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Psychometric Properties of the Kidney Disease Quality of Life 36-Item Short-Form Survey (KDQOL-36) in the United States

John D. Peipert, Peter M. Bentler, Kristi Klicko, and Ron D. Hays

Background: The Centers for Medicare & Medicaid Services require that dialysis patients' health-related quality of life be assessed annually. The primary instrument used for this purpose is the Kidney Disease Quality of Life 36-Item Short-Form Survey (KDQOL-36), which includes the SF-12 as its generic core and 3 kidney disease–targeted scales: Burden of Kidney Disease, Symptoms and Problems of Kidney Disease, and Effects of Kidney Disease. Despite its broad use, there has been limited evaluation of KDQOL-36's psychometric properties.

Study Design: Secondary analyses of data collected by the Medical Education Institute to evaluate the reliability and factor structure of the KDQOL-36 scales.

Settings & Participants: KDQOL-36 responses from 70,786 dialysis patients in 1,381 US dialysis facilities that permitted data analysis were collected from June 1, 2015, through May 31, 2016, as part of routine clinical assessment.

Measurements & Outcomes: We assessed the KDQOL-36 scales' internal consistency reliability and dialysis facility–level reliability using coefficient alpha and 1-way analysis of variance. We evaluated the KDQOL-36's factor structure using item-to-total scale correlations and confirmatory factor analysis. Construct validity was examined using correlations between SF-12 and KDQOL-36 scales and "known groups" analyses.

Results: Each of the KDQOL-36's kidney disease–targeted scales had acceptable internal consistency reliability ($\alpha = 0.83$-0.85) and facility-level reliability ($r = 0.75$-0.83). Item-scale correlations and a confirmatory factor analysis model evidenced the KDQOL-36's original factor structure. Construct validity was supported by large correlations between the SF-12 Physical Component Summary and Mental Component Summary ($r = 0.40$-0.52) and the KDQOL-36 scale scores, as well as significant differences on the scale scores between patients receiving different types of dialysis, diabetic and nondiabetic patients, and patients who were employed full-time versus not.

Limitations: Use of secondary data from a clinical registry.

Conclusions: The study provides support for the reliability and construct validity of the KDQOL-36 scales for assessment of health-related quality of life among dialysis patients.

Complete author and article information provided before references.

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Patients with a diagnosis of end-stage renal disease (ESRD) must use a renal replacement therapy to sustain life. Of the 678,000 prevalent patients with ESRD in the United States, 71% use some form of dialysis, a process in which a machine filters wastes and excess water from the patient's blood.[1] The majority of these patients receive hemodialysis (90%), whereas a much smaller proportion receive peritoneal dialysis (10%).[1] As the incidence of ESRD has increased during the past 20 years, so has the incidence of patients initiating dialysis therapy: from 1996 to 2014, the number of new patients per year increased from 75,540 to 117,568 in the United States.[1]

As patient survival on all types of dialysis has improved, care has increasingly focused on enhancing health-related quality of life (HRQoL).[2] According to their *Conditions for Coverage of Dialysis Facilities* (§494.90), the Centers for Medicare & Medicaid Services (CMS) require that all dialysis patients' HRQoL be assessed with an instrument covering their physical and mental health. Then patients' responses to the HRQoL assessment are incorporated into a clinical intervention to develop a personalized plan of care for each patient. The demands of clinical dialysis practice put significant limitations on the available time and necessitate a parsimonious HRQoL assessment. To date, the primary instrument used for this purpose is the Kidney Disease Quality of Life 36-Item Short-Form Survey (KDQOL-36).[3] Under this requirement, most dialysis patients in the United States are assessed with the KDQOL-36 on at least an annual basis.

The KDQOL-36 was derived from the original 134-item KDQOL instrument[4] and the 79-item Kidney Disease Quality of Life Short-Form Survey (KDQOL-SF).[4] Instead of using the Medical Outcomes Study's 36-Item Short-Form Health Survey (SF-36) as a generic core, as the KDQOL-SF does, the KDQOL-36 includes the Medical Outcomes Study's 12-Item Short-Form Health Survey (SF-12), one of the most widely used generic measures of HRQoL. Furthermore, the KDQOL-36 reduced the number of kidney disease–targeted scales from 11 to 3 and includes the Burden of Kidney Disease (Burden), Symptoms and Problems With Kidney Disease (Symptoms/Problems), and Effects of Kidney Disease (Effects) scales. The items used in these scales

are subsets of the KDQOL-SF scales. The original KDQOL scales were supported by a factor analysis, have been found to have adequate to excellent internal consistency reliability, and have evidenced construct validity.[4] Additionally, a factor analysis revealed 4 underlying factors representing general physical health, general mental health, kidney disease–targeted HRQoL, and patient satisfaction.

