Development of the Kidney Disease Quality of Life (KDQOL™) Instrument

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This paper describes the Kidney Disease Quality of Life (KDQOL™) Instrument (dialysis version), a self-report measure that includes a 36-item health survey as the generic core, supplemented with multi-item scales targeted at particular concerns of individuals with kidney disease and on dialysis (symptom/problems, effects of kidney disease on daily life, burden of kidney disease, cognitive function, work status, sexual function, quality of social interaction, sleep). Also included were multi-item measures of social support, dialysis staff encouragement and patient satisfaction, and a single-item overall rating of health. The KDQOL™ was administered to 165 individuals with kidney disease (52% female; 48% male; 47% White; 27% African-American; 11% Hispanic; 8% Asian; 4% Native American; and 3% other ethnicities), sampled from nine different outpatient dialysis centres located in Southern California, the Northwest, and the Midwest. The average age of the sample was 53 years (range from 22 to 87), and 10% were 75 years or older. Internal consistency reliability estimates for the 19 multi-item scales exceeded 0.75 for every measure except one. The mean scores for individuals in this sample on the 36-item health scales were lower than the general population by one-quarter (emotional well-being) to a full standard deviation (physical function, role limitations due to physical health, general health), but similar to scores for dialysis patients in other studies. Correlations of the KDQOL™ scales with number of hospital days in the last 6 months were statistically significant ($p < 0.05$) for 14 of the 19 scales and number of medications currently being taken for nine of the scales. Results of this study provide support for the reliability and validity of the KDQOL™.

Key words: Dialysis, end stage renal disease, kidney disease, instrument development, quality of life.

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Introduction

There is increasing recognition that what matters most to patients is how well they are able to function and how they feel about their day-to-day life. Thus, understanding the impact of chronic illness and associated treatments on functioning and well-being in physical, mental and social dimensions of life is essential, and efforts to incorporate quality of life into medical care outcome studies are increasing.[1] The need for a psychometrically sound instrument for assessing quality of life was emphasized recently at a Consensus Development Conference of the National Institute of Health[2] and at an Institute of Medicine meeting on quality of medical care for end-stage renal disease.[3]

This paper describes the Kidney Disease Quality of Life (KDQOL™) Instrument (dialysis version), a self-report measure developed for individuals with kidney disease and on dialysis. Developmental activities included focus groups with patients and staff to identify areas of particular concern for dialysis patients, and two versions of the instrument were pretested on small samples of patients and then revised. The revised instrument, the

KDQOL[TM], includes a generic core, supplemented with multi-item scales targeted at quality of life concerns of special relevance for individuals with kidney disease.[4] Summarized here are the results of administering the KDQOL[TM] to patients on dialysis in nine outpatient dialysis centres.

Method

Sample

Data were collected from 165 individuals with kidney disease sampled from nine different out-patient dialysis centres. Six of the centres were in Southern California, two were in the Northwest, and the other was in the Midwest. Three of the centres were hospital based or affiliated and six were free-standing facilities. Four were for-profit and five were not for-profit facilities. The patient sample was 52% female; 48% male; 47% White; 27% African-American; 11% Hispanic; 8% Asian; 4% Native American; 3% other ethnicities; 45% married; and 82% graduated from high school. Eleven percent were working full-time, 7% part-time; 36% disabled; 29% retired; 7% homemaker; 5% unemployed; 2% in school; and 3% other. The average age was 53 years (range from 22 to 87). Ten percent of the sample was 75 years of age or older.

Thirty-four percent had been diagnosed with kidney disease 10 or more years ago, 18% at least 6 years but less than 10 years ago, 27% at least 2 years but less than 6 years ago, 19% at least 6 months but less than 2 years ago, and 2% less than 6 months ago. The primary cause of kidney disease reported was hypertension for 23%, diabetes for 22%, chronic glomerulonephritis for 11%, poly-cystic kidney disease for 6%, other reasons for 20%, and 18% did not know. Table 1 compares the demographics for the study sample with the 1990 ESRD point prevalence reported through the Health Care Financing Administration (93% of the United States ERSD population).[5] This data illustrates how similar our sample demographics are to the population.

