Investigators may consider using the responses of a proxy to the QWB-SA in cases where a patient cannot respond on their own. Given many of the symptoms assessed are subjective and personal in nature, and the impact of the use of a proxy lacks adequate psychometric testing.

A-4. On-line

A web-based version of the QWB-SA is available on the Internet. Access codes and passwords providing access to the web-based QWB-SA are available to researchers through the UCSD Health Services Research Center. Identifying information is not necessary and security measures have been implemented. Response data is scored before being stored in a downloadable format and data for each research project is stored separately.

B. Scoring

Scoring algorithms are available to all individuals and entities signing a QWB-SA copyright agreement. The QWB-SA may be used free of charge by non-profit organizations that provide evidence of their non-profit status and agree to provide a copy of relevant, non-identifiable project data with UCSD. For-profit organizations are required to sign a usage contract in addition to the copyright agreement. Fees for usage are dependent on volume, length of intended usage, mode of administration, and other factors; but are usually quite affordable.

The UCSD Health Services Research Center provides complete data services for the administration, scoring, cleaning, and interpretation of the QWB-SA and other health outcome

measures. (A computer software-scoring program is also available for a fee, under certain circumstances and pre-arranged with HSRC personnel.)

For more information, or to complete a copyright agreement and begin using the QWB-SA, please contact the UCSD Health Services Research Center at 9500 Gilman Dr. #0994, La Jolla, CA 92093-0994, or call 858-622-1771.

VI. QWB-SA Normative Data

General Outpatient Medical Samples (controls)

Total Sample

Age	≤ 30	31-40	41-50	51-60	61-70	≥ 71
N	86	109	91	99	191	267
Mean	0.67	0.6428	0.6017	0.6161	0.6162	0.6075
Std Dev.	0.1286	0.1476	0.1323	0.1199	0.108	0.1354
Range	.286-1.0	.260-1.0	.285-.913	.273-.934	.260-.934	.151-1.0

Men Only

Age	≤ 30	31-40	41-50	51-60	61-70	≥ 71
N	29	42	35	27	65	96
Mean	0.6548	0.6743	0.6173	0.647	0.6351	0.6015
Std Dev.	0.1093	0.1604	0.1148	0.1044	0.1026	0.1494
Range	.397-.850	.260-1.0	.394-.874	.419-.934	.315-.934	.151-.934

Women Only

Age	≤ 30	31-40	41-50	51-60	61-70	≥ 71
N	57	67	56	72	125	171
Mean	0.6778	0.623	0.592	0.6045	0.6062	0.6108
Std Dev.	0.1377	0.1365	0.1424	0.1238	0.1103	0.1272
Range	.286-1.0	.348-1.0	.285-.913	.273-.871	.260-.903	.278-1.0

*Male and female subgroups may not add to total due to missing data on gender variable for some respondents

General Outpatient Medical Samples (controls)

Caucasian Only

Age	≤ 30	31-40	41-50	51-60	61-70	≥ 71
N	48	75	68	79	161	235
Mean	0.6742	0.6448	0.6047	0.6138	0.6177	0.6104
Std Dev.	0.1242	0.1538	0.1334	0.1208	0.1097	0.1281
Range	.391-1.0	.260-1.0	.285-.874	.273-.934	.260-.934	.264-.934

African American Only

Age	≤ 30	31-40	41-50	51-60	61-70	≥ 71
N	5	6	4	4	2	2
Mean	0.7297	0.5159	0.5245	0.6123	0.5063	0.617
Std Dev.	0.0925	0.1013	0.0561	0.0208	0.107	0.1032
Range	.649-.877	.348-.639	.477-.586	.589-.639	.431-.582	.544-.690

Hispanic Only

Age	≤ 30	31-40	41-50	51-60	61-70	≥ 71
N	13	6	8	6	9	3
Mean	0.6362	0.6259	0.6495	0.5512	0.5855	0.8657
Std Dev.	0.1556	0.0344	0.0995	0.0991	0.1067	0.1786
Range	.286-.871	.598-.680	.498-.815	.448-.732	.376-.737	.663-1.0

