Methodological Considerations in Using Patient Reported Measures in Dialysis Clinics
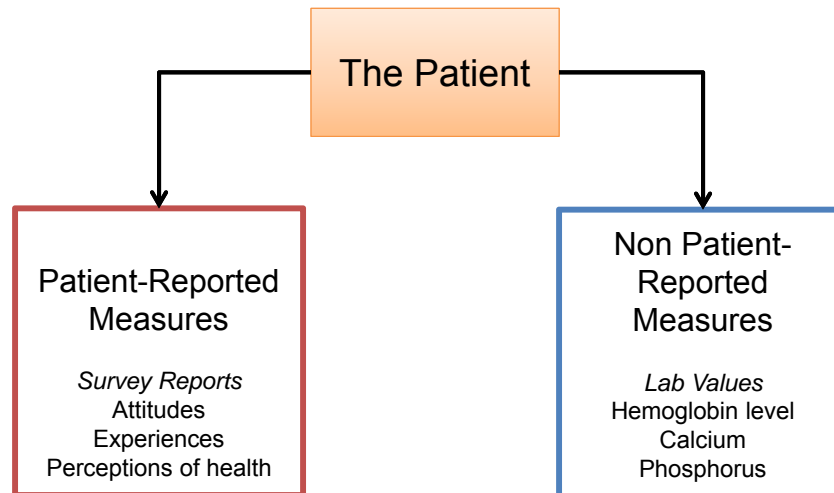
John D Peipert
Ron D Hays

Acknowledgements

Patient Reported Measures are Major Source of Data

```
                    ┌──────────────┐
                    │  The Patient │
                    └──────┬───────┘
           ┌───────────────┴───────────────┐
           ▼                               ▼
┌─────────────────────┐        ┌─────────────────────┐
│ Patient-Reported    │        │   Non Patient-      │
│ Measures            │        │   Reported          │
│                     │        │   Measures          │
│ *Survey Reports*    │        │                     │
│ Attitudes           │        │   *Lab Values*      │
│ Experiences         │        │   Hemoglobin level  │
│ Perceptions of health│       │   Calcium           │
│                     │        │   Phosphorus        │
└─────────────────────┘        └─────────────────────┘
```
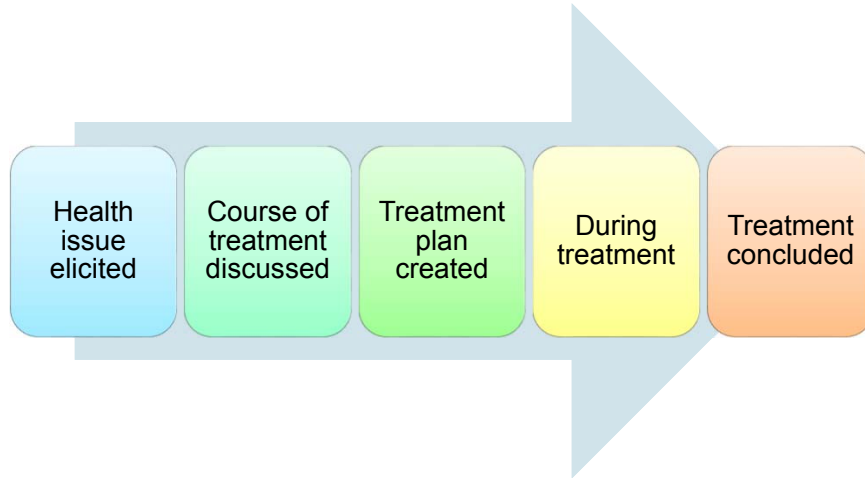
Definitions

- <u>Patient Reported Outcome (PRO)</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)

- <u>Patient-Reported Measures (PRMs)</u>: defined the same way, but more general and including PROs
  - *PROs are a type of PRM*

FDA. 2009.

Assessing PRMs along Stage of Provider-Patient Encounter

Health issue elicited	Course of treatment discussed	Treatment plan created	During treatment	Treatment concluded

Successes & Challenges Administering PRMs in Clinic

- Collection of patient-reported symptoms was associated with fewer ER visits and increased 1- and 5-year survival[1]

- Systematic review of administering PRMs showed improvements in processes and outcomes of care 40-50% of the time[2]

- Some providers may not change their care plan even when presented with PRM data[3]

[1]Basch et al. *J Clin Oncol.* 2016; [2]Valderas et al. *Qual Life Res.* 2008; [3]Fung & Hays. *Qual Life Res.* 2008

PRMs in Dialysis

- Used as performance measures
  - CMS incorporation of In-Center Hemodialysis – Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS®) in QIP

- Used for internal quality improvement
  - Kidney Disease Quality of Life (KDQOL^{TM})-36 incorporated into care plans