Twenty percent of the sample had previously received a kidney transplant and 17% had previously been on peritoneal dialysis. The majority of the patients had been coming to the same dialysis centre for more than two years (58%), 20% for 13–24 months, 13% for 7–12 months, and 9% for less than six months. Seventy-four percent had visited the centre (including the day of the study) 12 or more times during the last 30 days, 10% 8–11

Table 1. Demographics of study sample compared with 1990 Medicare ESRD programme enrolment of patients on dialysis

	Sample Percent	ESRD Population Percent
Age		
< 20	0	1
20–44	39	22
45–64	36	36
65+	26	38
Gender		
Male	48	52
Female	52	48
Race		
White	59	60
Black	27	35
Other	14	5
Primary Cause of Renal Failure		
Diabetes	22	27
Hypertension	23	27
Glomerulonephritis	11	16
Other known	26	16
Don't know	18	14

times, 4% 4–7 times, 9% 2–3 times, and 3% one time.

Measures

Functioning and well-being was assessed using the 36-item health survey (RAND 36-Item Health Survey 1.0 or SF-36[TM]) as a generic core.[6,7] This instrument includes eight multi-item measures that represent physical and mental health status: physical functioning (10 items), role limitations caused by physical health problems (4 items), role limitations caused by emotional health problems (3 items), social functioning (2 items), emotional well-being (5 items), pain (2 items), energy/fatigue (4 items), and general health perceptions (5 items).

The physical functioning scale assesses limitations in activities because of health, ranging from self-care to vigorous activities. One of the role limitations scales measures the extent to which physical health problems interfere with doing work or other regular daily activities; the other role limitations scale assesses the degree to which emotional problems impact on role activities. The extent to which health interferes with social activities with family, friends, neighbours or groups is assessed by the social functioning scale. The emotional well-being scale taps general mood or affect, including depressive symptoms, anxiety

and positive well-being. Pain frequency and extent of role interference due to pain are measured by the pain scale. The energy/fatigue scale assesses perceived energy level. General health perceptions are global evaluations of health, such as feeling well or ill.

Internal consistency reliabilities for each of these scales were 0.78 or greater in the Medical Outcomes Study.[6] Multi-trait scaling analyses[8] supported item discrimination across scales.[9] Additional empirical studies have provided support for the construct validity of the measures.[10,11]

To 'learn the vocabulary and discover the thinking pattern' (p. 39) of those with kidney disease,[12] we conducted three focus groups with patients. The first focus group included three males and one female currently on haemodialysis (two had tried peritoneal dialysis previously and three had had transplants). The second group consisted of three females and one male (one female left early because her ride was waiting). This patient population had a diversity of kidney disease history: three were currently on haemodialysis (two had renal transplants previously, one had tried peritoneal dialysis) and one was on peritoneal dialysis (and had had a transplant). The third group consisted of four females and one male, all currently on peritoneal dialysis (two had had a transplant and two had been on haemodialysis). All focus groups were run using a standardized protocol with open-ended questions and discussion.

Comments from focus group participants indicated that many were tired and had trouble concentrating on dialysis days. Several participants indicated that in the beginning they had overly optimistic expectations about how they would feel before starting dialysis (they thought that the machine would 'return them to normal'). All were very sick and nauseous when they first started dialysis, but over time nausea became less common and they developed strategies for coping with the treatment and symptoms (e.g., eating only doughnuts before dialysis, eating saltines to settle the stomach). A common theme among participants was that kidney disease reduced the number of 'good hours' in their day, thereby diminishing the quality of life. In addition, focus group members often stated that they did most of the same activities as other people, but they just did less of them on a given day and they did them more slowly. They emphasized the importance of moderation and acceptance of their limitations.

Based on these patient focus group interviews, a focus group with staff at dialysis centres, and a review of the literature on quality of life among kidney disease patients,[13-18] we designed a questionnaire with a range of kidney disease-targeted items.

