

# Patient-Reported Outcome Measures in Nephrology

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<http://gim.med.ucla.edu/FacultyPages/Hays/>

# Outline of Presentation

- Patient-reported measures figure
- Consumer Assessment of Healthcare Providers and Systems (CAHPS®)
- Kidney Disease Quality of Life measure
  - KDQOL™-36

# Patient-Reported Measures





# The Renal Network, Inc.

## ESRD Networks 4, 9 & 10

**Facilitates the achievement of optimal wellness for renal disease patients.**

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*Functional Status & Quality of Life*

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### [Exercise](#)

### [KDQOL](#)

*Tools for Technical Assistance:*

## CAHPS Resources

The **Consumer Assessment of Healthcare Providers and Systems (CAHPS)** program is a public-private initiative to develop standardized surveys of patients' experiences with ambulatory and facility-level care.

CAHPS is widely used to monitor and evaluate the relative performance of managed care health plans and compare managed care plans to fee-for-service health care. For more information on CAHPS go to the AHRQ CAHPS Web site <https://www.cahps.ahrq.gov/default.asp>.

The CAHPS family of survey tools is [available by download](#) in English or Spanish from the AHRQ web site. These survey tools are formatted in HTML, Microsoft Word, or Adobe PDF to accommodate most users.

### CAHPS In-Center Hemodialysis Survey

The CAHPS In-Center Hemodialysis Survey asks adults with end-stage renal

# Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Surveys

- Ambulatory Care Surveys
  - CAHPS Health Plan Survey
  - CAHPS Clinician & Group Survey
  - CAHPS Surgical Care Survey
  - ECHO® Survey
  - CAHPS Dental Plan Survey
  - CAHPS American Indian Survey
  - CAHPS Home Health Care Survey
- Facility Surveys
  - CAHPS Hospital Survey
  - CAHPS Nursing Home Survey
  - **CAHPS In-Center Hemodialysis Survey**

# CAHPS Design Principles

- Emphasis on patients
  - What patients value with respect to the setting of care
  - Aspects of care for which patients are the best or only source of information
- Dominated by reports rather than ratings of care
- Standardization
  - Surveys, data collection, analysis, reporting, benchmarking
- Many CAHPS surveys are NQF endorsed
- All CAHPS surveys and products are in the public domain

# Development process

- Literature review
- Technical Expert Panels
- Focus group feedback
- Cognitive interviews (English and Spanish)
- Field testing and psychometric analyses
- Public release

# CAHPS In-Center Hemodialysis Survey (In the last 3 months ...)

- How often did
  - your kidney doctors listen carefully to you?
  - your kidney doctors explain things in a way that was easy to understand?
  - your kidney doctors show respect for what you had to say?
  - your kidney doctors spend enough time with you?
  - you feel your kidney doctors really cared about you as a person?

Reporting Measures for the CAHPS® In-Center Hemodialysis Survey. Agency for Healthcare Research and Quality, Rockville, MD. Updated Dec 2007.

[https://www.cahps.ahrq.gov/cahpskit/files/509\\_ICH\\_Reporting\\_Measures.htm](https://www.cahps.ahrq.gov/cahpskit/files/509_ICH_Reporting_Measures.htm)



# *Health-Related Quality of Life is ...*

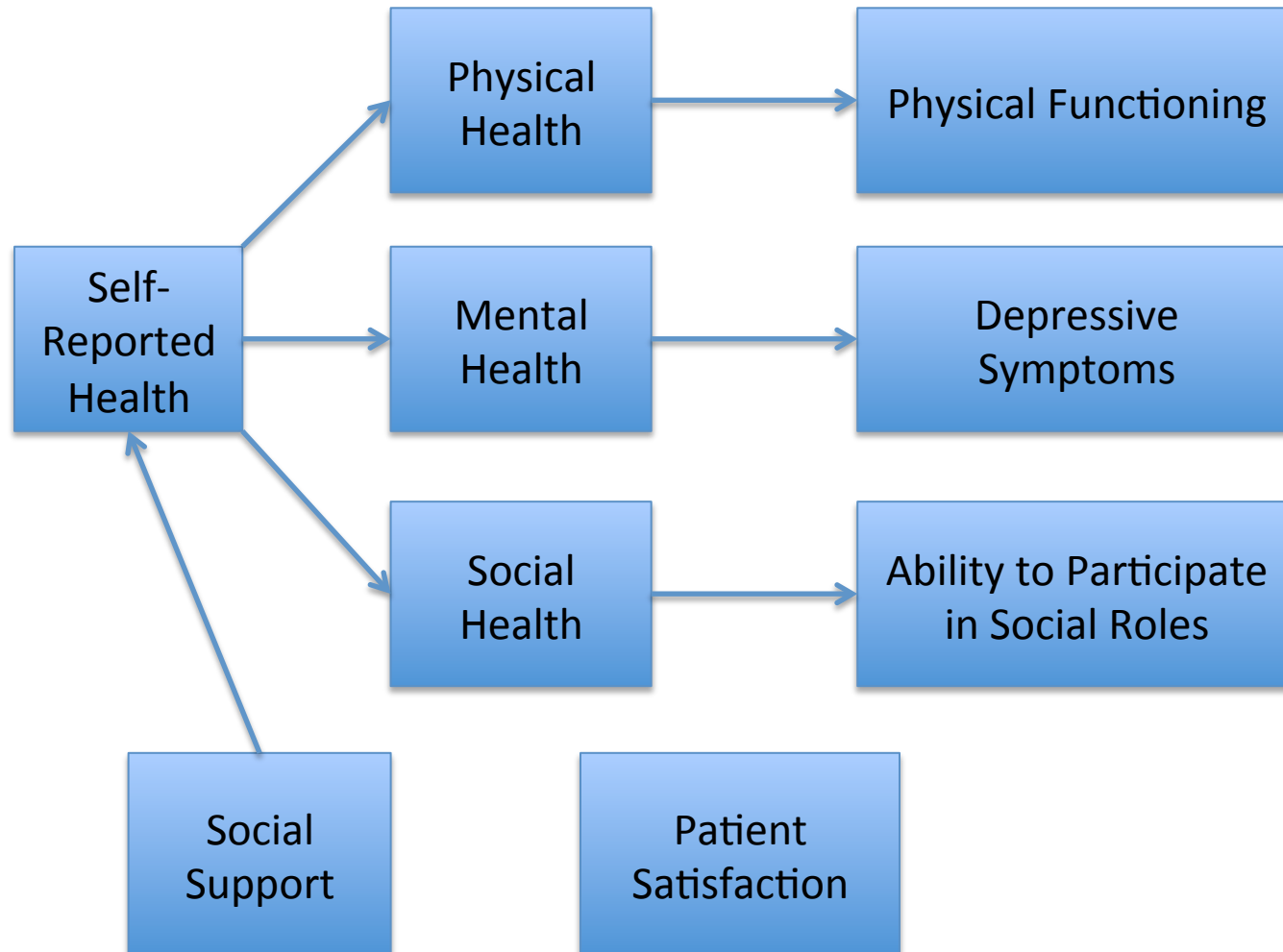
## What you can do.

