Assessing Patient-Reported Outcomes of Hemodialysis

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How do we learn about the health of patients?

Traditional Clinical Measures

Vital Signs Hemoglobin level Calcium Phosphorus



Patient-Reported Measures

Behaviors Care experiences Health perceptions



Patient-Reported Outcomes (PROs)

<u>PRO is</u> "any report coming from patients about a health condition and its treatment, without interpretation of the patient's response by a clinician or anyone else" (FDA)

Note: PROs are one type of patient-reported measure (PRM).

FDA. 2009.

PRM framework





Impact of Providing PRO Information to Health Care Providers

Systematic review of 28 studies published between 1978 and 2007 evaluated impact of administering PROs in clinical practice:

65% (15/23) found evidence of PROs improving processes of care

47% (8/17) found evidence of PROs improving outcomes of care

Valderas, et al. Qual Life Res. 2008



Basch. N Eng J Med. 2017.

Kidney Care Quality Alliance Commissioned Report on PRMs

PATIENT-REPORTED OUTCOMES FOR END-STAGE RENAL DISEASE: A FRAMEWORK & PRIORITIES FOR MEASUREMENT

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KIDNEY CARE QUALITY ALLIANCE

Kidney Care Quality Alliance. *Patient-Reported Outcomes for End-Stage Renal Disease: A Framework and Priorities for Measurement.* http://kidneycarepartners.com/kidney-care-quality-alliance-kcqa/. Washington, DC: 2017.

KCQA Steering Committee

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CMS Mandates for PRMs in Dialysis

- CMS Conditions for Coverage (42 CFR §494.90)
 - Each U.S. dialysis patient's physical and mental health be monitored.
 - Kidney Disease Quality of Life 36-item measure (KDQOL-36) most commonly used.
- Performance measure
 - In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS®) survey used in CMS Quality Incentive Program (QIP).
 - <u>https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/CAHPS/ichcahps.html</u>

Kidney Targeted HRQOL: KDQOL-36

- Developed with patient input
 - Focus groups with patients and dialysis center staf
 - Field test with patients from 9 different outpatient dialysis centers from California, the Northwest and Midwest.
 - Subsequent administration in Dialysis Outcomes and Practice Patterns Study
- Contains generic (universal) and targeted items
- Evidence of reliability and validity
- Administered with 1000's of dialysis patients; norms available for comparison

^aHays, et al. *Qual Life Res*. 1994

KDQOL-36 Scales

Composite	n items	Sample Item
Burden of Kidney Disease	4	"My kidney disease interferes too much with my life"
Symptoms/ Problems with Kidney Disease	12	"To what extent are you bothered by chest pain?"
Effects of Kidney Disease	8	"How much does fluid restriction from kidney disease bother you?"

+SF-12 as generic (universal) core: Physical Component Score (PCS) Mental Component Score (MCS)



Psychometric Properties of the Kidney Disease Quality of Life 36-Item Short-Form Survey (KDQOL-36) in the United States

John D. Peipert, Peter M. Bentler, Kristi Klicko, and Ron D. Hays

Sample

- **70,786** dialysis patients from 1,381 US dialysis facilities
- Assessed KDQOL-36 between 06/01/2015 and 05/31/2016 as part of routine clinical assessment
- Medical Education Institute (MEI) data

KDQOL-36 Scale Distributions

	KDQOL Burdens	KDQOL Symptoms/ Problems	KDQOL Effects
Sample size	70,022	70,004	69,938
Mean	52	79	74
Standard Deviation	30	16	22
% at Floor	5%	0.03%	0.3%
% at Ceiling	9%	4%	10%

Note: KDQOL scales above scored on 0-100 possible range, with 100 representing better Health.

Evaluation of KDQOL-36 Factor Structure

- Confirmatory factor analysis (CFA)
 - 3 correlated factors model
 - Robust maximum likelihood
 - Polychoric correlations to account for categorical items
- Model Fit
 - Comparative fit index (CFI) >0.95
 - Tucker-Lewis Index (TLI) >0.95
 - Root mean square error of approximation (RMSEA) < 0.06

CFA Model Results

- All items loaded on expected scale at >0.40
- Model Fit
 - TLI: 0.97 (meets criteria of > 0.95)
 - CFI: 0.98 (*meets criteria of > 0.95*)
 - RMSEA: 0.05 (*meets criteria of < 0.06*)

Conclusion

KDQOL factor structure provides good fit to the observed data.



Evaluation of Reliability and Validity

<u>Reliability</u>

- Internal consistency estimated with Cronbach's alpha (α)
- Dialysis facility-level reliability estimated with 1-way analysis of variance (ANOVA)

Construct Validity

• Known groups analyses

Reliability

≥0.70 acceptable
 ≥0.80 good
 ≥0.90 excellent



Sample sizes required for 0.70 facility-level reliability are 40, 38 and 24.