The symptom/problem scale assesses the extent of bother (Not at All, Somewhat, Moderately, Very Much, Extremely) during the last 30 days in terms of issues particularly relevant to patients with kidney disease, including soreness in muscles, pain (joint, back, chest), headaches, cramps during dialysis, bruising, itchy skin, shortness of breath, dizziness, lack of appetite, excessive thirst, numbness in hands or feet, trouble with memory, blurred vision, nausea, and clotting or other problems with the access site. Effects of kidney disease on daily life were assessed using the same five-point response scale used for the symptom/problem scale and included restrictions on fluid and dietary intake, and impact on work, carrying out family responsibilities, travel, lifting objects, personal appearance, and time available to get things done.

Work status was measured in terms of whether each person was able to work full- or part-time, was currently working, and the number of months worked for pay in the past 12 months. The cognitive function items are indicators of impaired-thinking derived from the SIP.[19,20] Adopted directly into the questionnaire were: the quality of social interaction scale from the Functional Status Questionnaire;[21] the MOS sexual function scale;[22] the SIP sleep subscale;[19] and a social support scale previously developed.[23] Six items were written *de novo* for this study to assess the extent to which dialysis staff encourage patients to be independent and lead as normal a life as possible. Patient satisfaction was evaluated using two items culled from an existing measure.[24]

The ideal quality of life instrument satisfies two important properties: (1) comprehensive assessment of important health domains (e.g., physical function, pain, emotional well-being); and (2) integration of domain-specific information into an overall score.[25] The combination of health domains yields a health 'state' for each person. An overall score is produced by assigning a value or weight to the health state. To provide an integrated measure of quality of life, we included an item that elicits an overall rating of health. This item asks respondents to rate their health on a 0–10 response scale ranging from 'worst possible (as bad or worse than being dead)' to 'perfect health'.

Table 2. Central tendency, variability (including floor and ceiling effects), and reliability of KDQOL™ scales

Measure	Number of Items	Mean	Standard Deviation	% Floor	% Ceiling	Internal Consistency Reliability
Kidney disease-targeted scales						
Symptom/problems	34*	71.62	16.34	0.0	0.6	0.93
Effects of kidney disease	20	59.32	23.41	0.6	1.2	0.94
Burden of kidney disease	4	49.62	30.27	6.1	8.0	0.83
Work status	4	23.27	35.78	60.0	13.1	0.88
Cognitive function	6	78.51	19.21	0.0	11.0	0.85
Quality of social interaction	4	79.73	16.87	0.0	14.0	0.68
Sexual function	4	69.12	34.08	7.4	39.9	0.92
Sleep	9	58.94	22.43	0.0	0.6	0.76
Social support	4	68.31	23.18	0.6	10.6	0.81
Dialysis staff encouragement	6	66.89	21.59	0.0	7.5	0.82
Patient satisfaction	2	73.07	19.96	0.0	19.4	0.89
36-item health survey scales**						
Physical functioning	10	51.83	29.73	3.6	3.6	0.92
Role—physical	4	32.46	39.68	49.4	20.4	0.87
Pain	2					
RAND scoring		60.40	30.11	3.1	20.2	0.87
SF-36™ scoring		57.60	29.70	3.1	20.2	0.90***
General health perceptions	5					
RAND scoring		42.88	24.32	3.0	1.8	0.78
SF-36™ scoring		43.87	24.75	3.0	1.8	0.78
Emotional well-being	5	69.54	20.36	0.6	4.3	0.80
Role—emotional	3	57.76	43.90	29.2	47.2	0.86
Social function	2	63.57	29.77	4.3	25.0	0.87
Energy/fatigue	4	45.89	24.06	2.4	1.2	0.90
Overall health rating	1	59.37	19.54	0.6	5.0	NA

* One of the 35 symptom/problems included in the questionnaire (high blood pressure) is not included here, because it did not contribute to the reliability of the scale.
** Also includes one item assessing change in health.
*** Internal consistency reliability estimate is inflated because scoring of one of the items is conditional on the value of the other.
NA Not applicable for a single-item measure.