- Functioning
  - Self-care
  - Role
  - Social

## How you feel about your life.

- Well-being
  - Emotional well-being
  - Pain
  - Energy

# HRQOL Framework



# SF-36® Generic Profile Measure

- Functioning
  - Physical functioning (10 items)
  - Role limitations/physical (4 items)
  - Role limitations/emotional (3 items)
  - Social functioning (2 items)
- Well-Being
  - Emotional well-being (5 items)
  - Energy/fatigue (4 items)
  - Pain (2 items)
  - General health perceptions (5 items)

# Generic vs. Disease-Targeted

- ✓ In general, would you say your health is:  
Excellent/ Very good/ Good/ Fair/ Poor?
- ✓ How much does kidney disease bother you  
in your ability to work around the house?

Not at all bothered/Somewhat bothered/  
Moderately bothered/Very much bothered/  
Extremely bothered

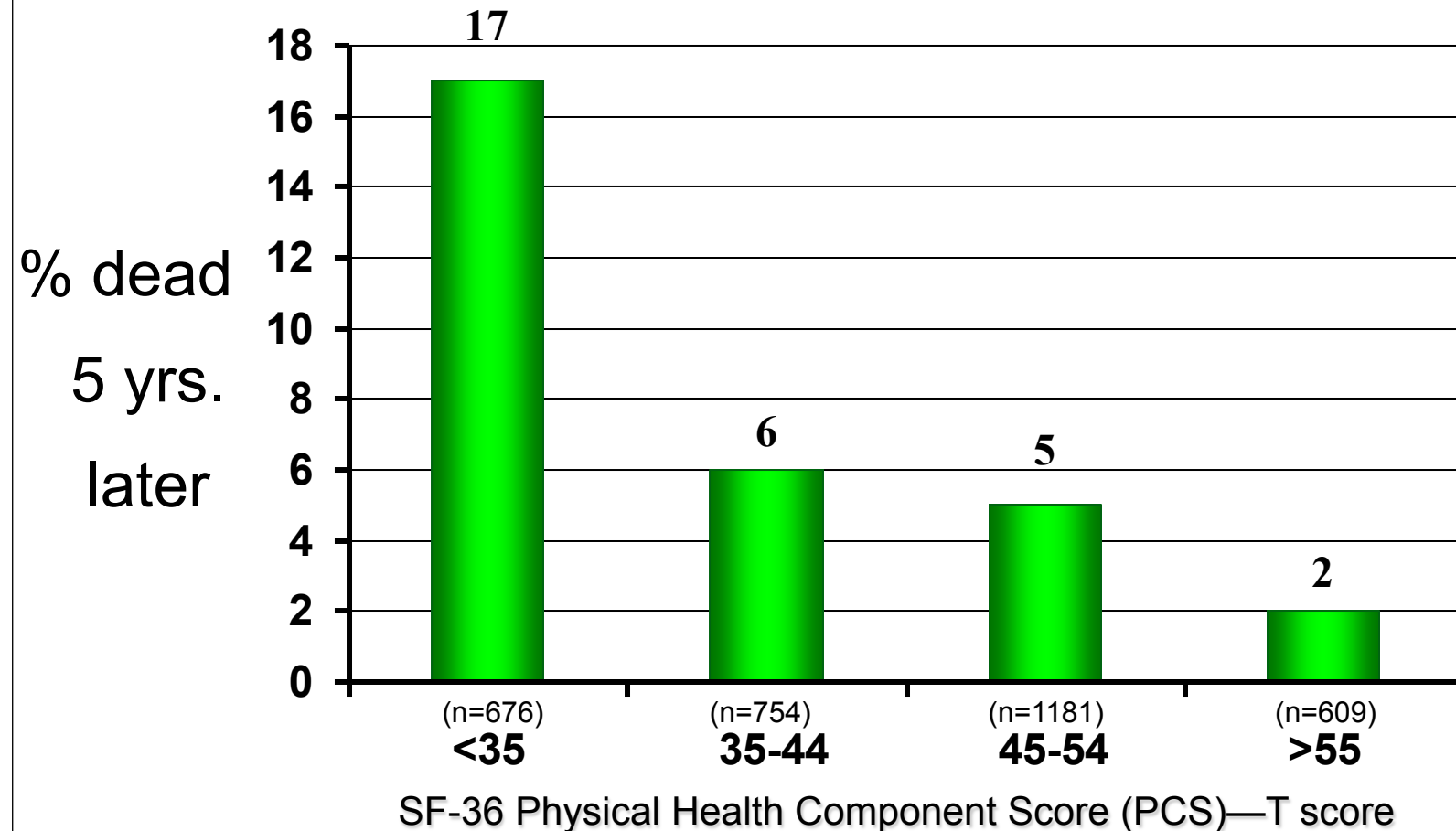
# Reliability of measures

0.0 (lowest) – 1.0 (highest possible)

- ~ 0.80 for blood pressure and other clinical measures
- 0.70-0.90 for multi-item self-report measures

Hahn, E. A., Cella, D., et al. (2007). Precision of health-related quality-of-life data compared with other clinical measures. Mayo Clin Proceedings, 82 (10), 1244-1254.

