

Time to Rethink Our Approach to Patient-Reported Outcome Measures for ESRD

Fredric O. Finkelstein* and Susan H. Finkelstein†

Clin J Am Soc Nephrol 12: 1885–1888, 2017. doi: <https://doi.org/10.2215/CJN.04850517>

Introduction

Patient-reported outcome measures (PROMs) have been incorporated into the care of patients with ESRD for several years, primarily as research tools exploring the relationships between these measures and “hard” outcomes, such as mortality and hospitalizations (1–3). It has been suggested that PROMs should also be incorporated as part of routine clinical practice (4,5). In fact, it is now mandated by the Centers for Medicare and Medicaid Services (CMS) that dialysis facilities ask patients to complete the In-Center Hemodialysis Survey Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS) semiannually and the Kidney Disease Quality of Life 36 (KDQOL-36) annually. In addition, patients are expected to be evaluated for depression and pain once a year. Despite these initiatives, there is now an increasing consensus among clinicians that these mandates have been of limited value in terms of adequately capturing the patients’ experience with their disease, and informing health care providers of patients’ symptoms and concerns (4,5). The ICH-CAHPS deals with generic facility issues, primarily with perceptions of care in the facility—the appearance of the facility, whether the facility is treating patients with respect, and whether it is providing appropriate education. The questionnaire, thus, although addressing issues of importance in terms of facility organization, may not be able to appreciate the specific concerns of an individual patient. The KDQOL-36 provides five summary scores—the physical component score, the mental component score, the burden of kidney disease score, the symptom and problem score, and the effect of kidney disease on daily life score. The problem from a clinician’s standpoint is that it is not clear how being informed of these scores translates into information that is clinically useful in the management of a patient’s problems. A low physical component score or mental component score does not define the particular areas of difficulty that a patient is experiencing and what could be done to improve the care of the patient. The burden of kidney disease and the effect of kidney disease on daily life scores ask very generic questions about burden, frustrations, and limitations imposed by kidney disease. The symptom and problems score uses 12 questions focused on specific symptoms—but these symptoms are rarely looked at as isolated symptoms requiring attention but are seen as part of the summed

symptom and problem score. What if an individual patient’s concerns are not addressed in the standardized questionnaire? How can health care providers capture the unique concerns of the patient—those that are important for an individual patient? Is it not possible that dynamic PROMs could be developed that will provide more useful information to health care providers—PROMs that explore the unique concerns of the individual patient?

PROMs and Hard Outcomes

Several PROMs (*e.g.*, the KDQOL-36 and depression questionnaires) have importantly been shown to correlate with “hard” outcome measures, such as mortality and hospitalization rates (1–3). It is noteworthy that mortality rates for patients with ESRD have decreased substantially over the past 20 years, and cross-sectional studies have shown that there has been an overall improvement in KDQOL-36 scores from the 1990s to the present time, with the most dramatic changes being seen in selected domains (6). Building on these improvements, it is now time to move toward a true patient-centered care approach.

Recent Emphasis on Patient-Centered Care

Recent work has emphasized the importance of appreciating patients’ experiences with their illness and health care delivery (4,5,7), suggesting that the focus of care shift from an arbitrary adherence to rigid standards of care toward more flexible standards that capture the patients’ perception of their experience—their symptoms, goals, and objectives of care—a true model of patient-centered care. This shift in patient management is especially important, because providers often do not appreciate patients’ symptoms (8), underscoring the importance of developing improved communication between patients and providers.

Certainly, meeting basic levels of care (*e.g.*, anemia, Kt/V targets, *etc.*) is important in providing a minimum standard. However, if meeting these standards becomes a primary objective of therapy, then patient care becomes compromised, and what the cornerstone of patient care should be (symptom management and meeting patients’ needs) will not be adequately addressed (4,5). As recently noted by Nissenson (9), the quality paradigm must shift if we are “to rekindle the aspirations of the creators of the [ESRD] program,

Departments of
*Medicine, Section of
Nephrology and
†Psychiatry, Yale
University, New
Haven, Connecticut

Correspondence:

Dr. Fredric O.
Finkelstein, Yale
University, 136
Sherman Avenue, New
Haven, CT 06515.
Email: fof@comcast.net

whose primary goal was to improve the lives of the patients.”

There are Major Limitations of the Measures Currently Being Used

Current approaches of assessing the patient's experience are not able to capture the individual patient's experience, thus limiting the ability to implement a true patient-centered care approach. There are three main reasons for this.

