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Patient-Reported Outcome Measures for Adults With Kidney Disease: Current Measures, Ongoing Initiatives, and Future Opportunities for Incorporation Into Patient-Centered Kidney Care

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Abstract

Tools that measure patients' experiences and perceptions of disease are increasingly being recognized as important components of a multidisciplinary, personalized approach to care. These patient-reported outcome measures (PROMs) have the ability to provide clinicians, researchers, and policymakers with valuable insights into patients' symptoms and experiences that are unable to be ascertained by laboratory markers alone. If developed rigorously, studied systematically, and utilized judiciously, PROMs can effectively incorporate the patient voice into clinical care, clinical trials, and healthcare policy. PROMs have continued to gain attention and interest within the nephrology community, but key challenges and opportunities for their seamless uptake and integration remain. In this narrative overview, we provide nephrologists with a comprehensive list of existing PROMs developed for adults with kidney disease with information on their gaps and limitations; a rationale to support the continued incorporation of PROMs into nephrology clinical trials, clinical care, and healthcare policy; and a summary of ongoing initiatives and future opportunities to do so.

Index words:

patient-reported outcomes (PROs); personalized care; clinical trial endpoints; qualitative research; psychometrics; patient-centered care; hemodialysis; transplantation; chronic kidney disease (CKD); end-stage kidney disease (ESKD); patient voice; patient-reported outcome measures (PROMs); qualitative research; symptom management; review

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Introduction

Patient-advocacy and an increasing appreciation of the central role that symptoms, emotions, and goals play in disease perceptions have led to a greater emphasis on the use of patient-reported outcome measures (PROMs) in clinical care. According to the National Quality Forum, a PROM is a measure of a patient's health conveyed directly by the patient, without interpretation by a clinician.[1] PROMs, which can describe specific symptoms, treatment preferences, or aspects of overall health, provide insights into a patient's well-being that are unable to be captured by laboratory data alone. The benefits of incorporating PROMs into clinical care are vast, as studies have demonstrated their ability to cultivate shared-decision making, allow for more nuanced predictions of disease trajectory, improve communication between physicians and patients, facilitate patient self-monitoring, reduce emergency department utilization, and enhance workflow efficiency.[2–9]

PROMs are particularly relevant to the care and health of kidney patients. Studies have shown that patients with end-stage kidney disease (ESKD) have poorer functional status than those with other chronic conditions, and that providers are largely unaware of the presence and severity of these symptoms.[10–11] In the Standardized Outcomes in Nephrology (SONG) initiative, a multidisciplinary effort between clinicians, researchers, and patients to establish a shared set of outcome measures across the spectrum of kidney disease, ESKD patients have ranked PROMs, reporting, for example, that self-reported quality of life holds greater weight than long-term survival.[12]

Though PROMs are increasingly being recognized as a key component of patient-centered kidney disease care, challenges to their seamless incorporation and uptake remain. In this narrative overview, we present an introduction to PROM development for nephrologists who may be less familiar with this subject, a list of PROMs developed for adults with kidney disease with limitations of each measure, ongoing initiatives and prior work related to the incorporation of PROMs into nephrology clinical trials healthcare policy, and a summary of future areas on which to focus.

Methods for Rigorous Development of PROMs

In order for a PROM to be considered methodologically rigorous, it must meet certain requirements. The Standards for Educational and Psychological Testing, a set of guidelines developed jointly by the American Educational Research Association, the American Psychological Association, and the National Council on Measurement in Education, include psychometric criteria for measure construction in psychology and education.[13] The Consensus-Based Standards for the Health Measurement Instruments (COSMIN) checklist and the Consensus-Based Standards for the Health Measurement Instruments Outcome Measures in Effectiveness Trials (COMET) also provide guidelines for PROM development.[14–15] Broadly speaking, these guidelines state that an ideal PROM must be valid, reliable, and responsive.

