Kidney Medicine

Preliminary Testing of the Discussion of Patient Life Goals Patient-Reported Outcome Measure for Dialysis Facilities

Claudia Dahlerus, Noelle E. Carlozzi, Katrina Price, Jennifer A. Miner, Richard A. Hirth, Garrett Gremel, Peisong Han, Wei Zhang, Jennifer Sardone, Jesse Roach, Wilfred Agbenyikey, Stephanie L. Clark, Golden Horton, Alexander Yaldo, and Joseph M. Messana

Rationale & Objectives: To test a new patient-reported outcome measure that assesses end-stage kidney disease (ESKD) maintenance dialysis patients' experience with life goals discussions with their dialysis facility care team.

Study Design: Observational cross-sectional study. Survey data collected via REDCap, paper form or telephone in a convenience sample of patients with ESKD receiving maintenance dialysis in the United States.

Settings & Participants: People aged 18 years or older with ESKD receiving maintenance hemodialysis or peritoneal dialysis in US dialysis facilities between the June and December 2020 study period.

Exposures: Testing of 6 items providing the core quality assessment and 1 item measuring whether 1 or more members of the treatment team discussed life goals with the patient.

Outcomes: Preliminary reliability and validity of the Discussion of Patient Life Goals survey (D-PaLS).

Analytic Approach: Exploratory factor analysis (EFA), confirmatory factor analysis (CFA), and item response theory methods, including the graded response model (GRM) and differential item functioning (DIF).

Results: Of 517 participants, 479 completed the survey via REDCap; 38 completed the survey via paper or telephone. EFA and CFA supported the unidimensionality of the 6 core items. GRM overall and item fit analyses and DIF analyses supported retention of all core items. Preliminary reliability data indicated very good internal consistency (Cronbach's alpha = 0.84). Known-groups validity was supported whereby individuals receiving home dialysis had more positive responses, than those receiving in-center hemodialysis.

Limitations: Study participants were not fully representative of the US ESKD dialysis population.

Conclusions: Preliminary analyses indicate the D-PaLS has excellent psychometric properties. The measure provides 2 important quality metrics: facilities' level of engagement talking with patients about their life goals and the percentage of patients reporting who on the treatment team talks with them about their life goals. Additional work is needed to establish comprehensive reliability and validity to support the clinical utility of this measure in patient care.

Complete author and article information provided before references.

Correspondence to C. Dahlerus (dahlerus@med.umich.edu)

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Centers for Medicare and Medicaid (CMS) regulations and clinical guidelines place patient life goals as the cornerstone of patient-centered decision-making and care planning for kidney replacement therapy.[1,2] However, studies have reported that up to a third of patients with end-stage kidney disease (ESKD) felt their selected kidney replacement treatment modality was not really their choice, or they had not made an informed choice[3-6]; even higher rates of "modality choice dissatisfaction" have been reported among in-center hemodialysis patients.[7] Because most long-term dialysis patients in the United States receive hemodialysis for 3-4 hours, 3 times a week in a dialysis center, treatment can pose an obstacle to patients pursuing their life goals, defined as personal goals that an individual (patient) thinks are important to achieve. These may include leisure time, work (paid or volunteer), time spent with family, hobbies, travel, or other aspirational goals. Patient and care team discussion of life goals as part of treatment planning and decision-making may help align treatment with patient aspirational life goals.

Discussion of patient-reported life goals was identified by a 2017 expert panel of patients with ESKD, and providers as a priority area for new patient-reported outcome (PRO) measure development to better inform patient modality decisions and treatment planning.[8,9] Patient-reported outcomes are "any report of the status of a patient's (or person's) health condition, health behavior, or experience with health care that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else".[10,11] The 2017 panel and subsequent stakeholder feedback established the conceptual basis and initial item development of the ESKD Discussion of Patient Life Goals PRO (D-PaLS).[9] The D-PaLS can be used to assess whether the dialysis facility care team is asking about life goals and taking these into consideration during treatment planning. In this paper, we report the initial reliability and validity testing of the new D-PaLS (Item S1).