Although it was created in 2000, to date, there has been little examination of the KDQOL-36's psychometric characteristics among US dialysis patients. One exception is a recent report from Ricardo et al[5] of the KDQOL-36's reliability and validity among English- and Spanish-speaking patients with chronic kidney disease (pre-ESRD) in the Chronic Renal Insufficiency Cohort (CRIC) Study. A significant gap remains around the KDQOL-36's measurement properties among patients with ESRD on dialysis therapy, the primary subgroup that is administered this measure in clinical settings. Given its very broad use in dialysis facilities throughout the United States, it is important that the psychometric properties of the KDQOL-36 are well understood. Therefore, the objectives of this study were to evaluate the factor structure, reliability, and construct validity of the KDQOL-36 kidney-targeted scales with a large US sample of dialysis patients.

Methods

Data Set and Participants

Data for this study were obtained from the KDQOL-Complete scoring service developed by the not-for-profit Medical Education Institute.[6] KDQOL-Complete is aimed at helping dialysis providers meet the CMS requirement to report the number of patients completing the KDQOL-36 instrument each year. This program also uses patients' responses to the KDQOL-36 in the development of a personalized plan of care and permits clinics to share results back to patients in a personalized summary report written at the 6th-grade reading level. The KDQOL-36 is administered to patients during their dialysis treatment using primarily paper-and-pencil administration (tablet administration is used for <1% of surveys). For this study, the Medical Education Institute provided a deidentified data set from clinics that permitted research use of their data from KDQOL-Complete.

Measures

Along with the KDQOL-36, the Medical Education Institute collects dialysis patients' demographic and clinical characteristics. The Medical Education Institute provided a deidentified data set containing patients' responses to the KDQOL-36 from June 1, 2015, through May 31, 2016. Because all data are deidentified, an institutional review board (IRB) exemption was granted by the University of California, Los Angeles Human Subjects Protection Committee (UCLA IRB #17-000313), including waiver from informed consent.

The KDQOL-36 has 36 items: the SF-12 version 1 and another 24 kidney-targeted items. The SF-12 yields the Physical Component Summary (PCS) and Mental Component Summary (MCS), both of which are scored on a T-score metric (mean = 50, standard deviation [SD] = 10, in the US general population).[7] The 3 kidney-targeted scales assess Burden of Kidney Disease, Symptoms and Problems of Kidney Disease, and Effects of Kidney Disease.[8] The Burden scale has 4 items (eg, "My kidney disease interferes too much with my life") that are prompted with the context "How true or false is each of the following statements?" and have 5 response options that range from "Definitely true" to "Definitely false." The Symptoms/Problems scale has 12 items, each representing a symptom or side effect of kidney disease (eg, "Washed out or drained?") that are given the context "During the past 4 weeks, to what extent were you bothered by each of the following?" and have 5 response options ranging from "Not at all bothered" to "Extremely bothered." The Effects scale has 8 items (eg, "Your ability to work around the house?") with the context "How much does kidney disease bother you in each of the following areas?" and the same response options as the Symptoms/Problems subscale. Each of these scales is scored by transforming all items to a 0 to 100 possible range and averaging across the items on each scale to create scale scores. KDQOL-36 items are all scaled so that higher scores indicate better HRQoL.[9] Previously published norms (unadjusted means) for these scales are Burden = 41, Symptoms/Problems = 71, and Effects = 63.[10] Finally, the KDQOL-36 has been translated into more than 25 different languages.[8]

Also documented were patients' race/ethnicity, age, presence of diabetes, dialysis type (in-center hemodialysis, peritoneal dialysis, conventional home hemodialysis, and other types of dialysis, including nocturnal in-center and home hemodialysis and daily home hemodialysis), vascular access site (arteriovenous fistula, arteriovenous graft, venous catheter, and peritoneal dialysis catheter), employment status, and the language of the survey. These variables were collected through CMS Form 2728 in the dialysis facilities or by the dialysis facilities themselves.