Validity begins with defining both the outcome of interest as well as the target population for whom the PROM is most relevant. This is followed by the development of a conceptual

framework based on a literature review of similar PROMs in other chronic illnesses and qualitative analyses of interviews with key stakeholders (target patients and their providers).[16] *Reliability* requires that the vicissitudes of time and mode of administration do not significantly affect PROM interpretation, and *responsiveness* entails that a PROM accurately detects changes in an outcome over time.

This rigorous selection and validation of PROM items is followed by cognitive debriefing interviews to assess participant comprehension of each question item, evaluate information recall strategies, and analyze participant decision-making processes.[17] Finally, once the PROM is field-tested in ethnically and socioeconomically-diverse populations, ambiguous measure items are removed to facilitate uniform interpretation across a variety of target patient stakeholders.

PROMs for Adults with Kidney Disease: An Overview and Remaining Gaps

To identify a comprehensive list of PROMs developed for use among adults with non-dialysis-dependent, dialysis-dependent, or post-transplantation kidney disease, we conducted an online search between January 2019 and April 2019 using MEDLINE, PubMed, and Ovid. Key words included ‘patient-reported outcomes,’ ‘patient-reported outcome measures,’ ‘dialysis,’ ‘end-stage kidney disease,’ ‘chronic kidney disease,’ ‘kidney transplantation,’ and ‘health-related quality of life.’ Studies among patients who were 18 years of age or younger were excluded, and results consisted of PROMs developed between 1985 and 2019. Table 1 is a comprehensive list of these PROMs, along with their validity, reliability, responsiveness, and key limitations.[18–55] Most PROMs developed among adults with kidney disease focus on physical and emotional symptom burden, social relationships, and overall health-related quality of life. Many show acceptable validity, reliability, and in some cases, responsiveness, but notable gaps remain. The vast majority focus on the in-center hemodialysis experience, limiting their validity among those patients who opt for peritoneal dialysis or home hemodialysis. Only four measures address sexual dysfunction, three assess for changes in physical appearance, one includes worries related to travel and finances, and only one elicits spiritual concerns. Additionally, chronic kidney disease (CKD) is a heterogeneous illness, and with the exception of a PROM specific to autosomal dominant polycystic kidney disease (ADPKD), disease-specific PROMs are largely lacking.

Concerns also exist regarding the feasibility of administering existing PROMs and interpreting their results. Several PROMs in Table 1 require patients to recall symptoms over the past month, which may subject their responses to recall bias, and many require a minimum of twenty to thirty minutes to administer and complete. Certain PROMs suffer from ceiling effects, which occur when a large proportion of respondents score the maximum value on an item measure. These effects may unintentionally reduce a PROM’s ability to adequately measure variation across a target population. Ordering effects, in which prior survey questions influence a participant’s subsequent responses, are also a concern.[56–57] Finally, few existing PROMs utilized cognitive debriefing techniques in their development or involved underrepresented groups, the latter of which is a concern given that ethnicity and socioeconomic status affect self-reported ratings of health in ESKD[58] In order for future PROMs for adults with kidney disease to be developed rigorously, maintain

feasibility, and retain the ability to be individualized, care must be taken to thoughtfully address these gaps and limitations.

PROMs in Nephrology Clinical Research: Adding Insight to Trial Results

PROMs are being recognized as key endpoints to be included in clinical trials. The Food and Drug Administration (FDA) and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) PRO extension have emphasized the need to include PROMs as trial endpoints, and the 2013 Consolidated Standards of Reporting Trials-Patient-Reported Outcome (CONSORT-PRO) extension includes guidance for PROM inclusion into clinical trials.[59–61] Additionally, a recent Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference recommended that PROMs be incorporated into clinical trials and kidney disease care registries.[62]

Other subspecialties such as cardiology and oncology have recognized and successfully incorporated PROMs into randomized-controlled trials (RCTs), and there exists immense opportunity for this to occur in nephrology.[63–64] Depressive symptoms and health-related quality of life (HRQoL) in hemodialysis are both PROMs that have been shown in observational studies to be associated with clinically-meaningful outcomes such as hospitalizations and mortality, but we need PROMs to more frequently be included as primary endpoints in RCTs.[65–73] Currently, there are 72 actively recruiting, ongoing, and recently-completed RCTs involving PROMs in nephrology. Of these, only 19 include PROMs as primary endpoints, and only ten originate in the United States (US).[74] This may be inappropriate considering their primacy in the minds of the patients with kidney disease who are trial participants.