PLAIN LANGUAGE SUMMARY

The Discussion of Patient Life Goals survey (Item S1) was developed based on conversations we had with people with kidney failure and kidney doctors who felt it was important that discussing patient life goals should be part of kidney replacement treatment planning. To make sure this patient survey accurately assesses patient-reported experience with dialysis facility care, we carried out a series of statistical tests. Our testing results showed that the survey meets the standards for initial reliability and validity. The patient life goals survey is also very short, which will make it easier for patients to take. The survey fills a need for more patient-reported outcome measures for people being treated for kidney failure.

METHODS

Study Population

Convenience sampling was used to recruit study participants to complete the survey once. Participants were recruited nationally using multiple methods that included emails sent to individuals and stakeholder organizations in the kidney community representing patients (National Kidney Foundation and American Association of Kidney Patients), nephrologists, and dialysis organizations (both for profit and not-for-profit). National patient organizations (eg, National Kidney Foundation, and American Association of Kidney Patients) supported recruitment and used social media and targeted recruitment messages. Several dialysis organizations (not-for-profit) shared recruitment information with their facilities and staff.

Participants were eligible if they were at least 18 years old, currently receiving long-term dialysis in the United States, and were able to read and understand English. Respondents were excluded if they did not answer at least one life goals question. All data were collected in accordance with the local institutional review board, and participants provided consent before the completion of the study-specific measures. Permission to link patient study and demographic/clinical data was provided by CMS under a Data Use Agreement for the CMS-funded contract supporting this study.

The D-PaLS Measure

Established measurement development standards (PROMIS Instrument Development and Psychometric Evaluation Scientific Standards),[12] which included qualitative and quantitative methods, were used to develop the Patient Life Goals measure. A panel of patients with ESKD and clinical dialysis providers was assembled for a Technical Expert Panel (TEP) on ESKD PROs in May 2017 (n=19). The TEP discussed patient-defined life goals as an area for new quality measure development. Discussion focused on the way achievement of life goals can be influenced not only by kidney disease but also by dialysis treatment. Item content was developed based on the TEP discussions and literature review of "life goals." Following concept elicitation, candidate items were generated and refined using an iterative process that included: expert review, focus groups with patients and providers, evaluation of item literacy level, cognitive debriefing with both patients and providers, and a translatability review to facilitate future translation of the measure into languages other than English. A summary describing the concept elicitation is reported elsewhere.[9]

The final pool included 8 items designed to identify patient life goals and evaluate facility engagement in discussions about these goals. This included (a) 2 'checklist' items (one reflecting the specific life goals selected by the patient, and one identifying the individual members of the treatment team the patient indicated has talked with them about his/her life goals), and (b) 6 core Likert response-type face-valid items that reflect the patient's experience with the treatment team regarding communication and discussion about patient life goals (see Item S1, supplemental appendix for survey items and response options). Three of the Likert response-type items have response options from "strongly disagree" to "strongly agree" and the response options for the other 3 items are from "never" to "always". These 6 Likert items were used to generate a D-PaLS quality score. The data and methodology for measure testing are provided below.

Clinical and Demographic Data

CMS clinical and administrative data from our ESKD database were used to obtain treatment history, including modality and duration of treatment event, and demographics for all US ESKD patients. Data elements included in the ESKD database were obtained from multiple sources including CMS, the Organ Procurement and Transplant Network, the Center for Disease Control, the End Stage Renal Disease (ESRD) Networks, and the US Census.

We also collected the following self-report data from survey participants: first name, last name, biological sex, birthdate, last 4 digits of their social security number (SSN), race, ethnicity, and level of education completed. The first 4 of these data elements were required; the last 4 elements participants could elect not to report. Using self-report first name, last name, last 4 digits of SSN, and birthdate, participants were then matched to our ESKD database. In some cases, we could not match participants to their data in the ESKD database if self-reported first and last name, birthdate, sex, or last 4 SSN digits were missing or incomplete. To identify ESKD treatment modality, we used selected demographic data (self-report first and last name, sex, last 4 digits of SSN, and birthdate). For descriptive statistics and statistical analysis, the ESKD database was the primary source for birthdate; self-reported birthdate was

used when that information was not available in the ESKD database. In cases with missing self-reported sex, race, and ethnicity data, we obtained those data from the ESKD database. Demographic data were not available for nonresponders.