The 134 items summarized in Table 2 were designed to provide a comprehensive assessment of quality of life for patients on dialysis, and to be sensitive enough to detect small differences in well-being. The majority of the quality of life measures listed in Table 2 are also indicators of health-related quality of life (HRQOL). Because HRQOL is generally restricted to constructs which 'end at the skin' of the target person, it is important to note that three of the kidney disease-targeted scales (social support, dialysis staff encouragement, patient satisfaction) are measures of quality of life but not HRQOL per se.

Data collection

The selection of patients and administration of the questionnaire varied at the nine dialysis centres, reflecting the wide variety of implementation options available. In five centres, nurses approached only patients who they felt were able to participate and self-administer the questionnaire ($n = 90$). There was no refusals to participate in this group of patients. In two centres, two trained interviewers (young females) approached patients and requested their participation in a survey. The interviewers offered their assistance (e.g., reading the questionnaire) to all the patients in these centres ($n = 38$). At these centres, the interviewers administered the questionnaire on a Monday in each unit, they approached all patients who were being dialyzed at the time (early morning), and stopped after 20 patients in each unit agreed to participate. There were three refusals to participate in these two centres. Additionally, in one of these centres, questionnaires with a sign requesting participation were left on a table where the patients weighed in before dialysis. In the remaining two centres, two volunteers (one male, one

female, both over age 50) asked a random sample of patients to participate and offered their assistance. There were five refusals to participate in these two centres.

Across all centres, 27% of the patients reported receiving assistance in completing the questionnaire. For reasons noted above (i.e., interviewers at some centres readily offered assistance to participants), this rate is believed to overestimate substantially the number of persons requiring assistance to complete the questionnaire. Further, we found that if the questionnaire was put in a half-inch, three-hole binder, patients were more likely to fill it out as they could place it easily on their lap while they were being dialyzed.

Analytic strategy

The frequencies of kidney disease-targeted symptoms/problems and effects of kidney disease were computed. Alpha internal consistency reliability coefficients were estimated for each multi-item scale.[26] This coefficient is calculated from a two-way fixed effects ANOVA model by subtracting the mean square error (interaction between respondents and items) from the mean square between, and dividing the difference by the mean square between.[27]

All scale scores were transformed linearly into 0–100 point scales with higher values representing better functioning and well-being. The RAND scoring algorithms[6] were employed for the 36-item health scales, but in order to compare with general population norms, we also scored the pain and general health perceptions scales using the SF-36^{TM} scoring algorithm.[9]

To summarize the intercorrelations among the 36-item health scales and the kidney-targeted scales, we performed exploratory factor analysis. Several criteria were examined to assess the appropriate number of factors to rotate: Guttman's weakest lower bound;[28] Cattell's scree test;[29] and parallel analysis.[30] Common factor analysis was conducted with squared multiple correlations as communality estimates and an oblique Promax rotation.[31]

We also regressed the overall rating of health item ('worst possible' to 'perfect health') on the 19 KDQOL^{TM} scale scores. Forward stepwise regression was run with scales entered into the model so long as they had a significant ($p < 0.05$) association with the criterion.

To assess construct validity, we examined the relative validity[32] of the measures to selected indicators of known group differences by comparing F-ratios from one-way ANOVAs. We constructed known groups using six different classification variables: self-reported number of good days in the last week (0–7 possible range); number of bad days in the last week (0–7 possible range); rating of one's life compared to people without kidney disease (0–10 scale from 'completely different' to 'the same'); the extent to which the individual is able to do everything they want to do (0–10 scale from 'able to do nothing' to 'able to do everything'); number of disability days in the last 30 days; and the 0–10 overall health rating described above.

Finally, we computed Pearson product-moment correlations between the KDQOL^{TM} scales and self-reports of the number of hospital days in the last 6 months and number of medications currently being taken.