Patient Sample Selection

From June 1, 2015, through May 31, 2016, the Medical Education Institute made 77,072 assessments of the KDQOL-36 with dialysis patients in the United States that were available for analysis. Of these, 69,068 were assessments with unique patients, and 8,004 records were of patients with multiple assessments. After selecting the first assessment from those with multiple assessments, 72,982 assessments remained. A further 1,273 assessments were excluded due to uncertainty about the assessment date, and 2 assessments were eliminated for incompleteness, leaving 71,707 assessments from unique patients. Finally,

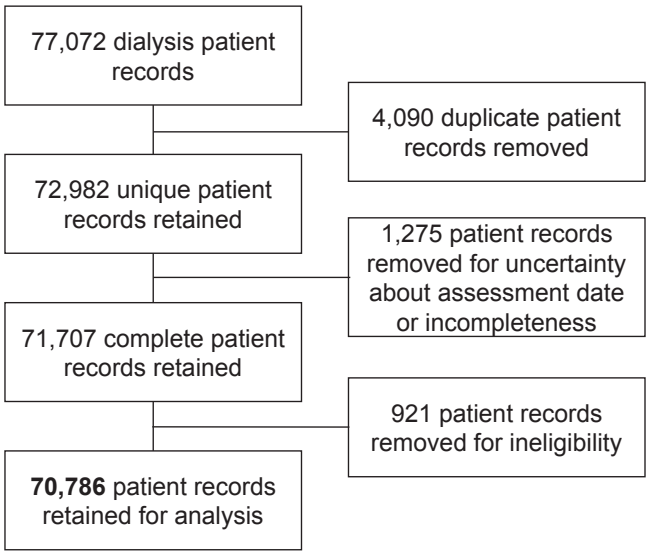

Figure 1. Patient selection flow chart.

an additional 585 patient assessments were omitted due to age younger than 18 years, and 336 were omitted due to being predialysis or having received a previous transplant, leaving a final sample of 70,786 patient assessments for analysis (Fig 1). These patients were drawn from 1,381 unique dialysis facilities, yielding an average of 51 patients per clinic.

Statistical Analyses

Patients' clinical characteristics were summarized with proportions, frequencies, means, standard deviations, and ranges, as appropriate. The distributions of the SF-12 PCS, SF-12 MCS, and KDQOL-36 scale scores were described with means, standard deviations, proportions at the floor and ceiling, and ranges. Then item-to-total correlations (corrected for item overlap with the total) were examined with multitrait scaling analysis[11] using the user-created SAS macro %MULTI.[12] Cohen's conventions for magnitude of correlations were used to determine the size of correlations: >0.10 to <0.243 = small; 0.243 to <0.371 = medium; and ≥0.371 = large.[13] Internal consistency reliability of the KDQOL-36 scales was estimated using Cronbach coefficient alpha. Because the KDQOL-36 may be analyzed at the dialysis facility level, we also estimated dialysis facility level reliability using 1-way analysis of variance models to partition between- versus within-facility variance.[14] The following standards were used to determine magnitude of reliabilities: 0.70 to <0.80, 0.80 to <0.90, and ≥0.90, indicating acceptable, good, and excellent reliability, respectively.[15]

The factor structure of the 24 items constituting the 3 kidney disease–targeted scales was examined using a confirmatory factor analysis (CFA) model. Due to the categorical distributions of the items, the models were run with the polychoric correlation matrixes.[16] We used a CFA model with robust maximum likelihood estimation and 3 correlated factors corresponding to the 3 KDQOL-36 scales, with loadings on other scales fixed to zero. All models were identified by setting the variances to 1. Model fit was determined with the Satorra-Bentler χ^2,[17] the comparative fit index (CFI), the Tucker-Lewis Index, the average absolute standardized residual, and root mean square error of approximation (RMSEA). Good model fit is evidenced by a nonsignificant Satorra-Bentler χ^2 test, CFI and Tucker-Lewis Index values > 0.95,[18] and average absolute standardized residual and RMSEA < 0.06.[17,18] However, given the large sample size, it is likely that the Satorra-Bentler χ^2 test would be significant even in the presence of good model fit. CFA analyses were conducted in EQS, version 6.2, for Windows (Multivariate Software, Inc).[19]

Finally, construct validity was assessed in 2 ways. First, we estimated Pearson product moment correlations