Survey Fielding

Participants completed the survey once between June 2020 and December 2020. Participants had 3 options for taking the survey: via REDCap through a study-specific URL; by telephone with study staff; or by paper form, which was returned to the study staff using a pre-paid mailer. Paper forms were made available later in the study period, beginning in September, to minimize direct contact, because of coronavirus disease (COVID)-19 precautions. Surveys administered via telephone or paper were then entered into REDCap by a member of the study team. Allowing telephone or paper completion was intended to include patients who are not comfortable with online surveys or do not have internet access.

Analytic Methods

Classical test theory and item response theory (IRT) were used according to established guidelines to develop our new measure.[12] These analytic methods were applied to the 6 core Likert scale items only (items 2a-2c and 3a-3c). This process involved the identification of a unidimensional set of core items among the 6 Likert scale items (using exploratory and confirmatory factor analyses). This was followed by IRT-based analyses employing Samejima's graded response model (GRM)[13] to assess overall item fit, evaluate differential item functioning (DIF; an index of item bias), and to estimate the measure's item parameters (ie, slopes and thresholds) used to generate measure T scores.

Establishing Measure Unidimensionality

Unidimensionality in a measure means that all the items are measuring aspects of one latent concept or domain. Exploratory and confirmatory factor analysis methods are used to determine if multiple items collectively measure one concept. In the case of the D-PaLS, the underlying concept is discussion of life goals by the facility. MPlus (version 8.4)[14] was used to conduct the exploratory factor analyses (EFA) and confirmatory factor analyses (CFA) iteratively examining the dimensionality of the core items of D-PaLS, 2a-2c, and 3a-3c.[15-17] With regard to EFA, essential unidimensionality was supported if the ratio of eigenvalue 1 to eigenvalue 2 was ≥4 and if eigenvalue 1 accounted for ≥40% of core item variance. These cutoffs are consistent with established measurement development standards for other PRO measures.[12]

Items were candidates for exclusion if they had sparse cells (ie, response categories with $n < 10$ respondents), their item-adjusted-to-total score correlations were low (ie, $r < 0.40$), or were nonmonotonic.[18] With regard to CFA, items were candidates for exclusion if they had a low factor loading ($\lambda < 0.50$) or demonstrated local dependence (ie, had a residual correlation > 0.20 or a correlated error modification index ≥ 100).[15-17]

IRT Modeling, Final Item Performance Assessments, Differential Item Function, Final CFA Modeling, and Scoring

IRTPRO (version 4.2.2, 2015) was used for the GRM-based analyses.[13,19] Core items with significant misfit (ie, S-X2/degrees of freedom [df] > 3.0) were candidates for exclusion. The R package LORDIF Version 0.3-3[20,21] was used to examine if there was presence of DIF (bias) in any of the 6-core Likert scale items 2a-2c and 3a-3c that ask whether anyone on the care team has asked, knows about or talks about life goals. The DIF factors of age, education, sex, and race were investigated. Core items with impactful DIF (Nagelkerke pseudo-R^2 change ≥ 0.20, plus >2% of DIF-corrected vs. uncorrected score differences exceeding uncorrected score standard errors) were candidates for exclusion. CFA was then used to confirm unidimensionality with the final item set and assess its overall model fit using the following fit thresholds: comparative fit index ≥ 0.95, Tucker-Lewis index ≥ 0.95, and root mean square error of approximation < 0.15.[22-25] IRT-based theta scores were estimated using the GRM; scores were then placed on a T score metric (mean = 50, standard deviation [SD] = 10), with higher scores indicating more patient life goals communication and discussion (ie, a better quality metric status).

Preliminary Reliability and Validity Analyses

The normality of the data was examined to determine when parametric or nonparametric statistics were more appropriate for the remaining analyses. Reliability testing was performed to establish the internal consistency of the multi-item measure that comprises the Likert scale items. Internal consistency was examined using Cronbach's alpha. Floor and ceiling effects were investigated (ie, the percentage of participants with the lowest and highest possible scores on the measure, respectively); floor and ceiling effects should be ≤ 20%.[26,27] Survey administration times were reported as an assessment of measure use feasibility. Categories for the item asking which member of their care team talks with them about life goals were combined into 3 categories for scoring purposes: the percentage indicating 1 member talks with them, more than 1 member talks with them, and the percentage reporting no one talks with them about life goals. For this analysis, we report the percentage of participants reporting no one on their care team talks with them about life goals. Higher values for this item would suggest a possible performance gap.