# SF-36 Physical Health Component Summary Score Predicts Mortality



Ware et al. (1994). SF-36 Physical and Mental Health Summary Scales: A User's Manual

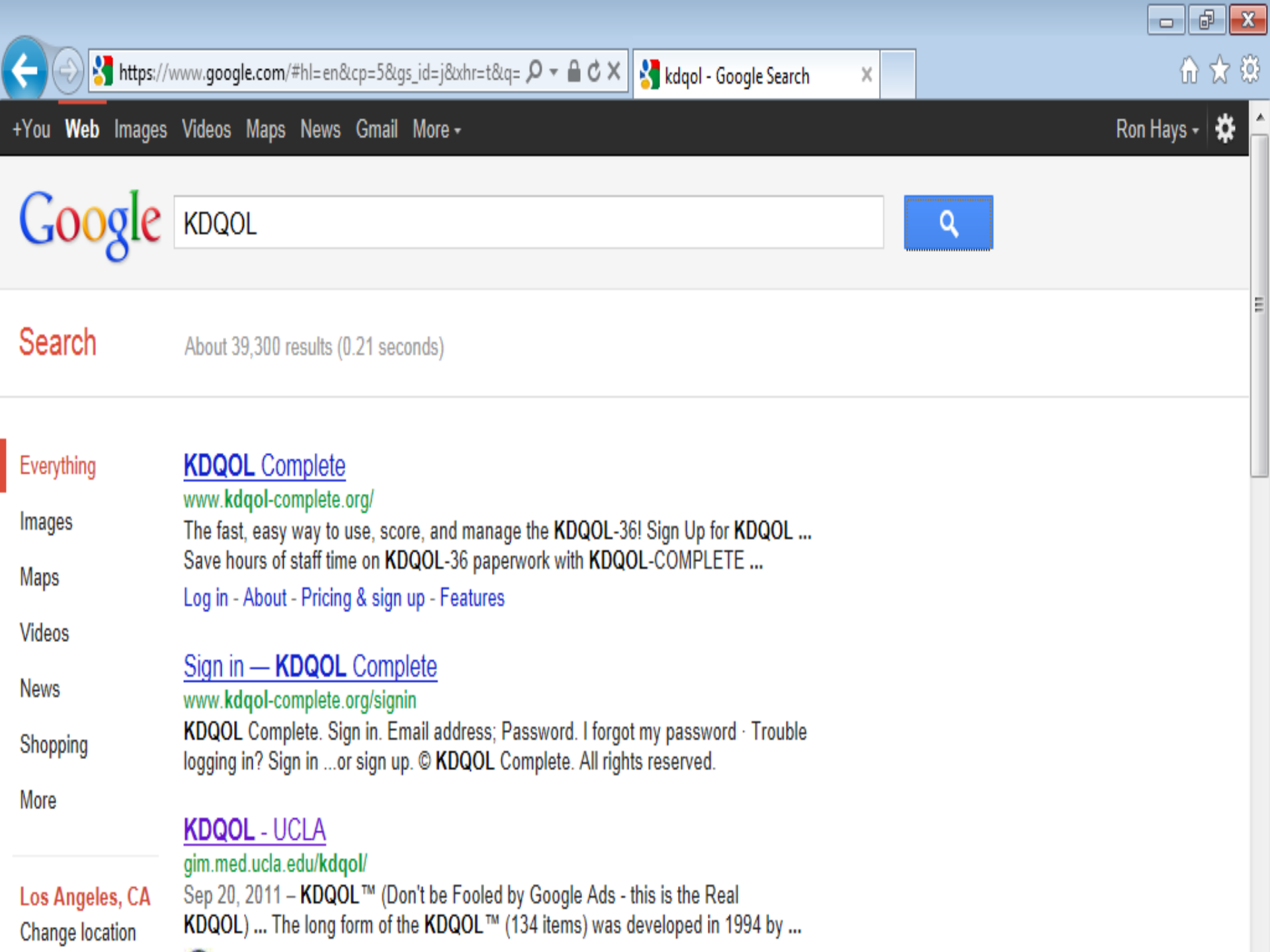
# HRQOL Predicts Mortality and Hospitalizations

- Kalantar-Zadeh et al. (2001, J Am Soc Nephrol)
  - “Total score and MCS”
- Lowrie et al. (2003, Am J Kidney Dis)
  - PCS and MCS
- Mapes et al. (2003, Kidney International)
  - PCS, MCS, and Kidney Disease Component Score (KDCS)
- Molnar-Varga et al. (2011, Am J Kidney Dis)
  - PCS predictive of mortality
  - MCS and Kidney Disease Quality of Life (KDQOL™)  
Symptom/problems predictive of transplant loss

# Kidney Disease Quality of Life (KDQOL™) Instrument

- ❖ Focus groups with patients and staff
- ❖ Pretests on small samples
- ❖ Field test with 165 persons with kidney disease at 9 dialysis centers
- ❖ Thousands of administrations since