Not all trials would benefit from having PROMs as primary endpoints, but incorporating PROMs would add great value to trials of treatments that may have direct effects on a patient's symptoms, emotions, or pill burden. In a systematic review of 168 RCTs aimed to measure outcomes related to vascular access in hemodialysis, only 19 trials assessed pain during cannulation, five reported HRQoL, and only one addressed needle phobia.[75] This is concerning, given the results of the SONG-Hemodialysis (HD) workshop, which revealed that these are PROs prioritized by patients.[76]

A number of existing, high-profile studies have benefited from the inclusion of PROMs. The Chronic Kidney Disease Antidepressant Sertraline Trial (CAST) evaluated the utility of sertraline for major depressive disorder among patients with non-dialysis-dependent CKD.[77] While the trial's primary outcome was a patient's score on the Quick Inventory of Depression Symptomatology (QIDS), a PROM not specifically developed in patients with kidney disease, researchers also captured scores on a version of the Kidney Disease Quality of Life-Short Form (KDQOL-SF) instrument. That neither of measure was significantly improved with sertraline administration suggested to the authors that, according to this study, the drug had minimal effects on a CKD patient's experience of depression. Furthermore, the trial's use of measures with continuous outcomes allowed for an efficient design that necessitated the enrollment of only 201 patients, rather than the thousands that would be necessary to evaluate dichotomous outcomes such as a suicide attempt.

PROMs can also give insight into treatment effects lost in the primary analysis of a trial. The Trial to Reduce cardiovascular Events with Aranesp Therapy (TREAT) study randomized 4,038 patients with diabetes, moderate anemia, and non-dialysis-dependent CKD to darbepoeitin alfa versus placebo.[78] No difference was observed in the rate of the primary composite outcome of cardiovascular morbidity or mortality, but secondary analyses demonstrated significant improvements on patient-reported fatigue scores as measured by the Functional Assessment of Cancer Therapy-Fatigue (FACT-Fatigue) instrument.[79] Including PROMs in such analyses offer a more comprehensive view of a medication's effects, allowing clinicians and patients to have a truly informed discussion about potential risks and benefits of therapies.

PROMs in Nephrology Healthcare Policy: Shifting the Quality Paradigm

Fortunately, there has been a call in the nephrology community to shift the quality paradigm of kidney patient care to focus more on PROs, and several notable initiatives exist that aim to achieve this.[80] In 2005, Kidney Care Partners, a group of dialysis healthcare professionals, patient advocates, and care providers convened the Kidney Care Quality Alliance (KCQA) to develop performance measures for the care of patients with ESKD. In 2016, the KCQA launched its Patient-Reported Outcomes Initiative to establish a framework and provide recommendations for future PROM research and development. KCQA stakeholders viewed PROMs as ways to provide unique information unable to be obtained by traditional clinical reporting measures. The group recommended that medication management, fluid control, and specific aspects of HRQOL such as post-dialysis recovery time and intradialytic symptoms be the focus of future PROMs in ESKD. The KCQA also recommended that PROMs be stratified by incident vs. prevalent hemodialysis patients and that maintaining patient privacy during PROM collection be a priority.[81]