Evidence of known-groups validity was obtained using independent sample t tests to compare mean scores based on treatment modality type; specifically, we compared

in-center hemodialysis patients to those on a home dialysis modality (peritoneal dialysis or home hemodialysis). We expected patients on a home dialysis modality to have more positive D-PaLS responses, measured by higher *T* scores, than in-center hemodialysis patients. Home dialysis patients tend to be a little younger, have fewer comorbid conditions, may have more social and financial resources to support treatment at home, and may have a tendency to be more proactive and involved in their care.[3,28,29] We also examined the percentage of participants whose scores were > 1 SD worse than the sample mean of 50 to determine if individuals that were receiving home dialysis reported greater D-PaLS scores than those that were using in-center dialysis. Rates that exceeded 16% for those receiving in-center dialysis would support this hypothesis.[30]

Sample Size Considerations

Sample size requirements were based on IRT-based analyses (ie, GRM modeling and DIF analyses). Sample size requirements for use of the GRM have been estimated to be between 200 and 1000, with larger sample sizes producing more stable parameter estimates.[31-33] For DIF analyses, a sample size ≥ 500 is recommended, given that there are at least 200 participants within each variable subcategory of interest.[34] For the present analyses we tested age (≥62 years, n=258 vs <62 years, n=259), education (<college, n=298 vs ≥college, n=219), sex (female, n=245 vs male, n=272), and, for exploratory purposes, race (White, n=364 vs other, n=153).

RESULTS

Study Participants

Detailed descriptive data are reported in Table 1. Of the 517 participants, 479 participants completed the survey online; 38 participants completed the survey via paper form or telephone. Overall, the mean age of participants was 62 years (SD = 13). The majority of participants were non-Hispanic (n=426; 82%) and White (n=364; 70% vs 18% for Black participants). There were slightly more male participants (53%; n=272) than female. Participants with a college degree or higher made up 43% of the sample. Seventy-three percent of participants were receiving in-center hemodialysis, and 12% and 15% were receiving home hemodialysis and peritoneal dialysis, respectively.

Table 1. Descriptive Data for D-PaLS Study Participants

Variable	Overall (N=517)	Online (N=479)	Paper or Phone (N=38)
Age (y)[a]			
Mean (SD)	62 (13)	62 (12)	64 (14)
Sex (%)			
Female	245 (47)	232 (48)	13 (34)
Male	272 (53)	247 (52)	25 (66)
Ethnicity (%)			
Not Hispanic or Latino	426 (82)	400 (84)	26 (68)
Hispanic or Latino	48 (9)	38 (8)	10 (26)
Do not wish to report	43 (8)	41 (9)	2 (5)
Race (%)			
White	364 (70)	344 (72)	20 (53)
Black/African American	94 (18)	88 (18)	6 (16)
Other	35 (7)	28 (6)	7 (18)
Do not wish to report	24 (5)	19 (4)	5 (13)
Education (%)			
Some high school	12 (2)	8 (2)	4 (11)
High school graduate or equivalent	90 (17)	84 (18)	6 (16)
Some college	192 (37)	180 (38)	12 (32)
College degree	127 (25)	118 (25)	9 (24)
Master degree or more	92 (18)	85 (18)	7 (18)
Do not wish to report	4 (0.77)	4 (1)	0 (0)
Dialysis modality[b] (%)			
In-center hemodialysis	337 (73)	310 (72)	27 (87)
Home hemodialysis	56 (12)	56 (13)	0 (0)
Peritoneal dialysis	70 (15)	66 (15)	4 (13)

Note. Entries in the Table represent N (%) of participants unless otherwise specified. Some percentages may not total to 100% because of rounding.
[a]n=516 overall, n=478 online only.
[b]Number of participants for which matching allowed for the identification of dialysis modality: n=463.

Unidimensional Analyses

Table 2 provides a summary of the iterative analytic process described above in Methods and detailed here below.

EFA/CFA and Initial Item Performance Assessments

Testing was conducted for the 6 core items of the D-PaLS item pool. Initial EFA evidence supported the essential unidimensionality of these items (Table 2). Items did not demonstrate problems with monotonicity; there were no items with sparse response category cells. We did not identify any items with low factor loadings; there was no evidence of item local dependence.