Variability of an Individual's PROM Results

Clinicians caring for patients with ESRD are very much aware of the dramatic changes that can occur for patients with ESRD over time with their health status because of their multiple comorbidities, myriad medications, and complex treatment regimens. Given the fluctuations in the physical, social, and psychologic status of patients, it is unlikely that giving the existing standardized questionnaires annually or semiannually will provide a meaningful and dynamic understanding of a patients' areas of difficulty (10).

Limitations in Terms of Capturing Individual Patient's Experiences

Although the questionnaires currently in use in dialysis facilities clearly document a marked reduction in many quality of life domains compared with in the general population, it is not clear how documenting this improves the clinicians' understanding of each patient's experience of dialysis. It is important to emphasize that each patient experiences events, treatments, and symptoms uniquely. Understanding that unique experience is a challenge for health care providers that may not be captured with standardized questionnaires.

Limitations in Terms of Using PROMs in the Management of Patients

One of the challenges with the use of PROMs in routine patient care is what one does with the results. Currently, the results of the annual KDQOL-36 are summarized in each patient's chart. Are individual symptoms addressed? Does the facility have the infrastructure to deal with the results—assess the data, develop treatment plans for domains of concern, *etc.*? Recently, most dialysis facilities have worked to address the issues necessary to meet Quality Incentive Program (QIP) and Five Star Rating requirements. For example, anemia and vascular access coordinators have been designated. What about identifying and treating the specific concerns of the individual patient? Can PROMs be developed that facilitate the understanding of each patient's unique areas of difficulty and thus, permit targeted interventions?

Lessons from Other Specialties

It is interesting that the importance of incorporating PROMs into patient care has been recognized in several other health areas. Studies clearly show that this inclusion is appreciated by both patients and clinicians and can result in improved outcomes for patients (7,10–12).

It is particularly interesting to note that electronic testing is now attracting increased attention and useful in facilitating reporting to clinicians, permitting more frequent testing, avoiding the drawbacks of repetitive testing, providing useful

feedback to clinicians, and improving outcomes (11). A robust literature has developed on the use of computerized adaptive testing (CAT) to establish diagnoses for patients with psychiatric disorders (11). Advantages noted of CAT include a high level of diagnostic precision, the use of a limited number of questions that are most relevant for an individual, and the ability to administer repetitive testing without response set bias, because the questions adapt to the patient responses.

Incorporating PROMs into both routine care and clinical trials has been getting increasing attention in the oncology literature in part because of the recognition that health care provider and patient assessment of patients' experiences, symptoms, and quality of life are discordant (7,12). The routine incorporation of PROMs into care enhances both the patients' as well as the clinicians' experience (7). Oncologists understand that, in assessing the value of an individual therapy, it is important to recognize that treatment values cannot be summarized in an individual metric—a multifaceted approach is necessary, focusing on what is important to the recipient of care: the patient (7,12).

Basch (7) has recently underscored the importance of using PROMs to “harness patient's voices to improve care.” He emphasizes the utility of using electronically administered PROMs, incorporating these into the electronic medical record accompanied by automatic notifications to health care providers of symptoms or issues of concern.

CAT offers a way to individualize administration of PROMs, minimizing the burden to patients, avoiding the problem of repetitive testing, and facilitating the monitoring of the overall quality of life of patients using a much-reduced number of questions with a high degree of reliability (7,11,12).

Challenges of Current ESRD Care in the United States and PROM Use

Despite the fact that studies have clearly shown a relationship between several PROMs and outcome measures and that PROMs are helpful in assessing patients' responses to modifications in ESRD treatment regimens (13), PROMs have not been well incorporated into the routine care of patients. The intense focus in dialysis units on meeting certain basic standards of care (primarily those of the CMS's Five Star Rating program and QIP) has encouraged the use of considerable resources to achieving these goals. Thus, dialysis units have placed a large emphasis on vascular access, anemia management, targeted Kt/Vs, *etc.* The resources in the dialysis units have not been directed at focusing attention on the patients' experience and symptom management (4,5).

Domains of difficulty for patients with ESRD have been well established using validated PROMs (Table 1). These problems span the breadth of a comprehensive review of systems from physical complaints to cognitive difficulties to psychosocial and interpersonal problems. The significance of each of these areas needs to be put in the context of the individual patient and his/her other problems—cardiovascular disease, hypertension, fluid overload, *etc.* For PROMs to be clinically useful, they need to be adaptable to the individual patient.

