Problems with analysis and interpretation of data in "Use of the KDQOL-36™ for assessment of health-related quality of life among dialysis patients in the United States"

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Several studies have provided support for the reliability and validity of the Kidney Disease Quality of Life (KDQOL™)-36 in dialysis patients (e.g., Peipert, Bentler et al., 2018a, 2018b). In addition, the KDQOL has been shown to be predictive of healthcare utilization and mortality (DeOreo, 1997; Mapes et al., 2003), outcomes that are clearly important and significant to patients, families of patients and health care providers who suffer from and treat this condition.

Cohen et al. (2019) analyzed KDQOL-36™ survey data collected from 240,343 adults (330,412 surveys) dialyzed at a large dialysis organization in the United States during 2014-2016. The authors reported the following mean scores on the 5 KDQOL-36 scales: SF-12 Physical Component Summary (PCS): 36.6; SF-12 Mental Component Summary (MCS): 49.0; Burden of kidney disease (BKD): 51.3; Symptoms/problems of kidney disease (SPKD): 78.1; and Effects of kidney disease (EKD): 73.0. They concluded that the SPKD scale "had the highest mean score (78.1) of the 5 subscales on the KDQOL-36™" (p. 4) and suggested that it exceeded the SF-12 PCS mean score by approximately 40 points. "Thus, the two scores convey very different messages about patient health: a PCS score in the 30's is suggestive of extremely poor overall health, whereas an SPKD score of 70 or higher suggests a relatively low symptom burden. This pattern is suggestive, although not proof positive, that the SPKD subscale may be topped out" (p. 7).

Cohen et al. do not account for the fact that the SF-12 PCS and MCS are not on the same numeric scale as the BKD, SPKD, and EKD. The SF-12 PCS and MCS are scored on a T-score metric, which has a mean of 50 and standard deviation of 10 in the U.S. general population, while the kidney-targeted scales are scored on a 0-100 possible range and have variable means and standard deviations. Therefore, scores on the SF-12 scales and the kidney-targeted scales are not directly comparable to allow the kind of conclusion drawn by Cohen et al. Their statement that a PCS score of 36.6 does indicate a physical health related quality of life score nearly a standard deviation and a half below the US general population, but it cannot be directly compared with the 0-100 SPKD scores.

In fact, each of the means reported by Cohen et al. are very similar to the means for the KDQOL-36 United States dialysis population norms (Peipert et al., 2019), as shown in Table 1 below. To aid in score interpretation, users of KDQOL instruments are encouraged to refer to the freely available scoring guide: https://www.rand.org/health-care/surveys_tools/kdqol.html

Table 1. Mean KDQOL-36 Scale Scores in Cohen et al. (2019) and Peipert et al. (2019)

KDQOL-36 Scale	Cohen et al. (2019)	Peipert et al. (2019)
SF-12 Physical Component Summary	36.6	37.8
SF-12 Mental Component Summary	49.0	50.9
Burden of kidney disease	51.3	52.8
Symptom/problems	78.1	79.0
Effects of kidney disease	73.0	74.1

One of the questions in the KDQOL-36 is the often used general health rating item (Hays et al., 2015). Cohen et al. stated that the response to that item (In general, would you say your health is) "was not correlated with any of the 5 subscale scores" (p. 7). These results are implausible and inconsistent with prior research. For example, correlations based on the Medical Education Institute dataset (Peipert et al., 2019) and another dataset that included 506 patients who completed the KDQOL-36 at the time of evaluation for transplant (Peipert, Caicedo, Friedewald et al., submitted) show highly significant and noteworthy associations. Table 2 shows product-moment correlations. (Spearman rank-order correlations were similar.)

Table 2: Product-moment correlations of the general health item with the KDQOL-36 scales

	In general, how would you rate your health? (Medical Education Institute)	In general, how would you rate your health? (Transplant data)
SF-12 Physical Component Summary	0.56	0.53
SF-12 Mental Component Summary	0.34	0.29
Burden of kidney disease	0.35	0.39

Symptom/problems of kidney disease	0.37	0.34
Effects of kidney disease	0.34	0.32

It is likely that there is an error in Cohen et al.'s scoring or analysis of the KDQOL-36. While errors such as these are sometimes made by researchers unfamiliar with the instrument being employed, the field relies on informal and formal peer review to discover these flaws prior to publication. This appears, however, not to be the case, and calls into question the validity of all of the analyses and conclusions reached.

Finally, Cohen et al. (2019) suggested that "new or revised HRQOL assessment tools may be designed to addressed those factors that are most important to dialysis patients" and that "improved instruments may in turn provide a more robust foundation to guide interventions aimed at improving HRQOL in patients with ESRD" (p. 8). Recently published reports provide concrete, actionable ways to improve the KDQOL-36. For example, Peipert and colleagues suggest replacing the SF-12 PCS and MCS with the Patient-Reported Outcomes Measurement Information System (PROMIS®) measures ((Peipert & Hays, 2017a, b; 2019; Cella et al., in press).

Improvements to patient-reported outcome measures like the KDQOL-36 often occur iteratively, across multiple analyses of diverse datasets. Datasets like the one analyzed by Cohen, et al. present an opportunity to advance our understanding of the KDQOL-36's performance in a large clinical sample. However, recommendations for improvement to the KDQOL-36 must be based on appropriate and accurate interpretation of its scores and rigorous statistical analyses. We would be happy to analyze datasets such as this one to help ensure the accuracy of results and validity of the conclusions. This would provide a counterbalance to the financial conflict of interest and DaVita's lack of transparency: "The datasets generated and/or analyzed during the current study are not publicly available due fact (sic) that they are derived from the proprietary database of a large dialysis organization" (Cohen et al., 2019, p. 8)..

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