IRT Modeling, Final Item Performance Assessments, DIF Studies, and Final CFA Modeling and Scoring

GRM analyses did not flag any core items for misfit, and there was no evidence of DIF for the factors age, education, sex, or (for exploratory purposes) race. The final CFA model indicated good overall model fit (Table 2). The final measure item parameters are shown in Table 3 and Table S1 (Supplemental Appendix). Summed score-to-*T* score conversions are included in Table S2.

Instrument Reliability and Validity

Internal consistency reliability was excellent (Table 4). The D-PaLS was devoid of floor and ceiling effects, and administration time was less than 2 minutes and 30 seconds (Table 4). Additionally, the percentage of patients responding no one on their care team talks with them about life goals was 24%. The distribution of all responses for this item are in Table S3 (Supplemental Appendix).

Table 2. Unidimensional Modeling and Analyses for D-PaLS Core Items

Item Pool	Core Item pool	Unidimensional Modeling					Initial Item Performance		IRT Modeling		
		EFA E1/E2 ratio (criterion >4)	Percent of variance for E1 (criterion >40)	1-factor CFA loading (criterion <.50)	1-factor CFA residual correlation (criterion >.20)	1-factor CFA modification index (criterion >100)	Item-adjusted total score correlations (Criterion <.40)	Sparse cells (criterion<10)	Problems with monotonicity	IRT item misfit	DIF	Interim/ Final item bank
D-PaLS	6 items	4.7	63	0 items	0 items	0 items	1 item	0 items	0 items	0 items	0 items	6 items

Abbreviations: CFA, confirmatory factor analysis; EFA, exploratory factor analysis; IRT, item response theory.

Known-groups validity was supported (Table 4), as those receiving in-center dialysis had worse D-PaLS scores than those on a home dialysis modality, as we had theorized. Additionally, participants who received in-center hemodialysis were at greater risk of having lower (-1 SD) D-PaLS scores relative to participants on a home dialysis modality.

DISCUSSION

Results from this study show that the D-PaLS PRO has strong psychometric properties, based on measurement procedures followed as well as evidence from our preliminary reliability and validation testing. All items were retained, resulting in a brief measure designed to minimize patient burden. The D-PaLS includes 2 quality scores that reflect facility performance in discussing life goals.

The first facility-specific score, made-up of the 6 Likert scale items, reflects general patient-reported satisfaction about how well a facility is doing in discussing life goals as part of the treatment planning process. For each patient at a given facility, a *T* score (M = 50; SD = 10) can be calculated that represents patient perceptions about how well the facility is doing in discussing life goals as part of the treatment planning process. In the future, a facility performance metric would be the average *T* score for patients treated at the facility (ie, sum of the *T* score for all patients at a specific site divided by the total number of patients). Facility *T* scores between 41 and 59 would be interpreted as facilities having average performance. Scores that are ≤40 suggest facility performance is worse than 84% of their peers, whereas scores ≤30 suggest facility performance is worse than 98% of their peers.

The second facility-specific score is the percentage of patients at a facility that report at least one member of the treatment team versus no one has discussed life goals with them. In our field testing we found that 24% of participants reported no one on their care team talked with them about life goals. This performance gap would suggest that, in general, quality improvements in communications with patients about their life goals are warranted.

The first item, the list of life goals is not part of a quality score. It is intended to be a starting point for the patient when considering their experience with the care team and the extent to which their life goals were asked about and taken into account as part of treatment planning or changes.

Results of the psychometric testing supported the reliability and validity of the D-PaLS. Specifically, known-groups validity was supported when we observed expected differences, namely, that home dialysis patients had more positive responses compared with those receiving in-center hemodialysis. We expected this because people receiving home dialysis tend to be more engaged in their care, treatment decisions, and making their life goals known to their care team. This translates into their care team more likely to know

Table 3. Final Item Parameters for D-PaLS Item Bank

Domain	Item Bank	CFI (criterion > 0.90)	TLI (criterion > 0.90)	CFA-based RMSEA (criterion < 0.15)	Alpha Reliability (criterion > 0.80)	IRT-based RMSEA (criterion <.15)	Response Pattern/ Person Reliability (criterion >.80)
D-PaLS PRO	6 items	0.98	0.97	0.14	0.84	0.07	0.91

Abbreviations: CFI, comparative fit index; TLI, Tucker-Lewis index; RMSEA, root mean square error of approximation.

about and discuss life goals with those patients, and those patients feeling like their goals are part of the care plan, when compared with people receiving in-center HD. Similar differences have been reported in other studies comparing decisional satisfaction and other markers of well-being for peritoneal dialysis patients.[3,28,29] Finally, the results of our DIF analysis did not suggest evidence for item score differences based on age, sex, education, or race.