Symptom management for patients with ESRD can indeed be challenging. For example, pain is commonly reported by

Table 1. Domains of difficulty for patients with ESRD

- (1) Depression
- (2) Anxiety
- (3) A wide variety of physical symptoms
- (4) Family and marital discord
- (5) Sexual dysfunction
- (6) Caregiver burden
- (7) Satisfaction with care and dialysis treatment regimen
- (8) Cognitive impairment
- (9) Effect of treatment regimen on their life
- (10) Physical functioning
- (11) Fatigue

patients with ESRD, and depression is prevalent, occurring in 25%–30% of patients on dialysis in cross-sectional analyses (14). However, management of these symptoms is difficult—even with the assistance of a trained nurse (14). A process for targeted interventions needs to be developed through a process of trial and error that will result in effective intervention strategies. Marital discord, sexual dysfunction, family problems, financial issues, *etc.* are also common among patients with ESRD; how does the unit find the resources to deal with these areas of difficulty (3)? This often requires someone to sit down and talk to the patient to explore those problem areas that are most impactful for that particular individual. Although social workers could be tasked to address these issues, they usually have large caseloads and are generally expected to focus on other issues. Moreover, simply documenting that an area of difficulty is present does not mean an individual patient wants to have this area addressed. For example, although many women receiving hemodialysis are sexually inactive, most are satisfied with their sexual life, and few wish to learn about treatment options (15).

Regulatory Concerns and Documentation

A concern with the use of PROMs in routine care is how they will be used by regulatory agencies as well as dialysis organizations. Standards have been set by the CMS to compare the quality of care among dialysis facilities, relying on assessments determined with easy to obtain measurements.

PROMs are different for several reasons. The PROMs that best capture the patients' experience have not been well defined. Therefore, there needs to be flexibility in

determining which PROMs are most useful and what are the best modes of administration. Arbitrary standardized measures cannot be recommended at this time. If a useful and efficient methodology is to be developed, facilities should be able to adapt and modify the routine use of PROMs, encouraging innovative approaches. An open dialogue between patient and provider should be encouraged. Patients will need to be educated to understand that their responses will be used by providers to address their needs and problems. Providers need to make sure that patients understand this and that reports of domains of difficulty will not be seen negatively by the provider.

It also is important to recognize that individual patient problems may be unrelated to the dialysis procedure itself, limiting the ability of the dialysis facility to affect these problems. Examples include development of unrelated illnesses, family difficulties, economic hardships, *etc.* Thus, using scores from PROMs to compare dialysis facilities is not appropriate and can, in fact, be counterproductive.

A major challenge facing the nephrology community with the incorporation of the routine use of PROMs into standard patient care is how regulatory agencies and dialysis providers can evaluate how each facility is addressing individual patient's symptoms and experience of dialysis. Importantly, the CMS and dialysis providers must not become so involved in the details of documenting PROMs that dialysis providers lose their focus on improving the care of the individual patient. In the absence of clear data supporting the specific use of PROMs and how these should be incorporated into routine care, it does not seem reasonable for the CMS or dialysis providers to mandate how and which PROMs should be administered. This is an area that requires creative research and the encouragement of innovative approaches to address this critically important area.

Conclusion, Recommendations, and How We Move Forward

How then can a dialysis facility and regulatory agencies be assured that PROMs are being administered and used to improve patient care? How can we make sure this is happening without stifling innovative thinking? This is indeed a challenge.

How we move forward is outlined in Table 2. PROMs should indeed be included as part of routine patient care.

Table 2. Recommendations for implementing patient-reported outcome measures into routine patient care: The way forward

- (1) Mandate that PROMs be incorporated into routine patient care, addressing some or all of the issues indicated in Table 1
- (2) Leave the mode and frequency of administration (paper, electronic, CAT) and the instruments to be used to the discretion of the facility
- (3) Encourage innovative approaches to the integration of PROMs into routine care given the lack of clear data on how PROMs should be incorporated into patient care and translated into improved patient experiences
- (4) Explore the use of smartphones, tablets, and computers and the incorporation of PROM data into electronic health records
- (5) Require that there be documentation that domains of individual patient concerns have been acknowledged and that a plan to address these concerns has been noted; plans could include addressing the problem using facility resources or making referrals to other health care providers or community resources

PROM, patient-reported outcome measure; CAT, computerized adaptive testing.

However, which instruments to use and how they are to be administered should not be specified, thus allowing for innovative approaches. Appropriate documentation should be provided in patients' records, plans should be outlined to address areas of concern by looking at what is and what is not useful, and appropriate follow-up evaluations should be clearly outlined.