The US Centers for Medicare and Medicaid Services (CMS) has also created initiatives to incorporate PROMs into dialysis quality metrics. HRQOL is required to be routinely assessed among patients of in-center hemodialysis facilities as part of the Conditions of Coverage.[82] In addition, the 2015 ESKD Prospective Payment System (PPS) final rule identified several examples of PROMs to help assess patients for major depressive disorder, and screenings for pain and depression were incorporated into the 2018 ESRD Quality Incentive Program (QIP).[83]

In 2013, CMS convened a Technical Expert Panel (TEP), which recommended that ESKD quality metrics include dialysis-specific HRQOL and functional status to better ascertain the tolerability of treatments.[84] A more recent TEP consisting of patients, physicians, psychometricians, and industry representatives, met to review existing HRQOL, dialysis recovery time, and Patient-Reported Outcomes Measurement Information System (PROMIS) measures; address the need for additional psychometric testing within the ESKD population; and develop recommendations on PRO-based performance measures.[85] As PROMIS instruments are administered using computer adaptive testing (CAT), freely available to the public, and use item response theory to generate individualized, brief measures that span multiple domains related to HRQOL, they were viewed as feasible and sustainable PROMs by several TEP members.[86] The TEP also identified two new topic areas

of interest of highest priority in PROM development: assessment of patient life goals and assessment of patient safety. Panel members agreed that assessing perceptions of safety and life goals were critical gaps in current assessments of a dialysis patient's illness experience and that incorporating these measures would not significantly add to survey fatigue. PROMs that incorporate life goals were also viewed as a potential way to encourage conversations related to shared decision-making in the setting of possible dialysis withdrawal, an aspect of care highlighted by both the Renal Physicians' Association (RPA) and the KDIGO Controversies Conference on supportive care.[87–88]

While these are important steps in aiming to achieving patient-centered kidney disease care, other measures need to be incorporated that allow clinicians to align with their patients' preferences, needs, and values.[89] Additionally, most existing kidney disease-specific PROMs focus on the in-center hemodialysis experience, and current policy initiatives do the same. Vast opportunity exists for PROMs to be incorporated into quality metrics for CKD and post-transplantation care.

PROMs in Nephrology Clinical Care: Acknowledging Challenges and Addressing Unmet Needs

The need to develop PROMs specific to kidney disease subtypes is being prioritized both in the US and abroad. During a symposium between the National Kidney Foundation and the FDA consisting of nephrologists, patients, and representatives from the pharmaceutical industry and the National Institutes of Health, ADPKD and nephrotic syndrome were determined to be conditions amenable to future measure development.[90] The Outcome Measures in Rheumatology (OMERACT) Vasculitis Working Group is exploring the utility of PROMIS measures and PROMs specific to anti-neutrophil cytoplasmic antibody (ANCA)-associated vasculitis.[91] Additionally, the SONG initiative is currently in the process of developing disease-specific measures related to glomerulonephritis and ADPKD.[92]

The added value of rigorously-developed and individualized PROMs is clear, but it is important to note the barriers that exist in their assessment and uptake in a health system. No standards exist to guide providers on how often to elicit PROMs from their patients or how to best incorporate them into a patient's medical record and care plan. It has also been demonstrated that certain PROMs vary over time and thus need to be assessed at routine intervals.[93] Patient burden, which includes factors such as measure length, time to completion, and comprehension should be taken into account, though some evidence suggests that daily PROM collection is feasible.[94] It also remains unknown how to aggregate data obtained from PROMs to be used as performance measures in healthcare systems, and PROMs are not yet routinely incorporated into risk stratification models for kidney disease.[95] PROMs must also be made suitable for long-term data collection and administered in interactive ways that accurately capture individualized patient information and decrease repetitive testing.[96] In addition to encouraging the use of adaptive questionnaires, researchers have also pointed to ecological momentary assessments, or capturing PROMs as patients experience them in real time as a viable path forward to overcome some of these

barriers.[97–98] Ultimately, if the ascertainment of PROMs occurs in conjunction with objective markers of kidney disease severity or progression, a more comprehensive picture of a patient's clinical status can be obtained, and effective communication between patients and providers regarding key issues can be facilitated.