There are no existing life goals measures tested and validated in the ESKD dialysis population. However, there are several perspective articles describing the importance of including life goals in decisions about ESKD kidney replacement therapy, such as selection of a dialysis modality, consideration of transplant, as well as selection of vascular access type for delivery of hemodialysis treatment.[2] Although earlier studies and clinical guideline bodies on clinical care for people with kidney disease highlight the importance of life goals discussions to inform modality and other treatment decisions,[3,5] these conversations are not always happening.[8,9] Even when they do, little is known about whether these discussions are associated with better outcomes for the involved patients. For example, the low uptake of home dialysis and access to transplant in the United States suggests the current approach to inform patient treatment decisions may be inadequate. This has resulted in a need for a paradigm shift in the delivery of predialysis and dialysis care as outlined by one international clinical guideline body.[2] Finally, the D-PaLS is intended to facilitate treatment planning including modality decisions, but it is important to emphasize that this survey is agnostic to dialysis modality and other elements of kidney replacement therapies. The purpose of the D-PaLS is to encourage treatment approaches tailored to the individual person and their goals.

Study Limitations

Our study was based on a nonrandom convenience sample of participants currently on long-term dialysis that responded to national level recruitment information disseminated via email and social media. Despite the availability of phone and paper surveys, a large majority of participants completed the survey via REDCap. Overall, respondents were younger, more educated, predominantly White, and technologically literate. Therefore, the sample is not fully representative of the US dialysis population. We recognize that may underrepresent subgroups of people for whom life goals are not asked about or discussed as part of treatment planning. We also do not have characteristics of nonrespondents because enrollment was initiated by participants, and we did not have access to a predefined sample of potential participants. Surveys were completed by patients between summer and fall 2020, during the first year of COVID-19 which may have had an impact on the types of life goals and discussions during that time. Furthermore, the psychometric data provided herein warrants additional replication in future independent samples.

CONCLUSIONS

This study reported on the development and testing of an item pool for a new measure on patient life goals. Our results show the items, as a set, have very good psychometric properties, making the instrument reliable and valid in assessing patient life goals in the study sample.

Table 4. Descriptive Data and Known-Groups Validity for the new D-PaLS Measure Score

Descriptive data[a]	N	Internal consistency reliability	M (SD)	% at Floor	% at Ceiling	Administration Time in seconds M (SD)[b]	N (%) "No one on my care team talks with me about my life goals"[c]
D-PaLS	510	0.84	20 (6)	0.39	6	150.3 (68.5)	121 (24)

	Peritoneal dialysis and home hemodialysis (n=125)		In-center hemodialysis (n=333)			
Known-groups validity	M (SD)	% of participants not satisfied with discussion of life goals[d]	M (SD)	% of participants not satisfied with discussion of life goals[d]	*t*	*p*
D-PaLS	53 (9)	9	49 (9)	18	4.8	<0.001

Abbreviations: M, mean; SD, standard deviation.
[a]Restricted to participants that answered all 6 core items.
[b]Restricted to online participants, N=463.
[c]Not restricted to participants that answered all 6 core items, N=514.
[d]D-PaLS scores ≤ 40.

SUPPLEMENTARY MATERIALS

Supplementary File (PDF)

Item S1: Patient Life Goals Survey (Version 0.5).

Table S1: Item Parameters for the D-PaLS PRO Item Bank.

Table S2: Scoring Conversion Table.

Table S3: Distribution of Item 8 Among Participants With Valid Surveys.