Asian Only

Age	≤ 30	31-40	41-50	51-60	61-70	≥ 71
N	12	10	4	6	11	0
Mean	0.6793	0.7218	0.6961	0.6861	0.6715	---
Std Dev.	0.1014	0.1397	0.1455	0.1714	0.0919	---
Range	.524-.850	.477-1.0	.604-.913	.148-.871	.537-.826	---

Native American Only

Age	≤ 30	31-40	41-50	51-60	61-70	≥ 71
N	1	2	0	0	1	14
Mean	0.4446	0.755	---	---	0.647	0.5546
Std Dev.	---	0.2531	---	---	---	0.1044
Range	---	.576-.934	---	---	---	.405-.701

Outpatient Medical Samples: Clinical Cohorts

Total Sample

Age	≤ 30	31-40	41-50	51-60	61-70	≥ 71
N	465	741	1244	946	536	202
Mean	0.6475	0.6505	0.6512	0.6437	0.629	0.599
Std Dev.	0.1257	0.1396	0.1432	0.1361	0.142	0.1629
Range	.161-1.0	.154-1.0	0-1.0	.151-1.1	.187-1.0	0-.990

Men Only

Age	≤ 30	31-40	41-50	51-60	61-70	≥ 71
N	72	167	289	329	227	107
Mean	0.6719	0.6653	0.667	0.6686	0.6514	0.6158
Std Dev.	0.1252	0.1502	0.1517	0.1437	0.1454	0.1552
Range	.332-1.0	.194-1.0	.193-1.0	.203-1.0	.260-1.0	.179-.990

Women Only

Age	≤ 30	31-40	41-50	51-60	61-70	≥ 71
N	390	563	955	611	304	94
Mean	0.6429	0.6456	0.6433	0.63	0.6143	0.583
Std Dev.	0.1258	0.136	0.1389	0.1301	0.1355	0.1686
Range	.161-1.0	.154-1.0	0-1.0	.151-1.0	.193-.934	0-.934

*Male and female subgroups may not add to total due to missing data on gender variable for some respondents

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Appendix B: QWB Data from Selected Studies

I. SHE study

Soy Health Effects Study (SHE) conducted under a National Institutes of Health grant to study the potential benefits of a dietary supplement of soy on the health of postmenopausal women. Subjects for the study consisted of women aged 45–74 y who attended screening and baseline visits and were subsequently enrolled in the Soy Health Effects (SHE) Study. The SHE Study is a randomized, double-blind, placebo-controlled trial designed to investigate the extent to which isoflavone use improves heart disease risk factors, bone density and quality of life in postmenopausal women. To be eligible for the SHE Study, women had to be at least 2 years postmenopausal, not using HRT for ≥3 mo, and not currently using lipid-lowering drugs, antidiabetic medications, tamoxifen, soy protein or herbal supplements. Women with a history of uncontrolled hypertension, stroke, transient ischemic attack, cancer diagnosed <5 y ago or myocardial infarction within 6 mo were excluded from the study. A total of 210 postmenopausal women were enrolled in the SHE study.

References:

None currently available

	N	Minimum	Maximum	Mean	Std. Dev.
QWB	210	0.273	1.000	0.694	0.118
CPX	210	0.000	0.559	0.294	0.107
MOB	210	0.000	0.010	0.000	0.001
PAC	210	0.000	0.102	0.010	0.023
SAC	210	0.000	0.096	0.002	0.010
AGE	207	44	74	56.79	6.38

Education	N	%
8th grade	3	1.4
High school	17	8.1
Some college	87	41.6
College grad	51	24.4
Some grad school	11	5.3
Post grad degree	40	19.1

Ethnicity	N	%
African American	10	4.8
Asian/Pac. Islander	10	4.8
Caucasian	163	78
Hispanic	23	11
Native American	3	1.4

II. Cataract

Between July & November 1998 patients were selected from the practices of 9 ophthalmaologists in a group practice of the Southern Ca. Kaiser-Permanente Med Group. All consecutive adult patients coming to cataract surgery were invited to participate.

Reference:

1. Rosen PN, Kaplan RM, David K. Measuring outcomes of cataract surgery using the Quality of Well-Being Scale and VF-14 Visual Function Index. J Cataract Refract Surg. 2005 Feb;31(2):369-78.