Table 1. Summary of Psychometric Methods

Concept	Explanation	Tests	Meaning of Results
Reliability	The ability of a measure to give the same result under the same set of circumstances; eg, a reliable measure would give the same score for 2 patients with the same level of health-related quality of life	Cronbach coefficient alpha 1 way ANOVA	Higher scores indicate higher reliability; reliabilities ≥ 0.70 are needed to be able to compare groups of patients
Factor structure	The underlying concept(s) represented by a set of questions (items); eg, several different questions about how a patient's life activities have been affected by kidney disease (eg, fluid intake, personal appearance) represent the overall effect of kidney disease.	Confirmatory factor analysis	High "loadings" indicate that questions represent the underlying concept to a greater degree
Construct validity	The degree to which a measure represents the concept it is intended to represent; this is determined by examining whether measures expected to be related are actually related; eg, different aspects of quality of life are expected to be correlated with one another	Correlations between measures; "known-groups" analyses	Higher correlations between measures expected to be correlated indicate greater validity; known-groups analyses results support a priori hypotheses

between the KDQOL-36 Burdens, Symptoms/Problems, and Effects scale scores with the SF-12 MCS and PCS scores. Second, "known groups" analyses were conducted by comparing scores on the PCS, MCS, and KDQOL-36 Burden, Symptoms/Problems, and Effects scales between key clinical subgroups, each examining a hypothesis supported by previous research. These included dialysis type (peritoneal dialysis hypothesized to have better HRQoL than hemodialysis),[20,21] whether the patient had diabetes (patients without diabetes hypothesized to have better HRQoL than patients with diabetes),[22,23] and employment (patients with full-time employment hypothesized to have better HRQoL).[24,25] Differences between mean scores across these groups were examined using mixed models with a random intercept for the dialysis clinic to test the a priori hypotheses stated above. Table 1 summarizes the psychometric aspects of our method.

Results

Patients were on average 61 years old, and the most common racial group was white (46%), with black patients the next most common (27%). Most surveys were administered in English (88%), with another 10% administered in Spanish. Additionally, the majority (83%) of patients were using in-center hemodialysis Table 2).

Mean SF-12 PCS and MCS scores were 38 and 51, respectively. Mean scores of the Burden, Symptoms/Problems, and Effects scales were 52, 79, and 74, respectively. These scales showed relatively high proportions at the ceiling, but relatively few at the floor (Table 3).

All 3 scales showed good internal consistency reliability, with Cronbach alphas ≥ 0.80 but <0.90. Facility-level reliabilities were slightly lower, but still acceptable to good at 0.75, 0.76, and 0.83 for the Burden, Symptoms/Problems, and Effects scales, respectively. Both sets of reliabilities indicated that the KDQOL-36 scales are reliable for use for comparisons of patient groups (Table 4).

Table S1 (provided as online supplementary material) shows results of the 3 correlated factors CFA model. Fit indexes showed that this model fit the data well, which provides evidence that the factor structure tested is supported.

All items were most correlated with the scales they were hypothesized to represent, as noted by a superscript c in Table 4. The smallest correlations were among items i16 (feel like burden on family), i28 (problems with your access/catheter site), and i35 (sex life) and their intended scales. However, in some cases, large correlations were also observed between items and other scales. For example, item i31 (your ability to work around the house), part of the Effects scale, correlated with the Effects scale at 0.60, but also correlated with the Burden and Symptoms/Problems scales at 0.47 and 0.53, respectively. There were also large correlations among the scales' scores (Table 4). These results indicate that although the 3 KDQOL-36 kidney-targeted scales provide unique information, they are highly related to one another.

Table 2. Dialysis Patient Characteristics

Characteristic	Value
Age, y	61 ± 14 (18-100)
Race	
White	32,573 (46%)
Black	19,217 (27%)
Asian	3,441 (5%)
Native Hawaiian/Pacific Islander	1,496 (2%)
American Indian/Alaska Native	1,060 (2%)
Missing	12,999 (18%)
Ethnicity	
Hispanic/Latino	13,594 (19%)
Not Hispanic/Latino	46,348 (66%)
Missing	10,844 (15%)
Language of survey	
English	62,489 (88%)
Spanish	7,228 (10%)
Other	1,062 (2%)
Dialysis type	
In-center HD	58,763 (83%)
PD	8,535 (12%)
Conventional home HD	2,294 (3%)
Other	1,194 (2%)
Dialysis access site	
Arteriovenous fistula	26,499 (37%)
Arteriovenous graft	4,166 (6%)
Venous catheter	14,273 (20%)
PD catheter	7,585 (11%)
Missing	18,263 (26%)
Diabetes status, yes	37,246 (53%)
Employment status	
Retired due to disability	21,647 (31%)
Retired due to age/preference	17,515 (25%)
Unemployed	6,903 (10%)
Employed full-time	4,435 (6%)
Employed part-time	2,447 (4%)
Homemaker	1,578 (2%)
Other	1,542 (2%)
Missing	14,719 (20%)

Note: n = 70,786. Values for categorical variables are given as number (percentage); for continuous variables, as mean ± standard deviation (range).
Abbreviations: HD, hemodialysis; PD, peritoneal dialysis.