ARTICLE INFORMATION

Authors' Full Names and Academic Degrees: Claudia Dahlerus, PhD, Noelle E. Carlozzi, PhD, Katrina Price, MPH, Jennifer A. Miner, MBA, Richard A. Hirth, PhD, Garrett Gremel, MS, Peisong Han, PhD, Wei Zhang, MHSA, Jennifer Sardone, BA, Jesse Roach, MD, Wilfred Agbenyikey, PhD, Stephanie L. Clark, MD, Golden Horton, MS, Alexander Yaldo, BS, and Joseph M. Messana, MD

Authors' Affiliations: University of Michigan, Kidney Epidemiology and Cost Center, Ann Arbor, MI (CD, NEC, KP, RAH, GG, PH, WZ, JS, AY, JMM); Division of Nephrology, Michigan Medicine, Ann Arbor, MI (CD, YMM); Department of Physical Medicine and Rehabilitation, Michigan Medicine, Ann Arbor, MI (NEC, JAM); Department of Biostatistics, University of Michigan, Ann Arbor, MI (KP, GG, PH, WZ, JS, AY); Department of Health Management and Policy, University of Michigan, Ann Arbor, MI (RAH); Centers for Medicare and Medicaid Services, Baltimore, MD (JR, WA, SLC, GH).

Address for Correspondence: Claudia Dahlerus, PhD, University of Michigan, Kidney Epidemiology and Cost Center, School of Public Health, 1415 Washington Heights – Suite 3645, Ann Arbor, MI 48109-1390. Email: dahlerus@med.umich.edu

Authors' Contributions: N. Carlozzi and C. Dahlerus led the data collection, analysis, and results interpretation for all 3 stages. K. Price and M. Kallen contributed to data analysis. J. Messana contributed to interpretation of analyses. W. Zhang contributed to data processing and development of analysis files. Each author contributed important intellectual content during manuscript drafting or revision and accepts accountability for the overall work by ensuring that questions pertaining to the accuracy or integrity of any portion of the work are appropriately investigated and resolved.

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REFERENCES

1. Department of Health and Human Services, Centers for Medicare and Medicaid Services: The Centers for Medicare and Medicaid Programs. Conditions for Coverage for End-Stage Renal Disease Facilities, Final Rule. 42 CFR Parts 405, 410, 413 Fed Regist 73(73), April 15, 2008. Accessed August 30, 2021. https://www.cms.gov/Regulations-and-Guidance/Legislation/CFCsAndCoPs/downloads/esrdfinalrule0415.pdf
2. Chan C, Blankestijn P, Dember L, et al. Dialysis initiation, modality choice, access, and prescription: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Controversies Conference. *Kidney Int*. 2019;96:37-47.
3. Dahlerus C, Quinn M, Messersmith E, et al. Patient perspectives on the choice of dialysis modality: results from the Empowering Patients on Choices for Renal Replacement Therapy (EPOCH-RRT) Study. *Am J Kidney Dis*. 2016;68:901-910.
4. Van Biesen W, van der Veer S, Murphey M, Loblova O, Davies S. Patients' perceptions of information and education for renal replacement therapy: an independent survey by the European Kidney Patients' Federation on information and support on renal replacement therapy. *PLoS One*. 2014;9:e103914.
5. Song M, Lin F, Gilet C, Arnold R, Bridgman J, Ward S. Patient perspectives on informed decision-making surrounding dialysis initiation. *Nephrol Dial Transplant*. 2013;28:2815-2823.
6. Winterbottom A, Bekker H, Conner M, Mooney A. Patient stories about their dialysis experience biases others' choices regardless of doctor's advice: an experimental study. *Nephrol Dial Transplant*. 2012;27:325-331.
7. Wuerth D, Finkelstein S, Schwetz O, Carey H, Kliger A, Finkelstein F. Patients' descriptions of specific factors leading to modality selection of chronic peritoneal dialysis or hemodialysis. *Perit Dial Int*. 2002;22:184-190.