Cataract baseline (pre-surgery scores)

	N	Minimum	Maximum	Mean	Std. Dev.
QWB	288	0.151	1.000	0.595	0.134
CPX	288	0.000	0.559	0.359	0.102
MOB	288	0.000	0.059	0.003	0.006
PAC	288	0.000	0.163	0.034	0.044
SAC	288	0.000	0.096	0.009	0.020
AGE	277	42	91	71.43	9.07

Education	N	%
8th grade	14	5.2
High school	84	31.2
Some college	87	32.3
College grad	38	14.1
Some grad school	19	7.1
Post grad degree	27	10.0

Ethnicity	N	%
African American	5	1.8
Asian/Pac. Islander	11	4.0
Caucasian	224	82.1
Hispanic	14	5.1
Native American	13	4.8
Other	6	2.2

III. DPP Study

The Diabetes Prevention Program is a large, multi-site, randomized, controlled clinical trial that compared the efficacy of an intensive lifestyle intervention to a glucose lowering drug and a placebo control. Between 1996 and 1999, 3234 non-diabetic persons who were at risk for developing diabetes were randomized to one of the 3 groups (1082 placebo, 1073 metformin (Glucophage), and 1079 lifestyle intervention).

Participants were recruited at 27 different sites nationwide. According to the study website, "Volunteers were recruited from populations known to be at particularly high risk for impaired glucose tolerance and NIDDM including the following: persons with a family history of NIDDM, the elderly, overweight individuals, women with a history of diabetes during pregnancy ("gestational diabetes"), and minority populations including African Americans, Hispanic Americans, Asian and Pacific Island Americans, and Native Americans. In order to be eligible, persons who are older than 25 years will have to demonstrate impaired glucose tolerance with plasma glucose levels 95-125 mg/dL (5.3-6.9 mmol/L) fasting and 140- 199 mg/dL (7.8 - 11.0 mmol/L) two hours after a 75 gram oral glucose tolerance test. The study-wide goal is that approximately 50% of the study population be composed of minorities and approximately 20% be 65 years of age or older"(1).

References:

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2. The DPP Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. New England Journal of Medicine 2002 Feb; 346(6);393-403.

IV. Validation of the QWB-SA in Musculoskeletal Disease

This project was conducted as part of the UCSD Multipurpose Arthritis Center and the primary goal was to demonstrate the construct validity of the QWB-SA in persons with musculoskeletal disease and to compare them to family medicine patients without arthritis. Individuals with arthritis were recruited from three rheumatology clinics in the San Diego area, while family medicine patients were recruited from four family medicine clinics in the San Diego area

The study examined the relationships between the score obtained with the QWB with those obtained using disease specific paper and pencil measures. Second, the study compared people with arthritis to people visiting family medicine clinics for a variety of reasons other than arthritis. Research assistants approached potential subjects in the waiting rooms of the cooperating clinics. Potential subjects were told that the purpose of the study was to validate a quality of life measure for persons with arthritis, and that participation would involve completing a set of questionnaires. Interested individuals approached in family medicine clinics were asked if they had ever been diagnosed with rheumatoid arthritis, osteoarthritis, fibromyalgia, lupus, or another musculoskeletal disease. Patients reporting one of the above diagnoses were grouped with arthritis
patients rather than family medicine subjects. Musculoskeletal diagnoses for participants recruited from rheumatology clinics were obtained from their physicians.

Reference:

1. Frosch D, Kaplan RM, Ganiats TG, Groessl EJ, Sieber WJ, Weisman M. Validity of self-administered quality of well-being scale in musculoskeletal disease. Arthritis Rheum. 2004 Feb;51(1):28-33.

MAC Study Data - Family Medicine Controls

- Subjects: 352 (59% female) age 18 to 83 years old (mean 40.4; sd 13.7)

	Minimum	Maximum	Mean	Std. Dev.
QWB	0.2600	1.0000	0.6427	0.1349
CPX	0.0000	0.5590	0.3219	0.1010
MOB	0.0000	0.0890	0.0019	0.0081
PAC	0.0000	0.1630	0.0224	0.0389
SAC	0.0000	0.0960	0.0111	0.0901

Education	N	%
8^{th} grade	4	1.0
High school	24	7.0
Some college	112	32.0
College grad	83	24.0
Some grad school	35	10.0
Post grad degree	89	26.0

Ethnicity	N	%
African American	19	6.0
Asian/Pac. Islander	28	8.0
Caucasian	251	73.0
Hispanic	28	8.0
Native American	4	1.0
Other	16	5.0