Finally, each KDQOL-36 subscale had a large and positive product-moment correlation coefficient (defined as ≥0.371) with the SF-12 PCS and MCS scores (Table 5). The largest correlations were between the KDQOL-36 scale and the SF-12 MCS scores, especially those for the Burden and Effects scales. There were small but significant differences between patients on peritoneal dialysis and hemodialysis or other dialysis therapy in the hypothesized direction on the SF-12 PCS and all 3 KDQOL-36 scale scores. Patients with diabetes had significantly lower scores on all scales, though the difference was small for the SF-12 MCS score. This pattern was also largely

Table 3. SF-12 Version 1 Physical and Mental Health Component and KDQOL Scale Scores

	SF-12 PCS Score	SF-12 MCS Score	KDQOL-36 Burden of Kidney Disease	KDQOL-36 Symptoms and Problems of Kidney Disease	KDQOL-36 Effects of Kidney Disease
Sample size	69,686	69,686	70,022	70,004	69,938
Mean score	38	51	52	79	74
Standard deviation	10	10	30	16	22
% at floor	0%	0%	5%	0.03%	0.3%
% at ceiling	0%	0%	9%	4%	10%
Score distribution					
Minimum observed	11	11	0	0	0
25th percentile	30	44	25	71	59
50th percentile (median)	37	53	50	81	78
75th percentile	46	59	75	91	91
Maximum observed	66	72	100	100	100

Abbreviations: KDQOL, Kidney Disease Quality of Life; MCS, Mental Component Summary; PCS, Physical Component Summary; SF-12, 12-Item Short Form Health Survey.

observed for scale score differences across employment status, with the exception of the KDQOL-36 Effects scale (Table 6).

Discussion

The analyses presented here provided evidence for the reliability and validity of the KDQOL-36's Burden, Symptoms/Problems, and Effects subscales, as well as their factor structure. These results provide additional support for the use of the KDQOL-36 to assess HRQoL with dialysis patients.

Previous studies examining the psychometric properties of the KDQOL-36 in earlier-stage CKD and non-US samples also found support for these scales. Investigators using data from the CRIC Study of patients with pre-ESRD chronic kidney disease reported comparable internal consistency reliabilities of the KDQOL-36 scales among English-speaking Hispanics, Spanish-speaking Hispanics, and non-Hispanic whites: Burden scale coefficient alphas ranged from 0.84 to 0.87, Symptoms/Problems scale coefficient alphas ranged from 0.82 to 0.83, and Effects coefficient alphas ranged from 0.81 to 0.83.[5] That study did not conduct factor analyses or use other latent-variable approaches to determine whether the factor structure of the scales is supported.

Several other recent studies have provided support for the KDQOL-36 subscales. First, Yang et al[26] conducted a study of the KDQOL-36 among hemodialysis patients in Singapore. Item-to-scale correlations in this study ranged between 0.76 and 0.90, while a confirmatory factor model showed good fit based on less-conservative cutoff criteria referenced in the current study[27]: CFI = 0.93 (good fit is >0.80). Using confirmatory factor models, Chen et al[28] found support for Cantonese-language KDQOL targeted scales among hemodialysis and peritoneal dialysis patients: RMSEA = 0.08 and CFI = 0.80. Additionally, Chao et al examined a Mandarin version with CFA among patients with chronic kidney disease stages 1 to 5.[29] After removing item i28, "Problems with your access/catheter site?," this model yielded reasonable fit: RMSEA = 0.06 and goodness-of-fit index = 0.83. In the present study, item i28 was also among the worst performing. We expect that this is due to potential differences in the impact of access site on HRQoL between hemodialysis and peritoneal dialysis patients or due to lack of variability in responses because 75% responded that they were "not at all bothered" by their catheter or access site. In addition to these studies, several other recent studies have found evidence for the reliability and validity of the KDQOL-36 scales.[30-32]

The psychometric performance of the KDQOL-36 Burden, Symptoms/Problems, and Effects subscales was superior to those of the mentioned non-American/non–English language studies. Therefore, although these scales have evidenced reliability and validity for their English-language version among dialysis patients in the United States, additional investigations into whether these scales should be culturally adapted should be conducted, including tests of measurement invariance of the scales. This recommendation includes further investigations among Spanish-speaking dialysis patients in the United States. Although the CRIC Study demonstrated reliability of the scales among this patient population, its factor structure was not investigated.

