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Patient-Reported Outcomes: Toward Better Measurement of Patient-Centered Care in CKD

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The term “patient-centered,” first used by Enid Balint in a lecture in 1968, is poorly understood by many in health care and overused by more.¹ Enshrined by the Institute of Medicine as an element of health care quality, to some it means that the needs of the patient come first. To others, it sounds like a threat, implying an unreasonable triumph of consumerism over professional expertise. Don Berwick² asserts that, at the core, patient-centeredness is a property of care that welcomes patients to assert their humanity and individuality.

In caring for patients, most of the measures at the clinician’s disposal are clinician-centered. Conventional clinical measures assess elements of physiologic functioning on the basis of biomedical and physical science. However, one of the primary goals of health care is to reduce symptoms and improve how the patient feels and functions in his or her daily life. Patient-reported outcome measures (PROMs) provide the means to measure these aspects of the patient’s

health. In this issue of the *Journal of the American Society of Nephrology* (JASN), two articles attempt to make advances in the development of PROMs for people with CKD.^{3,4} Here, we briefly describe what PROMs are, how they are developed, and how they have historically been used in nephrology. Then, we comment on the contributions of these two articles and the implications for clinicians, researchers, and policy makers.

As their name suggests, PROMs are reported by the patient and deal with aspects of health directly relevant to patients’ daily life, including symptoms, functional status, and psychologic wellbeing. A good PROM captures the specific domains relevant to the condition that patients care about. Each domain is assessed by one or more items that are scored and combined to produce a summary score. Sometimes, a PROM will contain multiple subscores, each representing a different but related domain that allows a patient to report the full extent of their outcomes.

The process of developing a PROM usually involves several steps. The first is domain development—determining what aspects of the patient’s life are most important to measure. This involves reviewing the literature and collecting input from patients, family members, providers, and clinical experts. Then, the developer creates a list of potential items relevant to the concept of interest. These items can be general (e.g., “In general, would you say your health is: excellent, very good, good, fair, poor”) or specific to a condition (e.g., “My kidney disease interferes too much with my life: strongly agree, agree, neither agree or disagree, disagree, strongly disagree”). The list of items is administered to a relevant clinical population, analyzed, and trimmed on the basis of two criteria.

The first criteria is reliability, or how consistently patients respond to the measure. If the PROM was measured again tomorrow, would it show the same result? If two different interviewers questioned the same patient, would they get the same results? There is a truism that states “if you are really interested in capturing a specific concept, ask more than one question about it.” This allows greater precision of measurement. However, although PROMs with more items generally produce more reliable scores, this increases the burden for patients and providers. This tradeoff between reliability and response burden is important for PROM creation, because practical considerations are also important. A relatively recent innovation, computer adaptive testing, in which patients’ responses to items influence the items that they see later, can allow for increased precision in a shorter time. However, this result needs to be shown in practice.

PROM developers must also consider the second criteria: a measure’s validity—whether the PROM measures what we want it to measure. Validity can be divided into several related concepts, two of which are content validity and construct validity. Content validity relates to how well the measure covers all potentially relevant aspects of the concept. Construct validity—how well the measure performs compared with other measures

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of the same concept—can help to identify PROMs that will be most useful.

After the list of items has been narrowed to a manageable number, the PROM is typically tested in a real-world population, and the results are published. Many PROMs developed as part of federal research grants have been aggregated into the PROMIS database, where they are freely available and searchable by researchers or clinicians wishing to incorporate PROMs into their research or practice.

PROMs originally intended for the general population, like the Short Form 36 (SF36), were among the first PROMs to be used in patients with CKD,⁵ but more disease-specific measures have been created. The Kidney Disease Quality of Life (KDQOL-36) instrument was developed using input from focus groups of patients with CKD.⁶ It built on the existing SF36 scale by adding questions specific to kidney disease, related domains like the patients' symptoms or problems, and effects and burden of kidney disease.⁶ The Choices for Healthy Outcomes in Caring for End-Stage Renal Disease (CHOICE) Health Experience Questionnaire was designed to be used to compare different modalities and doses of dialysis.⁷ In recent years, there has been a proliferation of PROMs for patients with CKD. A recent review of PROMs in patients on dialysis found 23 distinct measures with reported evidence for reliability or validity.⁸

PROMs are becoming increasingly important for patients and their providers, health systems, and policy makers. In general, PROMs can be used by clinicians for several purposes: as a screening tool to identify problems, monitor existing conditions, and inform treatment decisions. The provision of information itself can help the patient and clinician arrive at a shared view of the progress and goals of treatment, leading to improvement in patient behavior and satisfaction.⁹ For patients with CKD, the presence of symptoms is associated with both decreased quality of life and increased mortality,¹⁰ and the use of standardized PROMs to measure symptoms could identify the need for additional clinical attention. Health systems engaged in quality improvement efforts can use PROMs as indicators of success.¹¹ On the state or national level, PROMs may soon be incorporated into value-based payment reforms, where a portion of provider reimbursements from Medicare and Medicaid is tied to performance on these measures.

In this issue of JASN, Peipert *et al.*³ take the widely used KDQOL-36 and create a composite score and normative values for the kidney-specific domains. These enhancements have the potential to make KDQOL-36 scores easier for clinicians to understand, and also, they could make it easier for health systems to set attainable benchmarks for their patients with CKD. Ware *et al.*⁴ set off in a different direction, developing a very short six-item PROM and a three- to six-item computer adaptive testing instrument that still maintains a good level of reliability. This cake-and-eat-it-too solution has the potential to substantially reduce response burden for patients and make it easier for health systems to implement a PROM for patients with CKD.

There are some limitations to both approaches. The enhancements to the KDQOL-36 created a kidney-specific composite score, but that composite did not include domains for general physical and mental health.³ Thus, the KDQOL-36 still includes three scores, which could reduce its utility if a single score for health is desired. In addition, the national norms that they calculated were adjusted by race for comparison with clinic scores. If current practice reflects disparities in care that are related to race, then comparing clinic scores with the status quo could help perpetuate those disparities. Ware *et al.*⁴ suggest that their novel approach is both shorter and more comprehensive. However, the small number of items could potentially restrict the usefulness of this approach, particularly as an indicator of specific symptoms or problems. Additional studies are needed to provide evidence that this approach will produce clinically useful information.

These are problems that can be addressed with more research. The work by Peipert *et al.*³ can increase the acceptability of PROMs to clinicians by making them more like other laboratory tests. The envelope-pushing approach by Ware *et al.*⁴ acknowledges the clinical imperative for efficiency and deserves to be given the chance to work.

Together, these papers represent methodologic advances that could help propel patient-centeredness in CKD care. Systematically inviting patients with CKD to contribute their lived experience to the clinical encounter, where it can be considered alongside the clinical perspective, is a tactic for which the time has come.

DISCLOSURES

None.

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