Results

Internal consistency reliability estimates tended to be quite acceptable for the kidney disease-targeted measures, exceeding 0.70 for every scale except quality of social interaction (see Table 2). Reliability estimates for the eight scales of the 36-item health survey were also quite acceptable and ranged from 0.78 to 0.92. Mean values for the kidney disease-targeted scales ranged from 23.27 (work status, SD = 35.78) to 79.73 (quality of social interaction, SD = 16.87) on the percent of total possible (0–100) scores. Reliability estimates and average scores for the 36-item health survey pain and general health scales were very similar when scored using the RAND or SF-36^{TM} scoring algorithms,[6,9] although the RAND scoring yielded somewhat higher values for the pain scale, as previously noted.[6] Thus, we use only the RAND scoring for most of the subsequent analyses (except for comparisons with SF-36^{TM} general population data).

Table 3 provides frequencies of symptom/problems experienced by individuals in the sample, ordered in terms of the extent to which they bothered respondents during the last 30 days (from most to least prevalent). The most bothersome symptom/problem was dry skin (88% of the sample reported being bothered by this somewhat, moderately, very much, or extremely), followed by itchy skin (84%), fatigue/weakness (81%), and lack of strength (81%). Clotting or other access site problems, loss of taste, swelling of ankles, and

Table 3. Prevalence of kidney disease-targeted symptom/problems

Symptom/Problem	Not at all	Somewhat	Moderately	Very Much	Extremely
Dry skin	12	26	17	20	26
Itchy skin	16	30	21	15	18
Lack of strength	19	27	23	21	10
Fatigue, weakness	19	25	29	17	10
Washed out or drained	26	22	22	21	09
Muscle soreness	27	31	19	18	06
Excessive thirst	30	21	20	16	13
Dry mouth	32	28	19	15	06
Joint pain	32	22	21	11	14
Trouble sleeping	32	24	18	13	13
Easy bruising	34	18	22	13	12
Sleepiness during day	35	30	21	09	05
Cramps during dialysis	36	34	19	06	06
Joint stiffness	34	24	21	12	09
High blood pressure	36	25	16	12	11
Back pain	38	26	17	14	06
Numbness in hands or feet	41	24	17	12	06
Bone aches	42	20	14	12	11
Muscle spasms	43	28	16	09	03
Lack of appetite	43	32	18	05	02
Headaches	46	31	13	07	04
Nausea or upset stomach	46	25	20	06	03
Low blood pressure	48	24	15	08	05
Trouble with memory	48	36	11	04	01
Shortness of breath	51	27	17	04	02
Cramps after dialysis	52	28	14	04	01
Faintness or dizziness	52	26	15	06	02
Hot or cold spells	52	20	19	06	02
Trouble concentrating	55	27	13	04	01
Trouble getting breath	58	22	13	06	01
Blurred vision	59	19	12	07	03
Chest pain	61	22	14	02	01
Swelling of ankles	67	20	06	02	05
Loss of taste	68	18	11	03	00
Clotting or other access site problems	71	18	07	01	03

Percentage of the sample who selected the response choice is listed in the column. For these symptom/problems, respondents were asked to indicate the extent to which they were bothered by each during the last 30 days.

chest pain were relatively rare, with more than 60% of the sample not being bothered by these during the last 30 days.

The most common negative effects of kidney disease reported were reduction of energy levels (86% of the sample reported being bothered by this somewhat, moderately, very much, or extremely), limitations on what he or she can do (83%), difficulty lifting objects (83%), fluid restrictions (82%), and dietary restrictions (82%).

The mean SF-36™ scores for individuals in this sample are compared with those of 2474 adults in the general population,[9] 324 individuals with chronic renal failure,[17] 30 haemodialysis patients,[13] 541 persons with Type II diabetes,[9] 235 mixed diabetics from an endocrinology and metabolism clinic (150 Type I and 73 Type II),[33] and 64 VA patients with COPD/asthma who were in the emergency room with an acute exacerbation.[34] Without exception, the present sample of patients with kidney disease scored worse than the general population on the eight SF-36™ scales (see Table 4). The magnitude of these differences ranged between one-quarter of a standard deviation (emotional well-being) to one standard deviation (physical function, role limitations due to physical health, general health perceptions).