Guidelines exist which provide a general framework for the successful implementation of PROMs in healthcare.[99–100] The Patient-Centered Outcomes Research Institute (PCORI) released a set of standards to inform future PROM development: establish psychometric validity, minimize participant burden, affect meaningful change, disseminate results to patients and clinicians, incorporate health information technology, and include patients with poorer health literacy.[101] Informed by these guidelines, we conclude with a list of key considerations to inform best practices for seamless PROM implementation and uptake into patient-centered kidney care (Box 1).

Conclusion

A European Renal Association (ERA) and European Dialysis and Transplant Association (EDTA) Quality European Studies (QUEST)-funded consensus meeting emphasized the need to capitalize on the increasing recognition of PROMs, utilize the power of patient organizations to lobby legislators, develop a PROM registry, involve expert psychometricians at all stages of development and design, and continue to generate widespread public and stakeholder interest.[102] Patient stakeholders in a recent SONG implementation workshop stressed the need for researchers to convey to their nephrology colleagues the importance of PROMs, clarify PROM intent and meaning, foster trust in the rigor of PROM development, and ultimately, articulate a compelling case for a culture change.[103]

PROMs are unique in that they allow us to ascertain whether our actions and treatment decisions improve outcomes that matter most to patients. Challenges to developing and operationalizing PROMs into kidney patient care persist, but immense opportunities remain. The thoughtful incorporation of these instruments has the potential to provide deep insights into a patient's illness experience, advance knowledge gained from clinical trials, transform policy initiatives, and ultimately, individualize high quality care for patients suffering from kidney disease.

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Box 1.

Key considerations for successful implementation and uptake of PROMs into patient-centered kidney disease care

- Sample characteristics of patients likely to receive greatest benefit from PROMs
  - Unknown to the nephrologist, clinic, or dialysis facility
  - Uncertain disease prognosis
  - Newly-diagnosed with kidney disease
  - Recent dialysis start
  - Recent kidney transplant
  - Advancing CKD and approaching dialysis
  - Failing kidney transplant
  - Multiple comorbidities
  - History of behavioral issues
  - Increasingly caregiver-dependent
  - Extremes of age
- Method and mode of collection
  - Self-administered online surveys via tablet computer or smartphone
  - Nurse administered online surveys via tablet computer
- Setting and time of collection
  - Clinic intake room prior to appointment (CKD/transplant)
  - Dialysis facility during dialysis treatment
  - Home during home dialysis session
  - At home in between clinic appointments or dialysis sessions (via ecological momentary assessment)
- Storage
  - Integration into electronic medical record with password-protected access
- Interpretation
  - Incorporation into risk prediction models
  - Comparison with national benchmarks (ie: via USRDS data)
- Dissemination

- Regular sharing of results with patients, caregivers, and clinicians

- Action
  - Targeted, individualized treatments based on results (referral to psychologist, change in dialysis prescription, etc.)

Abbreviation(s): Patient-reported outcome measures (PROMs), chronic kidney disease (CKD), United States Renal Data System (USRDS)

Table 1.

Summary, key characteristics, and limitations of current patient-reported outcome measures developed for adults with kidney disease and kidney transplantation