Objectives

- Identify key PRMs relevant to dialysis patients
- Review key methodological issues around the use of PRMs in dialysis
- Make recommendations to KCQA for:
  - Selection of PRMs
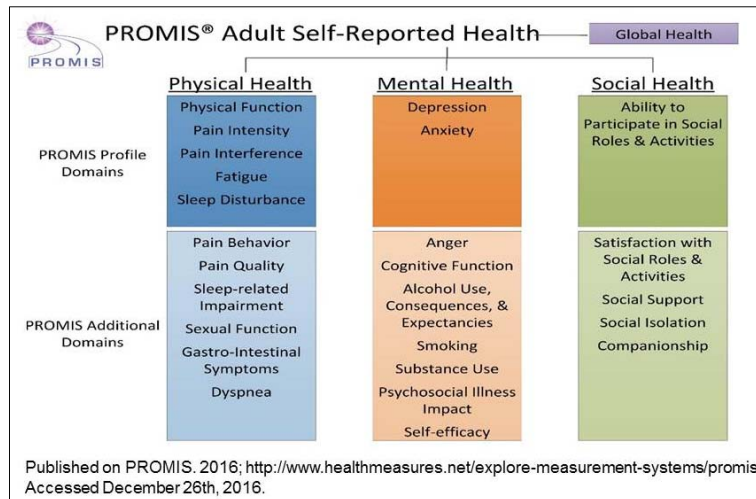 - Mode of Administration
  - Support for PRM Use in Dialysis

Identifying Key PRMs Relevant to Dialysis Patients

Fung & Hays PRM Framework
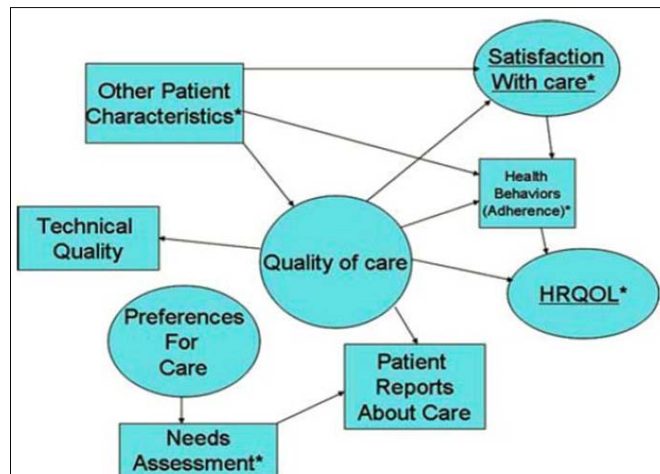
Originally published in Fung CH, Hays RD. Prospects and challenges in using patient-reported outcomes in clinical practice. *Qual Life Res*. 2008; 17(10):1297-1302.

Generic Health-Related Quality of Life (HRQOL)

PROMIS® Adult Self-Reported Health — Global Health

	Physical Health	Mental Health	Social Health
PROMIS Profile Domains	Physical Function, Pain Intensity, Pain Interference, Fatigue, Sleep Disturbance	Depression, Anxiety	Ability to Participate in Social Roles & Activities
PROMIS Additional Domains	Pain Behavior, Pain Quality, Sleep-related Impairment, Sexual Function, Gastro-Intestinal Symptoms, Dyspnea	Anger, Cognitive Function, Alcohol Use, Consequences, & Expectancies, Smoking, Substance Use, Psychosocial Illness Impact, Self-efficacy	Satisfaction with Social Roles & Activities, Social Support, Social Isolation, Companionship

Published on PROMIS. 2016; http://www.healthmeasures.net/explore-measurement-systems/promis. Accessed December 26th, 2016.

PROMIS (1)

- 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)
- Scored on T-score metric
  - Mean of 50, SD of 10, with the mean referenced to the U.S. general population

PROMIS (2)

- Measures for both adult and pediatric patients
- PROMIS-29: Multi-domain profile measure:
  – Physical function
  – Anxiety
  – Depression
  – Fatigue
  – Sleep disturbance
  – Ability to participate in social roles and activities
  – Pain interference
  – Pain intensity

Kidney Disease Quality of Life 36-item (KDQOL-36)

- Derived from KDQOL-SF, Hays, et al[a]
- SF-12 (12 items)
- Burden of KD (4 items; α = 0.85)
  - 5 point scale: "Definitely true" - "Definitely false"
  - E.g., "My kidney disease interferes too much with my life"
- Symptoms/Problems with KD (12 items ; α = 0.83)
  - 5 point scale: "Not at all bothered"-"Extremely bothered"
  - E.g., "To what extent are you bothered by chest pain?"
- Effects of KD (8 items; α = 0.85)
  - 5 point scale: "Not at all bothered"-"Extremely bothered"
  - E.g., "How much does fluid restriction from KD bother you?"