KDQOL



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About 39,300 results (0.21 seconds)

Everything

[KDQOL Complete](#)

[www.kdqol-complete.org/](http://www.kdqol-complete.org/)

The fast, easy way to use, score, and manage the KDQOL-36! Sign Up for KDQOL ...  
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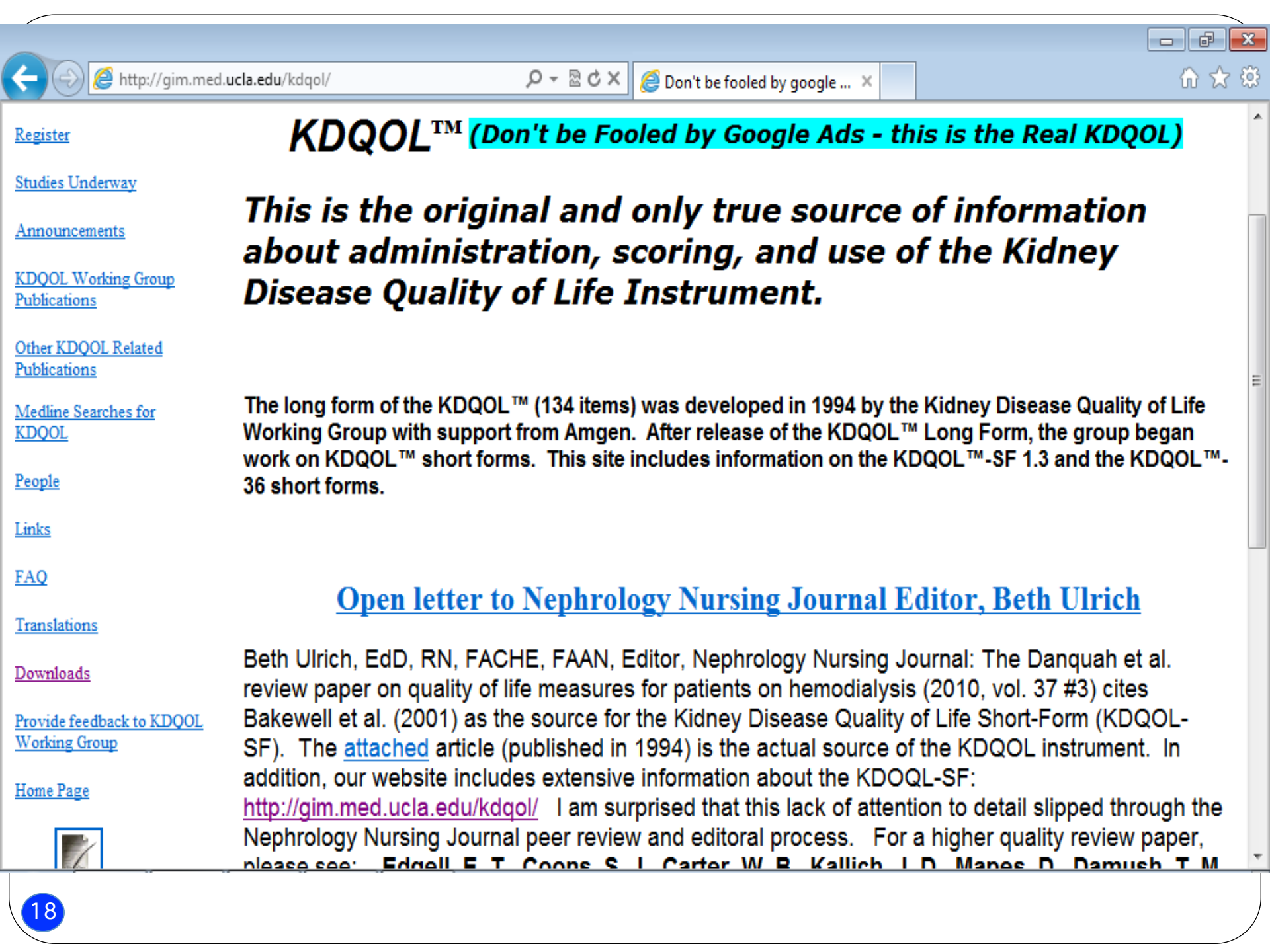
[www.kdqol-complete.org/signin](http://www.kdqol-complete.org/signin)

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[KDQOL - UCLA](#)

[gim.med.ucla.edu/kdqol/](http://gim.med.ucla.edu/kdqol/)

Sep 20, 2011 – KDQOL™ (Don't be Fooled by Google Ads - this is the Real KDQOL) ... The long form of the KDQOL™ (134 items) was developed in 1994 by ...



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# KDQOL™ (Don't be Fooled by Google Ads - this is the Real KDQOL)

***This is the original and only true source of information about administration, scoring, and use of the Kidney Disease Quality of Life Instrument.***

The long form of the KDQOL™ (134 items) was developed in 1994 by the Kidney Disease Quality of Life Working Group with support from Amgen. After release of the KDQOL™ Long Form, the group began work on KDQOL™ short forms. This site includes information on the KDQOL™-SF 1.3 and the KDQOL™-36 short forms.