Construct Validity

	KDQOL		KDQOL		KDQOL	
	Burden	p-value	Symptoms	p-value	Effects	p-value
Dialysis Type						
Peritoneal Dialysis	56	ref	80	ref	76	ref
In-Center						
Hemodialysis	52	<0.001	79	<0.001	73	<0.001
Conventional Home						
Hemodialysis	52	<0.001	80	0.03	75	< 0.001
Other	52	<0.001	80	0.48	74	0.008
Diabetes						
Yes	51	Ref	78	Ref	73	Ref
No	54	<0.001	80	<0.001	75	<0.001



- Content area experts, methodological experts, clinicians from academia, and NIH project officers
- Can be assessed as static "short forms" or through computer adaptive testing (CAT)
- Normed T-scores
 - Mean of 50, SD of 10, referenced to the U.S. general population

Universal Health-Related Quality of Life



Peipert and Hays 1st Recommendation

We recommend the continued use of the KDQOL-36 instrument with dialysis patients for the purposes of dialysis centers' internal quality improvement

> Improve KDQOL-36 by replacing SF-12 with PROMIS items

KCQA Recommendations

Rec. 1 "KDQOL is not an appropriate starting point for a facility-level, HRQOL-related PROM"

Rec. 2

"PROMIS should be considered [...] for any new, targeted HRQOL-related PROM/PRO-PM development." "KDQOL is not an appropriate starting point for a facility-level, HRQOL-related PROM"





1. Developed more than 20 years ago

- No compelling case made that dialysis patients HRQOL would be <u>fundamentally</u> <u>different</u> than it was in 1994
- Are the *Burdens of KD*, *Symptoms of KD*, and *Effects of KD* different than in 1994?

What do stakeholders care about today?



- Vascular Access Problems
- Death/Mortality
- Cardiovascular Disease
- Dialysis Adequacy
- Fatigue/Energy
- Ability to Travel
- Dialysis-Free Time Evangelidis, et al., Am J Kidney Dis. 2017.

KDQOL-36[™] Survey

- 28 13. My kidney disease interferes
 32 too much with my life
 - 14. Too much of my time is spent dealing with my kidney disease

KDQOL Symptoms/Problems Still Relevant



2. The KDQOL is an Individual-Level Measure, Not Facility-Level

 Most PRO-based performance measures for providers, facilities, or health-care plans are derived from individual measures

– E.g., Veterans RAND 36-Item Health Survey (VR-36)

- KDQOL-36 has demonstrated ability to distinguish between facilities already (center-level reliabilities)
- KDQOL-36 has great potential for facility-level assessment.

"PROMIS should be considered [...] for any new, targeted HRQOL-related PROM/PRO-PM development."

- PROMIS measures do represent the state of the science in generic/universal HRQOL measurement
- No kidney/dialysis-targeted measures or questions
 - Targeted measures are more responsive/sensitive
 - Targeted measures address condition-specific concerns/symptoms
- A combination of universal/targeted measures is recommended Cella, et al., Patient-

Cella, et al., *Patient-Reported Outcomes in Performance Measurement*. 2015

Experience with Care

"The range of interactions that patients have with the health care system, including their care from health plans, and from doctors, nurses, and staff in hospitals, physician practices, and other health care facilities" (AHRQ)

https://www.ahrq.gov/cahps/index.html

ICH-CAHPS Properties

Developed with patient input

Evidence of reliability and validity

Administered with 1000's of dialysis patients; norms available for comparison

In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS®)

Composite	n of Items	Sample Item
Nephrologists Communication and Caring	6	"In the last 3 months, how often did your kidney doctors explain things in a way that was easy for you to understand?"
Providing Information to Patients	9	"Did dialysis center staff at this center ever review your rights as a patient with you?"
Quality of Dialysis Center Care & Operations	17	"In the last 3 months, how often did the dialysis center staff show respect for what you had to say?"

+3 global items

Inclusion in Dialysis Facility Compare



ICH-CAHPS Reliability

≥0.70 acceptable
 ≥0.80 good
 ≥0.90 excellent

Composite	Alpha	Center- Level
Nephrologists Communication and Caring	0.89	0.77
Providing Information to Patients	0.93	0.84
Quality of Dialysis Center Care & Operations	0.75	0.79

Weidmer, et al., Am J Kid Dis. 2014

ICH-CAHPS Mean Differences

	Composite Scores			
Dialysis Center Characteristic	Nephrologist Communication (1–4)	Quality of Care (1–4)	Patient Information (0–1)	
Patients/nurse				
<5	3.69 [0.05]	3.56 [0.04]	0.91 [0.02]	
5 to < 8	3.69 [0.03]	3.52 [0.04]	0.84 [0.01]	
8 to <12	3.68 [0.04]	3.39 [0.05]	0.76 [0.02]	
≥12	3.71 [0.03]	3.41 [0.04]	0.84 [0.02]	
Overall	3.69 (P=0.97; n=371)	3.47 (P=0.04; n=371)	0.84 (P=0.001; n=369) ^a	

Wood, et al., Clin J Am Soc Neph. 2014

Peipert and Hays 2nd Recommendation

We recommend the continued use of the ICH-CAHPS for CMS's dialysis center performance monitoring

Improve parsimony by reducing number of items in scales.

Conclusions

- Many opportunities to improve current measures
 - Additional work is needed before KDQOL-based quality measure is ready for use
- Best chances to develop well-performing quality measures is to start with KDQOL-36 and ICH-CAHPS
 - Matches patients' concerns
 - Best measurement properties
 - Available norms for comparison

Thank you.



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