This sample also scored consistently lower on these health status measures than did the 541 Type II diabetics from the Medical Outcomes Study[9] and the 235 mixed diabetics.[33] The 324 chronic renal failure patients enrolled in the National Cooperative Recombinant Human (rHu) Erythropoietin Study and 30 haemodialysis patients from an outpatient dialysis unit[13] scored similarly to the current sample. In contrast, the dialysis patients in

Table 4. Comparison of SF-36™ scores for kidney disease patients in this study, with scores for general population, dialysis patients from other samples, diabetics, and chronic obstructive pulmonary disease (COPD/asthma) patients

Measure	Kidney Disease	General Population	Chronic Renal	Haemo-Dialysis	Type II Diabetics	Mixed Diabetics	COPD/ Asthma
Physical functioning	52.4	79.7	49.8	50.4	67.7	83.0	36.6
Role—physical	33.1	76.5	–	29.2	56.8	72.5	12.9
Pain	59.4	72.2	–	58.2	68.5	74.1	47.9
General health perceptions	44.3	68.9	49.3	41.0	56.1	58.5	19.5
Emotional well-being	70.1	75.2	72.4	69.8	76.7	71.7	55.5
Role—emotional	60.0	80.7	–	50.4	75.6	78.8	26.6
Social function	64.2	82.6	–	54.8	82.0	82.3	46.7
Energy/fatigue	46.2	60.3	52.4	42.2	55.7	57.5	38.2

Kidney disease refers to the 165 individuals on dialysis in this sample. General population represents mean scores from a sample of 2474 adults in the US general population[9] adjusted to the age and gender distribution of this sample. Chronic renal failure sample is 324 patients on dialysis enrolled in the National Cooperative rHu Erythropoietin Study.[17] Haemodialysis sample is 30 patients from an outpatient dialysis unit.[13] Type II diabetics is 541 patients from the Medical Outcomes Study.[9] Mixed diabetics refers to 235 patients (150 Type I: 73 Type II) from an endocrinology and metabolism clinic.[33] COPD/asthma is a sample of 64 VA patients with COPD/asthma who were in the emergency room with an acute exacerbation.[34]

Table 5. Obliquely rotated four-factor pattern matrix

	Factor Loadings*			
	Physical health	Mental health	Disease-targeted	Patient satisfaction
Physical functioning	0.83	−0.12	−0.06	0.07
Work status	0.65	−0.10	−0.01	−0.10
Role—physical	0.65	0.17	0.15	−0.15
General health perceptions	0.64	0.22	−0.04	0.09
Pain	0.53	−0.11	0.43	0.02
Energy/fatigue	0.52	0.16	0.16	0.19
Social function	0.43	0.41	−0.12	0.18
Emotional well-being	0.04	0.84	0.10	−0.09
Quality of social interaction	−0.22	0.75	0.22	0.09
Burden of kidney disease	0.19	0.53	−0.08	0.27
Social support	−0.09	0.52	0.00	0.25
Role—emotional	0.27	0.45	0.31	−0.30
Cognitive function	−0.11	0.19	0.70	−0.10
Symptom problems	0.28	−0.06	0.62	0.17
Effects of kidney disease	−0.02	0.18	0.54	0.33
Sexual function	0.14	0.05	0.34	0.05
Sleep	0.23	0.12	0.32	0.20
Patient satisfaction	−0.05	0.00	−0.01	0.62
Dialysis staff encouragement	0.01	0.05	0.02	0.59
Inter-factor Correlations				
Physical health	1.00			
Mental health	0.55	1.00		
Disease-targeted	0.59	0.60	1.00	
Patient satisfaction	0.52	0.49	0.48	1.00

* Standardised regression coefficients for predicting the scale scores from the factors.

this sample scored better than the sample of 64 VA patients with COPD/asthma.[34]