## [Open letter to Nephrology Nursing Journal Editor, Beth Ulrich](#)

Beth Ulrich, EdD, RN, FACHE, FAAN, Editor, Nephrology Nursing Journal: The Danquah et al. review paper on quality of life measures for patients on hemodialysis (2010, vol. 37 #3) cites Bakewell et al. (2001) as the source for the Kidney Disease Quality of Life Short-Form (KDQOL-SF). The [attached](#) article (published in 1994) is the actual source of the KDQOL instrument. In addition, our website includes extensive information about the KDOQL-SF: <http://gim.med.ucla.edu/kdqol/> I am surprised that this lack of attention to detail slipped through the Nephrology Nursing Journal peer review and editorial process. For a higher quality review paper, please see: [Edgell E T, Coons S J, Carter W B, Kallich L D, Manes D, Damush T M](#)

# Kidney Disease Quality of Life (KDQOL) Publications

- **Hays, R. D.**, Kallich, J. D., Mapes, D. L., Coons, S. J., & Carter, W. B. (1994). Development of the Kidney Disease Quality of Life (KDQOL™) Instrument. Quality of Life Research, 3, 329-338.
- Edgell, E. T., Coons, S. J., Carter, W. B., Kallich, J. D., Mapes, D., Damush, T. M., & **Hays, R. D.** (1996). A review of health-related quality of life assessment in end-stage renal disease. Clinical Therapeutics, 18(5), 887-938.
- Rao, S., Carter, W. B., Mapes, D. L., Kallich, J. D., Kamberg, C. J., Spritzer, K. L., & **Hays, R. D.** (2000). Development of subscales from the symptom/problems and effects of kidney-disease items in the Kidney Disease Quality of Life (KDQOL™) instrument. Clinical Therapeutics, 22, 1099-1111.

# KDQOL Targeted Domains (97 items and 43 items)

❖ Symptoms/problems	34	12
❖ Effects of kidney disease	20	8
❖ Burden of kidney disease	4	4
❖ Work status	4	2
❖ Cognitive function	6	3
❖ Quality of social interaction	4	3
❖ Sexual function	4	2
❖ Sleep	9	4
❖ Social support	4	2
❖ Dialysis staff encouragement	6	2
❖ Patient satisfaction	2	1

# KDQOL-36

- ❖ **Items 1-12:** SF-12
- ❖ **Items 13-16:** Burden of Kidney Disease (4)
- ❖ **Items 17-28:** Symptoms/Problems (12)
- ❖ **Items 29-36:** Effects of Kidney Disease (8)

Glover, C. et al. (2011). Understanding and assessing the impact of end-stage renal disease on quality of life: A systematic review of the content validity of self-administered instruments used to assess health-related quality of life in end-stage renal disease. Patient, 4(1), 19-30.

# Burden of Kidney Disease

- My kidney disease interferes too much with my life.
- Too much of my time is spent dealing with my kidney disease.
- I feel frustrated with my kidney disease
- I feel like a burden on my family.

# Symptom/Problems--

To what extent were you bothered by ...

- Soreness in your muscles?
- Chest pain?
- Cramps?
- Itchy skin?
- Dry skin?
- Shortness of breath?
- Faintness or dizziness?
- Lack of appetite?
- Washed out or drained?
- Numbness in hands or feet?
- Nausea or upset stomach?
- Problems with access (catheter) site?

# Effects of Kidney Disease—

How much does kidney disease bother you in ...

- Fluid restrictions?
- Dietary restriction?
- Your ability to work around the house?
- Your ability to travel?
- Being dependent on doctors and other medical staff?
- Stress or worries caused by kidney disease?
- Your sex life?
- Your personal appearance?



# Scoring

- ❖ Higher score = better health
- ❖ Transform linearly to 0-100 range
- ❖ Average items in each scale together

# KDQOL-36 Translations

Comparison KDQOL-SF 1.3 and KDQOL-36

KDQOL-SF 1.3	KDQOL-36
1	1
3 b	2
3 d	3
4 b	4
4 c	5
5 b	6
5 c	7
8	8
9 d	9
9 e	10
9 f	11
10	12
12 a	13
12 b	14
12 c	15
12 d	16
14 a	17
14 b	18
14 c	19
14 d	20
14 e	21
14 f	22
14 g	23
14 h	24
14 i	25
14 j	26
14 k	27
14 l	28 a (HD only)
14 m	28 b (PD only)
15 a	29
15 b	30
15 c	31
15 d	32
15 e	33
15 f	34
15 g	35
15 h	36

- ❖ Chinese
- ❖ Czech
- ❖ Danish
- ❖ Dutch
- ❖ English
- ❖ French
- ❖ German
- ❖ Greek
- ❖ Hebrew

- ❖ Hungarian
- ❖ Italian
- ❖ Malay
- ❖ Polish
- ❖ Portuguese
- ❖ Russian
- ❖ Spanish
- ❖ Swedish
- ❖ Turkish

<http://gim.med.ucla.edu/kdqol> (register for downloads)