8. University of Michigan Kidney Epidemiology and Cost Center: End-Stage Renal Disease Patient-Reported Outcomes Technical Expert Panel Summary Report. Prepared for the Centers for Medicare and Medicaid Services, 2017. Accessed August 30, 2021. https://www.dialysisdata.org/sites/default/files/content/ESRD_Measures/ESRD_Patient_Reported_Outcomes_TEP_Summary_Report.pdf
9. Dahlerus C, Carlozzi N, Hirth R, et al. Conceptual model development to inform an end-stage kidney disease patient life goals survey. *Kidney Med*. 2024. Under review.
10. National Quality Forum (NQF): NQF Patient Reported Outcomes (PROs) in Performance Measurement. January 2013. Accessed February 23, 2016. http://www.qualityforum.org/Projects/n-r/Patient-Reported_Outcomes/Patient-Reported_Outcomes.aspx
11. United States Food and Drug Administration: Guidance for Industry, Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims: Fed Regist 35:65132–65133, 2009. Accessed August 12, 2016. http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf
12. PROMIS® Instrument Development and Psychometric Evaluation Scientific Standards. Accessed August 30, 2021. http://www.nihpromis.org/Documents/PROMIS_Standards_050212.pdf
13. Samejima F, van der Liden WJ, Hambleton R. The graded response model. In: van der Liden WJ, ed. *Handbook of Modern Item Response Theory*. Springer, 1996:85-100.
14. Muthén L, Muthén B. Mplus User's Guide. Muthén and Muthén, 2011.
15. McDonald RP. Test theory: A unified treatment. Lawrence Erlbaum Associates, Inc, 1999.
16. Reise SP, Morizot J, Hays RD. The role of the bifactor model in resolving dimensionality issues in health outcomes measures. *Qual Life Res Suppl*. 2007;1:19-31.
17. Cook K, Kallen M, Amtmann D. Having a fit: Impact of number of items and distribution of data on traditional criteria for assessing IRT's unidimensionality assumption. *Qual Life Res*. 2009;18:447-460.
18. *TestGraf [*computer program]. McGill University, 2000.
19. IRTPRO for Windows [Computer software] [computer program]. Version 4.2.2. Lincolnwood, IL, Scientific Software International, 2015.
20. R: A language and environment for statistical computing. [computer program]. Vienna, Austria: R Foundation for Statistical Computing, 2014.
21. Choi S, Gibbons L, Crane P. Lordif: An R package for detecting differential item functioning using iterative hybrid ordinal logistic regression/item response theory and monte carlo simulations. *J Stat Softw*. 2011;8:1-30.
22. Kline R. *Principles and Practice of Structural Equation Modeling, Second Edition*. Guilford Press, 2005.
23. Bentler P. Comparative fit indexes in structural models. *Psychol Bull*. 1990;107(2):238-246.
24. Hu L, Bentler P. Cutoff criteria for fit indexes in covariance structure analysis: conventional criteria versus new alternatives. *Struct Equ Modeling*. 1999;6(1):1-55.
25. Hatcher L. A step-by-step approach to using SAS for factor analysis and structural equation modeling. SAS Institute, Inc, 1994.
26. Andresen E. Criteria for assessing the tools of disability outcomes research. *Arch Phys Med Rehabil*. 2000;81(12 Suppl 2):S15-S20.
27. Cramer D, Howitt D: The Sage dictionary of statistics. Sage, 2004.
28. Zee J, Zhao J, Subramanian L, et al. Perceptions about the dialysis modality decision process among peritoneal dialysis and in-center hemodialysis patients. *BMC Nephrol*. 2018;19(1):298.
29. Robinski M, Mau W, Wienke A, Girndt M: The Choice of Renal Replacement Therapy (CORETH) project: dialysis patients' psychosocial characteristics and treatment satisfaction. *Nephrol Dial Transplant*. 2017;32(2):315-324.
30. Heaton R, Miller S, Taylor J, Grant I. Revised comprehensive norms for an expanded Halstead-Reitan Battery: Demographically adjusted neuropsychological norms for African American and Caucasian adults. Psychological Assessment Resources, Inc, 2004.
31. Orlando M. Critical issues to address when applying item response theory (IRT) models. 2004. Paper presented at the Drug Information Association, Bethesda, MD.
32. Ruo B, Choi S, Baker D, Grady K, Cella D. Development and validation of a computer adaptive test for measuring dyspnea in heart failure. *J Card Fail*. 2010;16(8):659-668.
33. Muraki E. Fitting a polytomous item response model to Likert-type data. *Appl Psychol Meas*. 1990;14:59-71.
34. Clauser B, Hambleton R. Review of differential item functioning. *J Educ Meas*. 1994;31(1):88-92.
35. Dorough A, Forfang D, Mold J, Kshirsagar A, DeWalt D, Flythe J. A person-centered interdisciplinary plan-of-care program for dialysis: implementation and preliminary testing. *Kidney Med*. 2021;3(2):193-205.