[a]Hays, et al. *Qual Life Res.* 1994

KDQOL-36 Properties

- Developed with patient input
- Brief
- Contains generic and targeted HRQOL scales
- Evidence of reliability and validity
- Administered with 1000's of dialysis patients; norms available for comparison

Recommendation 1

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 PCS & MCS with PROMIS items

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)
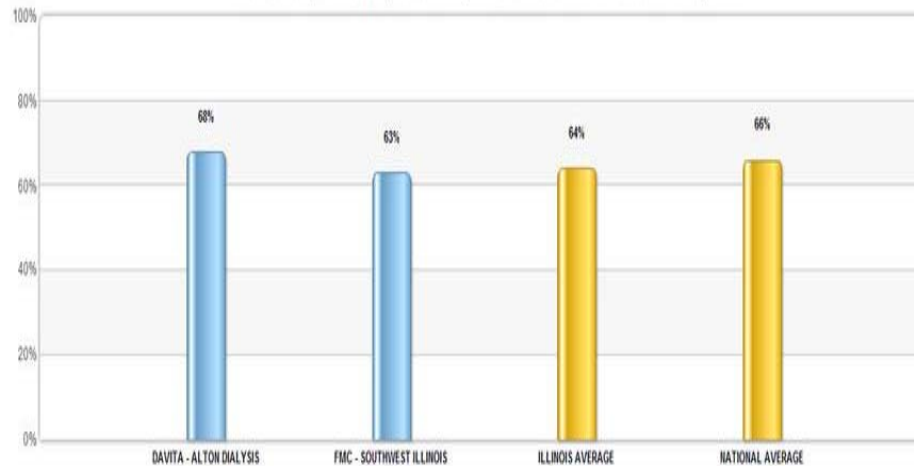

In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH-CAHPS®)

- 3 multi-item scales
  - Nephrologists Communication and Caring (α=0.89) (6 items; e.g., "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 (α=0.93) (9 items; "Did dialysis center staff at this center ever review your rights as a patient with you?")
  - Quality of Dialysis Center Care & Operations (α=0.75) (17 items; "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 CMS QIP and Dialysis Facility Compare

Patients who reported that kidney doctors "always" communicated well and cared for them as a person.

	DAVITA - ALTON DIALYSIS	FMC - SOUTHWEST ILLINOIS	ILLINOIS AVERAGE	NATIONAL AVERAGE
	68%	63%	64%	66%

ICH-CAHPS Properties

- Developed with patient input

- Evidence of reliability and validity

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

Recommendation 2

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.

Other PRMs:
Treatment Decision-Making

- Kidney patients can choose between multiple types of dialysis, multiple types of transplant
  - *All offer varying length and quality of life*
- Understanding risks and benefits of all options is required for informed consent
- CMS requires that all dialysis patients be informed of their option for transplant

Are patients being informed?

Table 2. Patient- and provider-reported provision of information about KT

Patient-Reported KTPI	Provider-Reported KTPI		Total
	No	Yes	
No	30	108	138
Yes	32	218	250
Total	62	326	388

Provision of information about KT was reported by patient and provider in 56.2% of participants, provider only in 27.8%, patient only in 8.3%, and neither in 7.7%. The interrater agreement between patients and providers was only slightly better than what would be expected by chance alone (63.9% observed agreement versus 59.8% expected agreement; $\kappa=0.10$).

Salter, et al. *JASN*. 2014.

Recommendation 3

We recommend that a PRM of whether patients have been informed about their option for transplant be adopted

Mode of Administration

How are PRMs Administered?

	In-clinic	Mail	Phone	Web
Self Administered	X	X		X
Interview Administered	X		X	
Computer Administered	X			X
Voice Activated			X	

Web-Based/Electronic Administration (1)

- Pros
  - Efficient data capture with simultaneous data entry
  - Convenient for patient
  - Flexible timing for data collection
- Cons
  - Difficult to ensure privacy
  - Upfront costs for the PRO system and maintenance
  - Potential software problems

Web-Based/Electronic Administration (2)

- Many surveys were designed for paper/pencil
- Often no need to completely redevelop, but additional testing for equivalence should be conducted
- Minor changes
  - Updates to instructions and formatting

Recommendation 4

Evaluate equivalence between electronic and paper versions of PRMs prior to widespread use of electronic administration

Support for PRM Use in Dialysis

Cost of Administering PRMs

- Burdensome for dialysis providers and dialysis patients
  - Dialysis staff have heavy workload
- Material costs
  - Paper Surveys
  - Electronic admin systems
- Data entry

Recommendation 5

We recommend that new explorations be launched to identify mechanisms for CMS to reimburse these costs

Training for Administering PRMs

- Skills required for interview administration
  - Understanding of standardized survey administration techniques
  - Ways to elicit unbiased, accurate responses
  - Trouble shoot when patients have questions
  - Understand potentially complex skip-patterns

- Skills required for self administration
  - Standardized data entry protocols

Recommendation 6

We recommend the continued development of effective, low-cost training programs to help providers administer PRMs, including e-learning programs

Conclusions

- A lot of successes in use of PRMs in dialysis
    - Good measures available
    - Use in dialysis is extensive
- Room for improvement on:
    - Measures
    - Administration methods
    - Support of staff administering PRMs

Thank you!

Questions?