# Dialysis Outcomes and Practice Patterns Study (DOPPS)

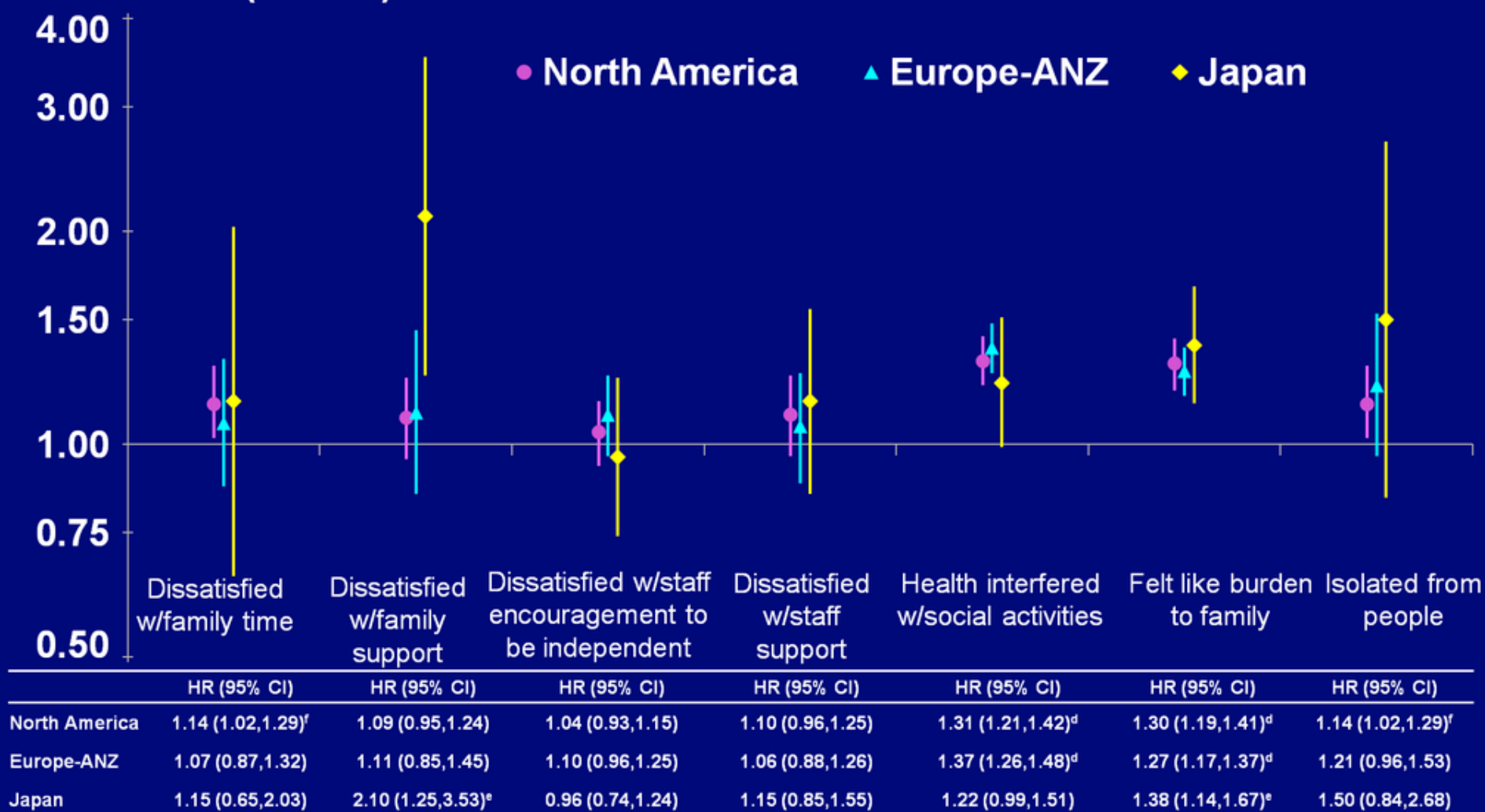
- Longitudinal study of hemodialysis patients and unit practices
  - Goal is to identify practice patterns associated with improved patient outcomes
- Uniform international data collection
  - Mortality
  - Health-related quality of life
  - Hospitalization
  - Vascular access
- Coordinated by Arbor Research Collaborative for Health

# DOPPS Data

- 308 dialysis facilities in DOPPS I
  - 12,465 patients from 7 countries
  - France, Germany, Italy, Japan, Spain, UK, US
- 320 dialysis facilities in DOPPS II
  - 10,551 patients from 12 countries
  - Same 7 above plus Australia, New Zealand, Belgium, Canada and Sweden
- 297 facilities in DOPPS III
  - 9,316 patients from the same 12 countries

**Figure 1: Association of patient self-reported social support and other psychosocial factors with all-cause mortality, by region**

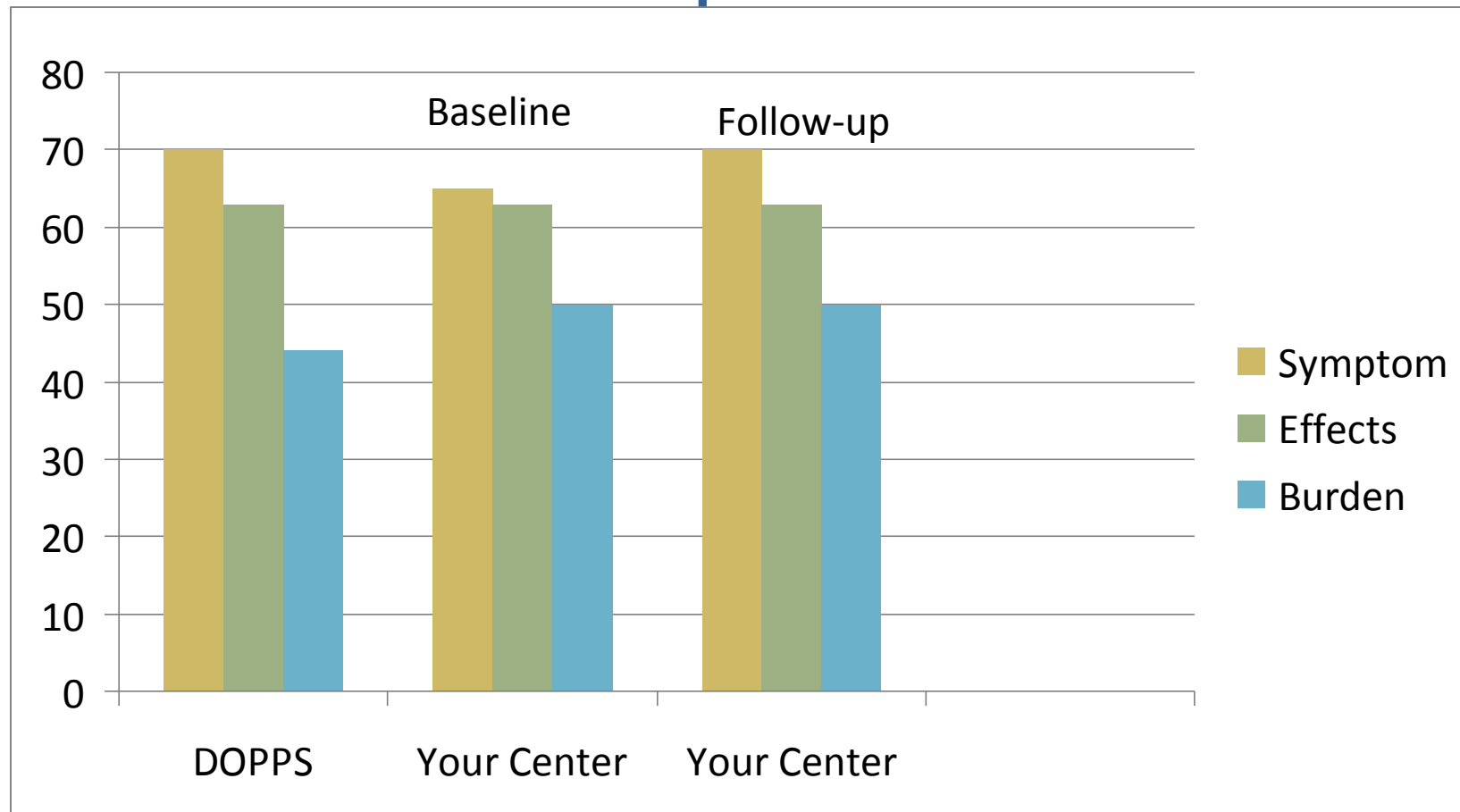
Hazard Ratio (95% CI)