Guttman's weakest lower bound was consistent with three to four factors (the 4th eigenvalue was just under 1.0), and four factors were indicated by parallel analysis and the scree test. The Promax obliquely rotated four-factor solution, selected because it best satisfied the criterion of simple structure,[35] is presented in Table 5. The loadings of the 19 scales on the four factors suggest that the

first dimension is physical health (defined by physical functioning, work status, absence of role limitations due to physical health problems, general health perceptions, freedom from pain, and energy), the second dimension is mental health (defined by emotional well-being, quality of social interaction, absence of burden of kidney disease, social support, and absence of role limitations due to emotional problems), the third dimension is kidney disease-targeted (defined by cognitive function, absence of symptoms/problems, minimal effects of kidney disease on daily life, sexual function, and sleep), and the fourth dimension is patient evaluation of care (patient satisfaction and perceptions of staff encouragement of dialysis patients). The social functioning scale loads equally on the physical and mental health factors, consistent with results from the MOS.[36]

The regression of the overall health criterion on the 19 KDQOL™ scales yielded five scales with significant direct associations F $(5\,132) = 54.42$, $p < 0.0001$, R-squared $= 0.66$): role limitations due to physical health ($\beta = 0.18$), general health perceptions ($\beta = 0.26$), energy/fatigue ($\beta = 0.26$), bur-

den of kidney disease ($\beta = 0.15$), and sleep ($\beta = 0.16$). The two kidney disease-targeted measures accounted for four percent unique variance beyond that accounted for by the three generic scales.

Table 6 presents F-ratios from one-way ANOVAs with the 19 KDQOL™ scales as dependent variables for the six different known group classifications: number of good days in the last week, number of bad days in the last week, self-rating of one's life compared to people without kidney disease, extent to which the individual is able to do everything they want to do, disability days, and overall health. The energy/fatigue scale (F = 22.5) and the symptom/problems scale (F = 17.8) were the most sensitive to differences in the number of good days reported for a typical week in the last 30 days. Noteworthy F-ratios were observed for the social function scale (F = 14.0) and the effects of kidney disease scale (F = 12.6) as well. The energy/fatigue scale was also most sensitive to the number of bad days, but the role limitations caused by physical problems scale was equally sensitive (Fs = 13.3). The symptom/problems scale was also

Table 6. Relative validity (F-ratios) of KDQOL™ scales to known group differences

KDQOL™ Scale	Good days	Bad days	Compared with others	Able to do	Disability days	Overall health
Kidney disease-targeted scales						
Symptom/problems	17.8	10.8	3.4	9.4	8.6	13.9
Effects of kidney disease	12.6	9.2	6.9	6.5	8.4	9.8
Burden of kidney disease	6.0	6.2	9.1	4.7	5.4	9.2
Work status	3.0	4.7	2.8	2.4	0.7	2.3
Cognitive function	6.1	6.6	2.7	2.8	5.0	6.4
Quality of social interaction	5.5	4.3	3.7	4.0	8.0	6.1
Sexual function	3.7	5.0	1.8 ns	3.5	3.1	4.4
Sleep	8.1	6.4	3.9	5.9	9.2	9.7
Social support	4.4	2.0	4.1	4.1	1.6 ns	5.0
Dialysis staff encouragement	2.6	2.5	4.8	3.7	1.1 ns	3.2
Patient satisfaction	2.3	1.2 ns	2.3	1.6 ns	1.3 ns	1.7 ns
36-item health survey scales						
Physical functioning	5.9	7.9	3.4	10.0	3.0	7.6
Role—physical	10.6	13.3	6.9	10.5	4.3	12.7
Pain (RAND scoring)	10.2	10.0	3.5	6.1	8.5	6.9
General health perceptions (RAND scoring)	10.5	8.1	9.5	10.8	7.7	20.1
Emotional well-being	9.4	8.4	5.2	5.2	7.3	7.6
Role—emotional	6.9	8.4	4.3	4.6	5.4	6.6
Social function	14.0	8.1	7.1	10.7	4.5	9.5
Energy/fatigue	22.5	13.3	7.1	16.3	7.2	21.5

Table entries are F-ratios from one-way ANOVAs with KDQOL™ scales as the dependent variables and columns 2–7 as classification (known groups) variables. All F-ratios, except those denoted 'ns' were statistically significant ($p < 0.05$). Good days = number of good days in the last seven days; Bad days = number of bad days in the last seven days; Compared with others = rating of one's life compared with people without kidney disease; Able to do = extent to which the individual is able to do everything they want to do; Disability days = days health caused one to stay in bed for one-half day or longer during the last 30 days; Overall health = rating of health on a 0–10 scale ranging from worst possible to perfect health.

quite sensitive to the number of bad days
($F = 10.8$).