Acknowledgments

Support for this work was provided by the Kidney Care Quality Alliance.

The content of this article does not reflect the views or opinions of The American Society of Nephrology (ASN) or the *Clinical Journal of the American Society of Nephrology* (CJASN). Responsibility for the information and views expressed therein lies entirely with the author(s).

Disclosures

None.

References

- Mapes DL, Lopes AA, Satayathum S, McCullough KP, Goodkin DA, Locatelli F, Fukuhara S, Young EW, Kurokawa K, Saito A, Bommer J, Wolfe RA, Held PJ, Port FK: Health-related quality of life as a predictor of mortality and hospitalization: The Dialysis Outcomes and Practice Patterns Study (DOPPS). *Kidney Int* 64: 339–349, 2003
- Lopes AA, Albert JM, Young E, Goodkin D, Mapes D, Combe C, Piera L, Held P, Gillespie B, Port FK: Dialysis Outcomes and Practice Patterns Study (DOPPS): Depression as a predictor of mortality and hospitalization among hemodialysis patients in the United States and Europe. *Kidney Int* 62: 199–207, 2002
- Finkelstein FO, Arsenaault KL, Taveras A, Awuah K, Finkelstein SH: Assessing and improving the health-related quality of life of patients with ESRD. *Nat Rev Nephrol* 8: 718–724, 2012
- Finkelstein FO: Performance measures in dialysis facilities: What is the goal? *Clin J Am Soc Nephrol* 10: 156–158, 2015
- Kliger AS: Quality measures for dialysis: Time for a balanced scorecard. *Clin J Am Soc Nephrol* 11: 363–368, 2016
- Merkus MP, Jager KJ, Dekker FW, de Haan RJ, Boeschoten EW, Krediet RT; The NECOSAD Study Group: Predictors of poor outcome in chronic dialysis patients: The Netherlands cooperative study on the adequacy of dialysis. *Am J Kidney Dis* 35: 69–79, 2000
- Basch E: Patient reported outcomes—harnessing patients' voices to improve clinical care. *N Engl J Med* 376: 105–108, 2017
- Weisbord SD, Fried LF, Mor MK, Resnick AL, Unruh ML, Palevsky PM, Levenson DJ, Cooksey SH, Fine MJ, Kimmel PL, Arnold RM: Renal provider recognition of symptoms in patients on maintenance hemodialysis. *Clin J Am Soc Nephrol* 2: 960–967, 2007
- Nissenson AR: Improving outcomes for ESRD patients: Shifting the quality paradigm. *Clin J Am Soc Nephrol* 9: 430–434, 2014
- Pittman ZC, John SG, McIntyre CW: Collection of daily patient reported outcomes is feasible and demonstrates differential patient experience in chronic kidney disease. *Hemodial Int* 21: 265–273, 2017
- Gibbons RD, Weiss DJ, Frank E, Kupfer D: Computerized adaptive diagnosis and testing of mental health disorders. *Annu Rev Clin Psychol* 12: 83–104, 2016
- Basch E, Deal AM, Kris MG, Scher HI, Hudis CA, Sabbatini P, Rogak L, Bennett AV, Dueck AC, Atkinson TM, Chou JF, Dulko D, Sit L, Barz A, Novotny P, Fruscione M, Sloan JA, Schrag D: Symptom monitoring with patient-reported outcomes during routine cancer treatment: A randomized controlled trial. *J Clin Oncol* 34: 557–565, 2016
- Finkelstein FO, Schiller B, Daoui R, Gehr TW, Kraus MA, Lea J, Lee Y, Miller BW, Sinsakul M, Jaber BL: At-home short daily hemodialysis improves the long-term health-related quality of life. *Kidney Int* 82: 561–569, 2012
- Weisbord SD, Mor MK, Green JA, Sevick MA, Shields AM, Zhao X, Rollman BL, Palevsky PM, Arnold RM, Fine MJ: Comparison of symptom management strategies for pain, erectile dysfunction, and depression in patients receiving chronic hemodialysis: A cluster randomized effectiveness trial. *Clin J Am Soc Nephrol* 8: 90–99, 2013
- Mor MK, Sevick MA, Shields AM, Green JA, Palevsky PM, Arnold RM, Fine MJ, Weisbord SD: Sexual function, activity, and satisfaction among women receiving maintenance hemodialysis. *Clin J Am Soc Nephrol* 9: 128–134, 2014

Published online ahead of print. Publication date available at www.cjasn.org.