All models were adjusted for age, sex, race, time on dialysis, marital status, living status, 13 summary comorbidity classes, serum albumin, and spKt/V; stratified by phase, and accounted for facility clustering



# KDQOL™ Scores Compared to National Sample of Patients

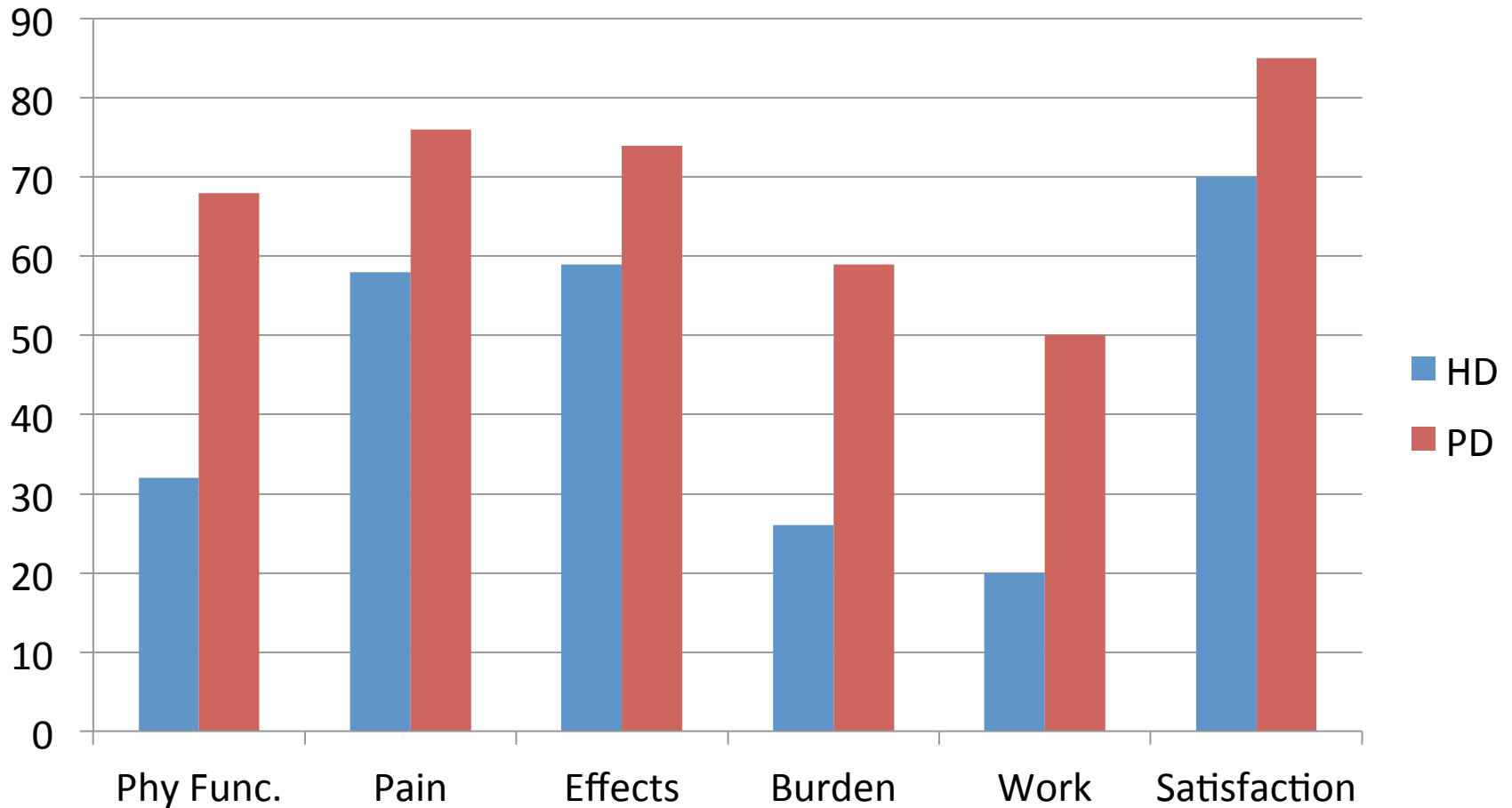


**Dialysis Outcomes and Practice Patterns  
Study (DOPPS) 55-64 year old age group**

**Means and Standard Deviations for KDQOL™ Scales by Age Group in Dialysis Outcomes and Practice Patterns Study (Females, n = 2265)**