The general health perceptions and the burden
of kidney disease scales were the most strongly
associated with comparisons of self to others
without kidney disease (Fs of 9.5 and 9.1, respect-
ively). The energy/fatigue scale was the most
closely related to the extent to which the individual
was able to do everything they would like to do
($F = 16.3$). Sleep ($F = 9.2$), symptom/problems
($F = 8.6$), and pain ($F = 8.5$) were most strongly
related to disability days. Energy/fatigue ($F = 21.5$)
and, not surprisingly, general health perceptions
($F = 20.1$) were most strongly associated with
overall health.

Correlations of the 19 scales with number of
hospital days in the last 6 months were statistically
significant ($p < 0.05$) for 14 of the 19 scales (not
significant for work status, sleep, social support,
dialysis staff encouragement, and patient satisfac-
tion). The largest correlation was observed for
emotional well-being ($r = -0.31$, $p < 0.0001$). The
number of medications currently being taken
correlated significantly with nine of the scales,
with the largest correlation being with physical
functioning ($r = -0.23$, $p < 0.01$).

Discussion

This paper describes the development of the
KDQOL™, a self-report instrument for assessing
quality of life among persons with kidney disease.
The KDQOL™ was designed to provide a compre-
hensive assessment of both generic and kidney-
disease targeted areas of quality of life for indi-
viduals on dialysis. Results of administering the
134-item KDQOL™ to a sample of 165 patients
from eight different outpatient dialysis centres
provide strong support for the reliability and
validity of the instrument. Internal consistency
reliability estimates exceeded 0.75 for each of the
19 scales, except for one scale that was slightly
below this level of reliability. Scores on the 36-item
health survey indicated, as expected, that patients
in this sample have poorer HRQOL than the
general population, similar HRQOL to other pa-
tients with kidney disease, and better HRQOL
than individuals with COPD/asthma.

The importance of including disease-targeted
items as well as the generic 36-item health survey
measures was made evident in several analyses.
Exploratory factor analyses of the KDQOL™
scales revealed four correlated quality of life

dimensions: physical health; mental health; kid-
ney-disease targeted; and patient evaluation of
care. Regression models showed that the burden
of kidney disease scale and the sleep scale had
unique associations with an overall health criterion
measure. Relative validity analyses demonstrated
that kidney disease-targeted scales were among
the most sensitive to known group differences in
number of good days and bad days during a
typical week (e.g., symptom/problems), rating of
self compared to those without kidney disease
(burden of kidney disease), and disability days
(sleep and symptom/problems).

The results of this study provide rich informa-
tion about the impact of kidney disease that
dialysis patients find especially bothersome. Con-
sistent with a major theme identified in the focus
groups conducted prior to constructing this instru-
ment, we found that low energy level and lack of
strength were major concerns in our respondents.
We also found that fluid and dietary restrictions,
difficulty lifting objects, and limitations on what
one could do were frequently cited irritations of
kidney disease. Dry skin, itchy skin, feeling
washed out or drained, muscle soreness, excessive
thirst, dry mouth, joint pain, and trouble sleeping
were also commonly noted to be bothersome.

In summary, the results of this initial admini-
stration of the KDQOL™ supports the reliability
and validity of the instrument. Based on these
findings, we recommend the KDQOL™ as a
quality of life outcome measure for use in either
medical efficacy or effectiveness studies of thera-
pies for kidney disease. For example, we are
currently using the KDQOL™ in a national clinical
trial that will enroll over 1000 patients on dialysis.
The 134-item KDQOL™, which takes about
30 min to complete, is available upon request to
those interested in measuring quality of life of
patients on dialysis.

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