MAC Study Data – RA Subjects

- Subjects: 220 (72% female) age 20 to 91 years old (mean 52.4; sd 15.5)

	Minimum	Maximum	Mean	Std. Dev.
QWB	0.0000	0.9897	0.4966	0.1542
CPX	0.0000	0.5590	0.3846	0.1077
MOB	0.0000	0.0593	0.0027	0.0079
PAC	0.0000	0.1630	0.0662	0.0492
SAC	0.0000	0.0960	0.0272	0.0294

Education	N	%
8th grade	8	4.0
High school	26	12.0
Some college	86	39.0
College grad	51	23.0
Some grad school	14	6.0
Post grad degree	34	16.0

Ethnicity	N	%
African American	13	6.0
Asian/Pac. Islander	14	6.0
Caucasian	161	74.0
Hispanic	16	7.0
Native American	9	4.0
Other	5	2.0

V. Glycemia and Quality of well-being in patients with diabetes

The study used the QWB-SA to explore the relationship between measures of glycemia and health-related quality of life. Glycemia was measured with self-reported frequency of symptomatic hypoglycemia and hyperglycemia, and HbA1c. HRQOL and health utility scores were assessed with the QWB-SA.

As described in the study methods, the sample "included 1522 patients: 634 with type 1 diabetes and 888 with type 2 diabetes who attended endocrinology, diabetes, and ophthalmology clinics at the University of Michigan Health System between June 29,1998 and March 15,2001 and had HbA1c measurements on the day of the visit. All patients were over 18 years of age or older, able to give informed consent, and able to either self-administer the questionnaires or, if visually impaired, to respond to a research assistant reading the questionnaires" (Tabaei, et al.)

References:

1. Tabaei BP, Shill-Novak J, Brandle M, Burke R, Kaplan RM, Herman WH. Glycemia and the quality of well-being in patients with diabetes, Quality of Life Research (in press).

2. Coffey JT, Brandle M, Zhou H, Marriott D, Burke R, Tabaei BP, Engelgau MM, Kaplan RM, Herman WH. Valuing health-related quality of life in diabetes.
Diabetes Care. 2002 Dec;25(12):2238-43.

VI. Depressed inpatients & outpatients

A convenience sample of 39 inpatients and 19 outpatients from the San Diego VA diagnosed with current Major Depressive Episode. Participants were 78% male with an average age of 46 (range 20-70). While the study demonstrated strong sensitivity of the QWB-SA to depression severity, the results reported here are for baseline only. Data is reported on inpatients and outpatients separately, with no data on separate QWB-SA component scores.

Reference:

1. Pyne, J.M., Sieber, W.J., David, K., Kaplan, R.M., Rapaport, M.H., and Williams, D.K. (2003). Use of the Quality of Well-Being – Self-Administered version (QWB-SA) in assessing health-related quality of life in depressed patients. Journal of Affective Disorders, 76, 237-247.

	Total QWB-SA score(sd)
Inpatients	.383 (.118)
outpatients	.479 (.115)

VII. Migraine

A total of 89 adults (87% women) living in Canada were recruited by a market research firm; all were known to suffer migraine headaches. Each participant completed both the interviewer-administered QWB and the QWB-SA on non-headache as well as on headache days. Mean age was 42 (range 36 to 64).

Reference:

1. Sieber, W.J., David, K , Adams, J., Kaplan, R.M. and. Ganiats, T.G. (2000). Assessing the Impact of migraine on health-related quality of life: An additional use of the Quality of Well-Being Scale - Self-Administered (QWB-SA). Headache, 40(8), 662-671

Migraine Study (headache)

	Mean	Std. Dev.
QWB	0.492	0.157
CPX	0.406	0.009
MOB	0.004	0.011
PAC	0.067	0.070
SAC	0.031	0.028

Migraine Study (no headache)

	Mean	Std. Dev.
QWB	0.628	0.149
CPX	0.330	0.013
MOB	0.001	0.005
PAC	0.025	0.047
SAC	0.009	0.020

Appendix C: QWB-SA Preference Weights

Preference weights for each item on the QWB-SA (in order of presentation on questionnaire)