Measure	Domains and Subscales* | Original population for usage	Content validity	Reliability and Responsiveness	Limitations
100 Category Checklist[18]	body functions, body structures, activities and participation, environmental factors | ESKD	qualitative interviews of 32 HD pts w/ vintage > 5 y; content experts		
Agarwal CKD symptom assessment[19]	past month: neuropsychiatric, cardiovascular, uremia, anemia | CKD	qualitative interviews conducted by primary author w/CKD pts known to primary author; extensive literature review	reliable after 2 mo	data from qualitative interviews not reviewed by content experts; sample mostly white men > 65 y w/ DM
Autosomal Dominant Polycystic Kidney Disease Impact Scale (ADPKD-IS)[20]	physical burden, fatigue, emotional burden | ADPKD	literature review; focus groups of 285 ADPKD pts from 16 countries; cognitive debriefing interviews of 15 pts; expert interviews of 26 health care providers; clinical evaluation in 6-mo intervals for up to 3 y	reliable after 1 mo	ceiling effects for physical burden, fatigue, emotional burden subscales; floor effects for physical burden, fatigue, emotional burden subscales; significant differences on subscale scores for pts w/ CKD1 vs CKD3b; need further exploration of ADPKD-related pain
Basel Assessment of Adherence to Immunosuppressive Medication Scales (BAASIS)[21]	past month: taking medications, timing of medications, omitting medications, dose reduction of medications | kidney Tx pts on IS			
Chinese Dialysis Quality of Life Scale (CDQOL)[22]	overall QoL | ESKD	literature review; qualitative interviews of 7 ESKD pts; 2 rounds of content analysis	reliable after 2 wk	data from 3 dialysis centers in Hong Kong area (limits external validity)
Chronic Kidney Disease-Symptom Burden Index (CKD-SBI)[23]	past month: prevalence of symptoms, symptom distress, symptom severity, frequency of symptoms | CKD, ESKD	literature review; expert panel; pilot-testing w/ bilingual non-CKD sample of 25 participants	reliable after 1 wk	reliability only measured in mostly healthy university students; test-retest reliability measured only 1 wk apart; participants may have memorized responses
CHOICE Health Experience Questionnaire (CHEQ)[24]	past month: health perceptions, physical, social, physical role, emotional role, pain, mental health, energy, cognitive functioning, sexual functioning, sleep, work, recreation, travel, finances, general quality of life, diet, freedom, body image, dialysis access, symptoms | ESKD	structured literature review of 53 different instruments; 5 focus groups w/ HD pts, PD pts, nephrologists; survey of 110 dialysis providers re features of different modalities; semistructured survey of 25 ESKD pts		several subscales had moderate floor and ceiling effects
Chronic Kidney Disease Quality of Life (CKD QOL)[25]	past month: role functioning, energy/fatigue, social functioning, psychological distress/well-being, life interference, limitations in ability to concentrate | CKD, ESKD (inc post-Tx)	review of items from CHEQ; interviews w/ 40 pts w/ CKD3–5 or ESKD; recommendations from a clinical advisory board; cognitive testing of patients w/ CKD		mostly white patients
Curtin et al[26]	past month: fatigue/sleep, sexual concerns, mobility | ESKD	literature review; over 100 interviews of ESKD pts		symptoms reported may not apply to majority of ESKD pts (sample