In the present study, mean scores on the KDQOL-36 scales were consistently higher than those reported by the Dialysis Outcomes and Practice Patterns Study (DOPPS) for their US sample, which used the KDQOL-SF instrument.[10] The mean SF-36 PCS, SF-36 MCS, and Burden, Symptoms/Problems, and Effects scale scores reported by DOPPS were, respectively, 33, 47, 41, 71, and 62. Conducted between 1996 and 1999, DOPPS had a sample of 2,885 patients from the United States on hemodialysis therapy only.[33] A factor that may explain this difference is the potential that HRQoL has increased along with patient survival over the past 2 decades.[1] Additional research to generate new normative scores for the KDQOL-36 subscales should be untaken.

This study has some limitations. First, the data were not collected for the specific objectives of the study,

Table 4. Item-to-Total Correlations of KDQOL-36 Scales

	KDQOL-36 Burden of Kidney Disease	KDQOL-36 Symptoms/ Problems of Kidney Disease	KDQOL-36 Effects of Kidney Disease
Item (item name)[a]			
My kidney disease interferes too much with my life (i13)[b]	0.72[c]	0.39	0.52
Too much time is spent dealing with kidney disease (i14)[b]	0.73[c]	0.37	0.50
I feel frustrated dealing with my kidney disease (i15)[b]	0.72[c]	0.42	0.53
I feel like a burden on my family (i16)[b]	0.56[c]	0.40	0.48
Soreness in your muscles? (i17)[d]	0.33	0.54[c]	0.43
Chest pain? (i18)[d]	0.23	0.44[c]	0.29
Cramps? (i19)[d]	0.25	0.46[c]	0.33
Itchy skin? (i20)[d]	0.26	0.51[c]	0.35
Dry skin? (i21)[d]	0.28	0.54[c]	0.39
Shortness of breath? (i22)[d]	0.28	0.51[c]	0.36
Faintness or dizziness? (i23)[d]	0.28	0.51[c]	0.36
Lack of appetite? (i24)[d]	0.26	0.45[c]	0.34
Washed out or drained? (i25)[d]	0.43	0.61[c]	0.53
Numbness in hands or feet? (i26)[d]	0.29	0.50[c]	0.38
Nausea or upset stomach? (i27)[d]	0.29	0.53[c]	0.39
Problems with your access/catheter site? (i28)[d,e]	0.20	0.31[c]	0.28
Fluid restriction? (i29)[f]	0.36	0.39	0.54[c]
Dietary restriction? (i30)[f]	0.38	0.41	0.58[c]
Your ability to work around the house? (i31)[f]	0.47	0.53	0.60[c]
Your ability to travel? (i32)[f]	0.45	0.42	0.62[c]
Being dependent on doctors and other medical staff? (i33)[f]	0.47	0.45	0.63[c]
Stress or worries caused by kidney disease? (i34)[f]	0.57	0.54	0.68[c]
Your sex life? (i35)[f]	0.34	0.33	0.47[c]
Your personal appearance? (i36)[f]	0.42	0.45	0.59[c]
Cronbach coefficient alpha	0.85	0.83	0.85
Center-level reliability[g]	0.75	0.76	0.83
Correlation with KDQOL-36 Burden of Kidney Disease scale	1.0	—	—
Correlation with KDQOL-36 Symptoms/Problems scale	0.48	1.0	—
Correlation with KDQOL-36 Effects of Kidney Disease scale	0.62	0.62	1.0

