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# Expanding the Patient's Voice in Nephrology with Patient-Reported Outcomes


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As patient-oriented care has expanded in health care, the use of patient-reported outcomes (PROs) to evaluate patients' health has increased as well. A PRO is defined by the US Food and Drug Administration as "any report coming from patients about a health condition and its treatment, without interpretation of the patient's response by a clinician or anyone else."[1,2] PROs can complement more traditional, biologically based, clinical measures of patients' health, such as BP or albuminuria, by adding information about the patient's perceptions of their own health. For example, PROs measuring health-related quality of life (HRQOL) look into how the patient feels (wellbeing) and what they can do (functionality). HRQOL includes physical, mental, and social health, and provides a comprehensive view of how a patient is affected by an illness like ESKD. Applications for PROs in ESKD include monitoring of individuals or groups of patients in clinic, evaluating the effectiveness of new treatments, and performance and quality monitoring of kidney clinics.

Implementation of PROs has begun to yield benefits in many fields, such as oncology and orthopedics. For example, in a landmark publication in *JAMA* of patients with metastatic cancer who were receiving routine chemotherapy, Basch *et al.*[2] found that electronic monitoring of symptoms using PROs, and sending alerts to clinicians when distressing symptoms were indicated, was associated with improved patient survival compared with a control group (hazard ratio for death, 0.83; 95% confidence interval, 0.70 to 0.99; $P=0.04$). Because the PRO-based electronic symptom monitoring system used in this study allowed for brief, easy-to-complete symptom assessments, these findings also point to efficiency gains in patient management possible with PROs. In orthopedics, because of their salience in characterizing postsurgical health and recovery,[3] PROs capturing physical functioning have been embraced by the American Orthopedic

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Foot and Ankle Society and are administered systematically in ten clinical sites throughout the United States and included in a registry.[4] This example demonstrates the value of PROs in capturing the outcomes both patients and clinicians value, and how these outcomes can be used in population health monitoring.

There is opportunity for increased application of PROs to improve clinical monitoring of patients' health and treatment evaluation in ESKD. Previous research comparing disease burden of several chronic conditions found that patients with ESKD had worse physical functioning than any of the other conditions included in the study (*e.g.*, diabetes, symptomatic AIDS), with the exception of multiple sclerosis.[5] The recent work of the Standardized Outcomes in Nephrology group has corroborated these findings and demonstrated that ESKD patients and caregivers prioritize outcomes like fatigue, ability to travel, overall effect of ESKD on the family, and ability to work over more traditional outcomes such as mortality and hospitalizations.[6] The time is ripe to expand and refine the use of PROs with patients with ESKD.

One issue facing ESKD clinicians and researchers who would like to use PROs is whether to use a measure with content targeted specifically toward ESKD-related health issues or "universal" (generic) measures that apply equally well to patients with all types of chronic conditions. On one hand, there is some evidence that disease-targeted measures are more sensitive and responsive to change. For example, in this issue of the *Journal of the American Society of Nephrology* (*JASN*), Ware *et al.*[7] find that a new disease-targeted measure, the CKD Quality of Life instrument, is more responsive to differences in health among patients with CKD than the Medical Outcomes Study Short Form 12 summary measures, the Physical Component Summary (PCS), and the Mental Component Summary (MCS). Yet, there are important benefits to using a generic measure as well. Among the most important of these benefits is the ability to establish a common metric for comparison of HRQOL and symptoms across multiple conditions, or to capture relevant aspects of HRQOL for patients with multiple chronic conditions, as is the case for the vast majority of patients with ESKD. Of course, one reasonable approach may be to include both generic and kidney-disease targeted scales in a single instrument. This is the approach taken by the widely used Kidney Disease Quality of Life (KDQOL) scales, which include Medical Outcomes Study Short Form 12 or 36 items, depending on the version of the KDQOL.[8,9] Peipert *et al.*, in this issue of *JASN*, advance the interpretability of the KDQOL-36 measure by providing normative values referenced to the national United States dialysis population, as well as support for a new, single-score composite using the KDQOL-36's items.[10]

Whether accompanied by kidney-targeted measures or used on their own, PROs focused on generic HRQOL are relevant to ESKD. This is especially the case for the National Institutes of Health's Patient-Reported Outcomes Measurement Information System (PROMIS) suite of measures. PROMIS has been innovative in multiple ways. PROMIS measures use item response theory and can be administered through computer adaptive testing, which draws from large banks of questions to generate reliable and parsimonious measures of patients' HRQOL across multiple physical, mental, and social domains.[11] All PROMIS measures are scored on a user-friendly T-score metric with a mean value of 50 and SD of 10, normed to the United States general population. This scoring approach allows any individual's or group's score on PROMIS measures to be compared with the average individual from the United States general population. For instance, if a patient with ESKD scores 40 on a PROMIS physical function measure in the clinic, a clinician knows immediately that the patient's level of physical function is 1 SD below the United States general population value, which may indicate clinically significant dysfunction. Every PROMIS measure is brief and poses little burden on respondents; average completion times of $<1$ minute for PROMIS computer adaptive testing have been documented.[12] Critically, all PROMIS measures are free to use and available to the public. Users can browse PROMIS measures at http://www.healthmeasures.net/, then download paper versions of each instrument and supporting documentation without registration. However, many users will find electronic implementations of PROMIS measures in the electronic medical record *via* Epic and Research Electronic Data Capture (REDCap) software to be most efficient.

Despite the significant benefits offered by PROMIS, these measures have been infrequently used among patients with ESKD, with the exception of notable implementations among the Midwest Pediatric Nephrology Consortium[13] and kidney transplant patients.[14] Noting the extensive opportunity and need to routinely assess HRQOL among patients on dialysis, there is a much larger role for PROMIS measures in ESKD. One way to fulfill this role is to replace the Short Form-12 PCS and MCS in the KDQOL-36, which is among the most commonly used measures to fulfill the Centers for Medicare and Medicaid Services requirement to assess HRQOL on an annual basis. This transition could be eased by the ability to create a "crosswalk" linking PCS and MCS scores to PROMIS measures using advanced psychometric approaches, which has already been accomplished for multiple legacy measures in PROMIS[15–17] and as part of the PROsetta Stone initiative (http://www.prosettastone.org/Pages/default.aspx).

Whether using PROMIS measures or others, patients with ESKD stand to benefit significantly from a variety of new clinical and evaluation opportunities with PROs. Doing so will help align ESKD care with patient priorities and open up new, efficient channels for provider–patient communication. The burden of disease for patients with ESKD is formidable and affects many aspects of patients' lives. Adopting PRO-based approaches to manage the health

of patients with ESKD is a very promising way to ease this burden.

## DISCLOSURES

None.

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