Measure	Domains and Subscales* | Original population for usage	Content validity	Reliability and Responsiveness	Limitations
				had fewer w/ DM and more w/ unknown cause of kidney disease)
Dialysis Symptom Index (DSI)[27]	past week: physical symptom burden, symptom severity | ESKD	literature review of previous health-related QoL surveys, inc CHEQ and KDQOL-SF; qualitative interviews of focus groups (2 w/ dialysis pts, 1 w/ nephrologists); expert review	reliable after 4–7 d	scale administered during HD, which may have reflected answers related to dizziness (hypotension-induced); focus groups were small
End-Stage Renal Disease Severity Index (ESRD-SI)[28]	Cardiovascular, cerebrovascular, bone disease, peripheral vascular disease, peripheral neuropathy, respiratory disease, deficient vision, autonomic neuropathy, Gl disease, dialytic access and events, DM | ESKD	meetings among clinicians		
End Stage Renal Disease-Symptom Checklist Transplantation Module (ESRD-SCLTM)[29]	limited physical capacity, limited cognitive capacity, cardiac and renal dysfunction, side effects of corticosteroids, increased growth of gum and hair, Tx-associated psychological distress | kidney Tx pts on IS	based on 458 pt interviews; GN was most common cause for need for Tx	reliable after 1 y	scale only applied to pts with successful Tx; would need further studies of pts before and after Tx
Ferrans and Powers Quality of Life Index[30]	Healthcare, physical health and functioning, marriage, family, friends, stress, standard of living, occupation, education, leisure, future retirement, peace of mind, faith, life goals, personal appearance, self-acceptance, general happiness, general satisfaction, 3 additional dialysis-specific scales | ESKD		reliable after 2 wk	reliability may have been overestimated
Focal Segmental Glomerulosclerosis (FSGS) Symptom Diary[31] ; FSGS Symptom Impact Questionnaire[31]	past 24 h (Diary) or 7 d (Questionnaire): physical symptoms, social issues, emotional symptoms | primary FSGS pts with GFR > 40 w/ inadequately controlled disease after ≤ 2 treatments	concept elicitation interviews based on semi-structured interview guide developed specifically for this project; cognitive debriefing interviews conducted to assess content, clarity, comprehensiveness, relevance		sample mostly white women w/ college degree; most debriefing interviews were performed by Latino/Hispanic men w/ less college exposure; no pts w/ GFR < 40
Fluid Management Survey[32]	volume overload, symptom burden, fluid management strategy, preferences, dialysis treatment characteristics, physical function, demographics | ESKD	literature review; surveys at 18 geographically diverse dialysis facilities; content reviewed by dialysis professionals; field-tested for pt comprehension w/ 50 ESKD pts and repeated 2 wk later among 48 ESKD pts	reliable after 2 wk	some dialysis unit and demographic data were self-reported; incorrect reporting may have introduced misclassification bias
Hemodialysis Fatigue Scale[33]	reduction in vigor and motivation, reduction in physical ability, reduction in mental ability, reduction in daily activities, distress and loss of control in mood | ESKD			specific to pts in Taiwan (limits external validity)
Hemodialysis Quality of Life Questionnaire (HQL)[34]	symptoms related to ESKD, symptoms related to treatments, mood, sociovocational, family-sexual | ESKD	concept elicitation and prioritization from 75 ESKD pts and 13 health care professionals		small sample size
Hemodialysis Stressor Scale (HSS)[35]	total stress, physiologic stress, psychosocial stress | ESKD	literature review; review by 6 dialysis nurses; pilot tested with ESKD pts		