Variable	18-24	25-34	35-44	45-54	55-64	65-74	75+	SD
<u>Kidney disease-targeted Scales</u>								
Burden of kidney disease (k=4)	26.64	41.07	44.12	40.52	43.55	42.46	41.85	29.73
Quality of social interaction (k=3)	64.91	72.27	74.00	73.98	77.03	78.90	81.24	19.24
Cognitive function (k=3)	67.72	76.84	78.60	76.37	77.34	76.73	77.67	21.32
Symptoms/problems (k=12)	69.44	69.06	68.70	68.29	70.36	71.03	72.45	17.87
Effects of kidney disease (k=8)	56.42	58.69	60.13	58.49	63.44	66.71	69.10	23.83
Sexual function (k=2)	83.93	77.94	65.18	68.18	68.87	74.69	82.14	36.36
Sleep (k=4)	63.11	55.59	57.21	56.86	57.53	60.91	61.72	20.50
Social support (k=2)	78.95	71.35	72.94	68.92	73.84	77.47	76.88	27.29
Work status (k=2)	26.32	21.88	21.26	15.37	14.72	19.56	24.94	29.32
Dialysis staff encouragement (k=2)	75.66	80.53	75.77	81.73	82.97	81.34	84.03	21.71
Pt satisfaction rating	62.28	71.62	68.72	68.51	72.92	73.16	74.75	22.06
Overall health rating	58.42	59.64	57.48	53.91	53.58	56.38	54.63	21.74
<u>SF-36 Scales</u>								
Physical functioning	57.38	62.14	50.49	41.95	33.96	32.67	26.66	28.70
Role limitations--physical	31.25	45.69	38.24	30.13	29.81	28.45	24.52	38.93
Pain (NEMC scoring)	62.00	54.95	55.26	53.81	53.31	53.77	54.72	28.41
General health (NEMC scoring)	39.60	47.26	41.11	39.05	38.60	41.01	41.44	22.09
Emotional well-being	58.32	66.28	67.47	64.53	66.73	67.43	68.59	21.40
Role limitations--emotional	51.67	61.61	55.35	51.58	53.02	49.86	50.33	44.43
Social function	67.50	64.02	62.89	60.85	61.82	59.89	60.03	29.35
Energy/fatigue	49.12	47.45	45.80	41.38	42.20	40.87	38.53	23.04
SF36 physical composite T-score (NEMC)	38.30	38.42	34.85	32.39	30.60	30.53	28.98	10.40
SF36 mental composite T-score (NEMC)	43.42	45.74	46.45	45.58	47.42	47.20	47.93	11.80

# Hemo. vs. Peritoneal Dialysis



Fructuoso et al. Quality of Life in chronic kidney disease. Nefrologia, 2011, 31, 91-96.



# Future Directions

<http://www.nihpromis.org/>

- Item banks to assess HRQOL and allow for computer-adaptive testing (CAT)
- Reliability =  $1 - SE^2 = 0.90$
- SE = 3.2 for T-score (mean= 50 & SD = 10)

# Anger CAT<sup>1</sup> (In the past 7 days )

I was grouchy

- Never
- Rarely
- Sometimes
- Often
- Always

- Theta = 56.1 SE = 5.7

## <sup>2</sup>In the past 7 days ...

I felt like I was ready to explode

- Never
  - Rarely
  - Sometimes
  - Often
  - Always
- 
- $\text{Theta} = 51.9 \quad \text{SE} = 4.8$

# <sup>3</sup>In the past 7 days ...

I felt angry

- Never
  - Rarely
  - Sometimes
  - Often
  - Always
- Theta = 50.5 SE = 3.9

<sup>4</sup>In the past 7 days ...

I felt angrier than I thought I should

- Never
  - Rarely
  - Sometimes
  - Often
  - Always
- $\text{Theta} = 48.8 \quad \text{SE} = 3.6$

## <sup>5</sup>In the past 7 days ...

I felt annoyed

- Never
  - Rarely
  - Sometimes
  - Often
  - Always
- 
- $\text{Theta} = 50.1 \quad \text{SE} = 3.2$

## <sup>6</sup>In the past 7 days ...

I made myself angry about something just by thinking about it.

- Never
  - Rarely
  - Sometimes
  - Often
  - Always
- 
- $\text{Theta} = 50.2 \quad \text{SE} = 2.8$

# Theta and SE estimates

- Item 1: 56 and 6
- Item 2: 52 and 5
- Item 3: 50 and 4
- Item 4: 49 and 4
- Item 5: 50 and 3
- Item 6: 50 and  $<3$



<http://jwrginc.com/projects/current-projects>

### **Functional Health Computer Adaptive Test (CAT) in Chronic Kidney Disease**

*NIH Agency:* The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

*Summary:* This study completes a 4-year NIH-funded project designed to evaluate improvements in CKD-specific impact measures used to estimate health related quality of life outcomes among adult non-dialysis and non-transplant patients at Stages 3-5, dialysis patients, and transplant patients. Previous phases (I and II) analyzed Internet-based survey data to conduct psychometric tests of a new CKD-specific impact bank. Data from this new clinic-based study are being analyzed to replicate prior psychometric tests using Item Response Theory (IRT) as well as extend the research to include clinical tests of discriminant validity and responsiveness for new and legacy tools. JWRG and Tufts Medical Center are supporting project completion out of their own research funds. Investigators: JE Ware and K Meyer (Co-Investigators).

Thank you. [http://  
gim.med.ucla.edu/kdqol/](http://gim.med.ucla.edu/kdqol/)