Note: Item-to-total correlations are corrected for overlap.
Abbreviations: KDQOL, Kidney Disease Quality of Life; KDQOL-36, Kidney Disease Quality of Life 36-Item Survey.
[a]Some items' wording has been reduced to fit table.
[b]Item context is "How true or false is each of the following statements for you?"
[c]KDOQL-36 scale for each item.
[d]Item context is "During the past 4 weeks, to what extent were you bothered by each of the following?"
[e]For hemodialysis patients, access site is asked about; for peritoneal dialysis, catheter site is asked about.
[f]Item stem is "How much does kidney disease bother you in each of the following areas?"
[g]Estimated from 1-way analysis of variance partitioning between versus within facility variance. The minimum number of patients per clinic to obtain 0.70 reliability is: 0.70 (1 − reliability observed)/(0.30 × reliability observed). Therefore, sample sizes required for 0.70 reliability are 40, 38, and 24 for the Burden, Symptoms/Problems, and Effects scales, respectively.

limiting the availability of some variables that would have been useful in conducting validity analyses. Although some construct validity tests were conducted, future studies should continue to investigate the construct validity of the KDQOL-36. Second, because the data were deidentified and could not be linked to national dialysis registries such as the US Renal Data System, a limited number of clinical factors could be obtained. Third,

Table 5. Product Moment Correlations of SF-12 PCS and MCS Scores With KDQOL-36 Scales

	SF-12 PCS Score	SF-12 MCS Score
KDQOL-36 Burden of Kidney Disease	0.40	0.52
KDQOL-36 Symptoms and Problems of Kidney Disease	0.47	0.48
KDQOL-36 Effects of Kidney Disease	0.43	0.50

Note: All correlations significant at $P < 0.001$.
Abbreviations: KDQOL, Kidney Disease Quality of Life; KDQOL-36, Kidney Disease Quality of Life 36-Item Survey; MCS, Mental Component Summary; PCS, Physical Component Summary; SF-12, 12-Item Short Form Health Survey.

Table 6. Known Groups Differences on Scale Scores Between Clinical Subgroups

	SF-12				KDQOL-36					
	PCS	*P*	MCS	*P*	Burden of Kidney Disease	*P*	Symptoms/ Problems of Kidney Disease	*P*	Effects of Kidney Disease	*P*
Dialysis type										
Peritoneal dialysis	39	Reference	51	Reference	56	Reference	80	Reference	76	Reference
In-center HD	38	<0.001	51	<0.001	52	<0.001	79	<0.001	73	<0.001
Conventional home HD	39	<0.001	51	0.05	52	<0.001	80	0.03	75	<0.001
Other	38	0.006	51	0.3	52	<0.001	80	0.5	74	0.008
Diabetes										
Yes	37	Reference	51	Reference	51	Reference	78	Reference	73	Reference
No	39	<0.001	51	<0.001	54	<0.001	80	<0.001	75	<0.001
Employment										
Employed full-time	43	Reference	52	Reference	58	Reference	83	Reference	75	Reference
Employed part-time	42	<0.001	52	0.002	55	<0.001	81	<0.001	74	0.06
Retired due to disability	37	<0.001	50	<0.001	51	<0.001	78	<0.001	73	0.2
Retired due to age/ preference	37	<0.001	52	<0.001	54	<0.001	80	<0.001	76	<0.001
Unemployed	39	<0.001	49	<0.001	49	<0.001	77	<0.001	71	<0.001
Homemaker	37	<0.001	50	<0.001	52	<0.001	78	<0.001	75	0.004
Other	40	<0.001	50	<0.001	50	<0.001	80	<0.001	72	<0.001

Abbreviations: HD, hemodialysis; KDQOL, Kidney Disease Quality of Life; MCS, Mental Component Summary; PCS, Physical Component Summary SF-12, 12-Item Short Form Health Survey.

although this sample is very large, it may not be representative of the national dialysis population. However, because the KDQOL is often administered to all dialysis patients annually and the Medical Education Institute serves many thousands of patients across hundreds of dialysis facilities, this sample is not likely to be substantially biased. However, because the data were collected as part of a clinical intervention, the sample may reflect selection bias. Finally, because results of KDQOL-36 surveys used in this study were later reviewed by dialysis providers, there is some potential for social desirability bias in the responses.

The KDQOL-36 may be an appropriate instrument for implementing CMS's requirement of annual HRQoL assessment for dialysis care planning with every dialysis patient in the United States. This report provides new evidence about psychometric properties that may support its use by dialysis facilities. Nonetheless, additional validation analyses could yield more information about its measurement properties. Next steps for research with the KDQOL-36 should include additional tests of its construct validity and measurement invariance testing across key clinical subgroups of patients.

Supplementary Material

Table S1: Confirmatory factor analysis of KDQOL-36 items.

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