Measure	Domains and Subscales* | Original population for usage	Content validity	Reliability and Responsiveness	Limitations
Kidney Disease Behavior Inventory (KDBI)[36]	past month: behaviors associated with improved kidney health (diet control, medication adherence, etc) | CKD, ESKD		reliable after 3 and 6 mo	behaviors not objectively verified
Kidney Disease Questionnaire (KDQ)[37]	physical symptoms, fatigue, depression, relationships with others, frustration | ESKD	qualitative interviews of 50 ESKD pts	reliable after 2 mo	
Kidney Disease Quality of Life (KDQOL)[38]	symptoms/problems, effects of kidney disease, burden of kidney disease, work status, cognitive function, quality of social interaction, sexual function, sleep, social support, dialysis staff encouragement, patient satisfaction, physical functioning, role physical, pain, general health perceptions, emotional well-being, role emotional, social function, energy/fatigue | ESKD	focus groups of sample ESKD pts		floor effects for work status, role physical, role emotional; ceiling effects for sexual function, role emotion
Kidney Disease Quality of Life Short Form (KDQOL-SF) Version 1.3[39]		focus groups of sample ESKD pts		
Kidney Disease Quality of Life - 36 (KDQOL-36)[40]	SF-12 core, burden of kidney disease, symptoms and problems of kidney disease, effects of kidney disease | ESKD	focus groups of sample ESKD pts		ceiling effects for effects of kidney disease subscale; data collected as part of a clinical intervention, so sample may reflect selection bias
Kidney Disease Quality of Life Modified[41]	Pain, psychological dependency, cognitive functioning, social functioning, dialysis-related symptoms, cardiopulmonary symptoms, sleep, energy, cramps, diet, appetite | ESKD			ceiling effects for cognitive functioning, appetite subscale
Kidney Disease Quality of Life - 36 Summary Score (KSS)[42]	burdens of kidney disease, symptoms and problems of kidney disease, effects of kidney disease | ESKD	58,851 ESKD pts from Medical Education Institute KDQOL Complete program; 443,947 ESKD pts from USRDS		does not include measures of fatigue or mental health
Kidney Disease Questionnaire[43]	previous 2 wk: physical symptoms, fatigue, depression, relationships with others, frustration | ESKD	interviews of 55 ESKD pts and nephrology nurses; literature review of other QoL measures	reliable after 2 mo	
Kidney Transplant Questionnaire (KTQ)[44]	physical symptoms, fatigue, uncertainty/fear, appearance and emotions | kidney Tx	qualitative interviews of 50 pts	responsive after 6 mo	
Modified Transplant Symptom Occurrence and Symptom Distress Scale (MTSOSD)[45]	side effects and symptoms of immunosuppressants | kidney Tx pts on IS			
Palliative Care Outcome Scale-Symptoms (POS-S) (Renal)[46]	symptom burden and general QoL			
Parfrey Symptom Assessment[47]	physical symptoms, emotional symptoms, subjective QoL, objective QoL | ESKD (inc kidney Tx)	interviews of 107 ESKD pts and 119 Tx pts		specific psychometric properties not reported
Physical Symptom Distress Scale[48]	previous week: fluid and electrolyte imbalance, disturbance in neuromuscular function | ESKD	literature review; investigator's personal clinical experience	reliable after 2 wk	specific to patients in Taiwan (limits external validity)

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Measure	Domains and Subscales* | Original population for usage	Content validity	Reliability and Responsiveness	Limitations
Perceived Kidney Disease Self-Management Scale (PKDSMS)[36]	self-confidence in kidney disease self-management | CKD, ESKD		reliable after 3 and 6 mo	
Pittsburgh Symptom Score Index[49]	Fatigue, trouble sleeping, difficulty concentrating, restless legs, change in taste, loss of appetite, nausea or vomiting, pruritus, bone pain, muscle pain, weakness | ESKD			
Quality of Life Index (QLI) 3.0[50]	general QoL | ESKD	literature review		
Renal Dependent Quality of Life Questionnaire (RDQOL)[51]	illness impact and general QoL | HD/PD, kidney Tx	qualitative interviews of 40 HD, PD, and Tx pts		specific psychometric properties not reported
ReTransQol (RTQ)[52]	past month: physical health, mental health, medical care, fear of losing graft, treatment | kidney Tx	in-depth interviews cognitive debriefing in 10 pts	reliable after 6 mo	specific to pts in France (limits external validity)
Short-Version Checklist[53]	body functions, body structures, activities and participation, environmental factors | ESKD	based on 100 Category Checklist		specific to pts in Japan (limits external validity)
Transplant Effects Questionnaire (TxEQ)[54]	worry about Tx, guilt regarding donor, disclosure, adherence, responsibility | kidney Tx	literature review; focus groups; individual interviews	reliable after 1 mo	
World Health Organization Quality of Life Brief Scale in Dialysis (WHOQOL-BREF Dialysis)[55]	WHOQOL-BREF, physical, psychological, social, relationship, environment | ESKD	focus group of 10 ESKD pts and 3 nephrologists	reliable at 1–2 mo	specific to patients in Taiwan (limits external validity)

CKD, chronic kidney disease; DM, diabetes mellitus; eGFR, estimated glomerular filtration rate (in mL/min/1.73 m2); GN, glomerulonephritis; Gl, gastrointestinal; HD, hemodialysis; inc, including; IS, immunosuppression; PD, peritoneal dialysis; pt, patient; QoL, quality of life; Tx, transplant; USRDS, US Renal Data System

*including recall period if available