Symptoms (CPX)

blindness, or severely impaired vision in both eyes	0.523
blindness or severely impaired vision in only one eye	0.358
speech problems such as stuttering, or being unable to speak clearly	0.358
missing or paralyzed hands, feet, arms or legs	0.423
missing or paralyzed fingers or toes	0.297
any deformity of the face, fingers, hand/arm, foot /leg, or back	0.408
general fatigue, tiredness or weakness	0.256
a problem with unwanted weight gain or weight loss	0.233
a problem with being under or overweight	0.225
problems chewing your food adequately	0.204
any hearing loss or deafness	0.274
any noticeable skin problems (i.e., bad acne, large burns or scars)	0.187
eczema or burning/itching rash	0.187
health aides used:	
dentures	0.153
eye glasses or contact lenses	0.066
hearing aide	0.148
any problems with your vision not corrected with glasses or contact lenses	0.293
any eye pain, irritation, discharge, or excessive sensitivity to light	0.389
a headache	0.189
dizziness, earache or ringing in your ears	0.299
difficulty hearing or discharge or bleeding from an ear	0.35
stuffy or runny nose or bleeding from the nose	0.178
a sore throat, difficulty swallowing, or hoarse voice?	0.204
a tooth ache or jaw pain	0.298
sore or bleeding lips, tongue, or gums	0.271
coughing or wheezing	0.386

Symptoms (CPX) cont.

shortness of breath or difficulty breathing	0.208
chest pain, pressure, palpitations, fast or skipped heart beat or other discomfort in the chest	0.343
an upset stomach, abdominal pain, nausea, heart burn or vomiting	0.260
difficulty with bowel movements, diarrhea, constipation, rectal bleeding, black tar-like stools, or any pain or discomfort in the rectal area	0.278
pain, burning, or blood in urine	0.424
loss of bladder control, frequent night-time urination or difficulty with urination	0.259
genital pain, itching, burning, or abnormal discharge, or pelvic cramping or abnormal bleeding (does not include normal menstruation).	0.369
broken arm, wrist, foot, leg, or other broken bone (other than in back)	0.365
pain, stiffness, cramps, weakness or numbness in the neck or back	0.318
pain, stiffness, cramps, weakness or numbness in the hips or sides	0.365
pain, stiffness, cramps, weakness or numbness in any of the joints or muscles of the hand, feet, arms or legs	0.318
swelling of ankles, hands, feet, or abdomen	0.306
fever, chills, or sweats	0.320
loss of consciousness, fainting, or seizures	0.517
difficulty with your balance, standing or walking	0.377
trouble falling asleep or staying asleep	0.296
spells of feeling nervous or shaky	0.286
spells of feeling upset, downhearted, or blue	0.327
excessive worry or anxiety	0.324
feelings that you had little or no control over events in your life	0.430
feelings of being lonely or isolated	0.311
feelings of frustration, irritation or close to losing your temper	0.378
a hangover	0.297
any decrease of sexual interest or performance	0.307
Confusion, difficulty understanding the written or spoken word, or significant memory loss	0.559
thoughts or images you could not get out of your mind	0.255
take any medication including over-the-counter remedies (aspirin/Tylenol, allergy medications, insulin, hormones, estrogen, thyroid, prednisone)	0.160
to stay on a medically prescribed diet for health reasons	0.201
a loss of appetite or over-eating	0.223

Mobility

spend any part of the day or night as a patient in a hospital, nursing home, or rehabilitation center	0.089
either not drive a motor vehicle or not use public transportation because of your health or need help from another person to use	0.031

Physical Activity

have trouble climbing stairs or inclines or walking off the curb	0.072
avoid or have trouble walking, or walk more slowly than other people your age	0.072
limp, use a cane, crutches or walker	0.072
avoid or have trouble bending over, stooping or kneeling	0.072
have any trouble lifting or carrying everyday objects such as books, a briefcase or groceries.	0.072
have any other limitations in physical movements	0.072
spend all or most of the day in a bed, chair or couch	0.163
spend all or most of the day in a wheelchair	0.102
If in wheelchair, someone else controlled its movement	0.163

Social & Self-care activity

need help with your personal care needs, such as eating, dressing, bathing, or getting around our home	0.096
avoid, need help with, or were limited in doing some of your usual activities, such as work, school, or housekeeping?	0.054