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# Methodological Considerations in Using Patient Reported Measures in Dialysis Clinics

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# Thanks to My Co-author: Ron Hays



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# How do we learn about patients' health and healthcare experiences?

## Non Patient-Reported Measures

*Lab Values*  
Hemoglobin level  
Calcium  
Phosphorus



## Patient-Reported Measures

*Survey Reports*  
Attitudes  
Experiences  
Perceptions of health



# Definitions

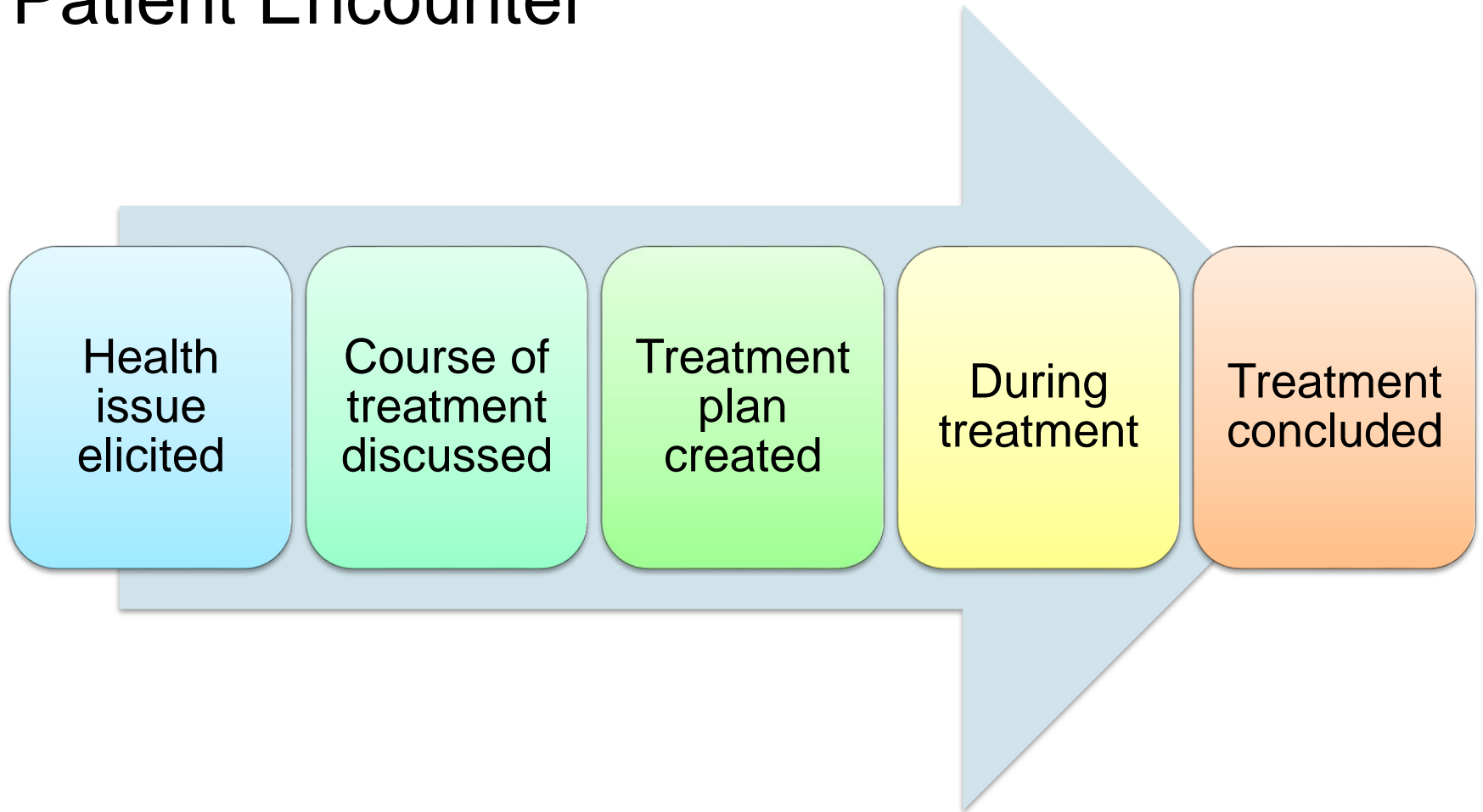
Patient Reported Outcome (PRO): “any report coming from patients about a health condition and its treatment, without interpretation of the patient’s response by a clinician or anyone else” (FDA)

Patient-Reported Measures (PRMs): defined the same way, but more general and including PROs

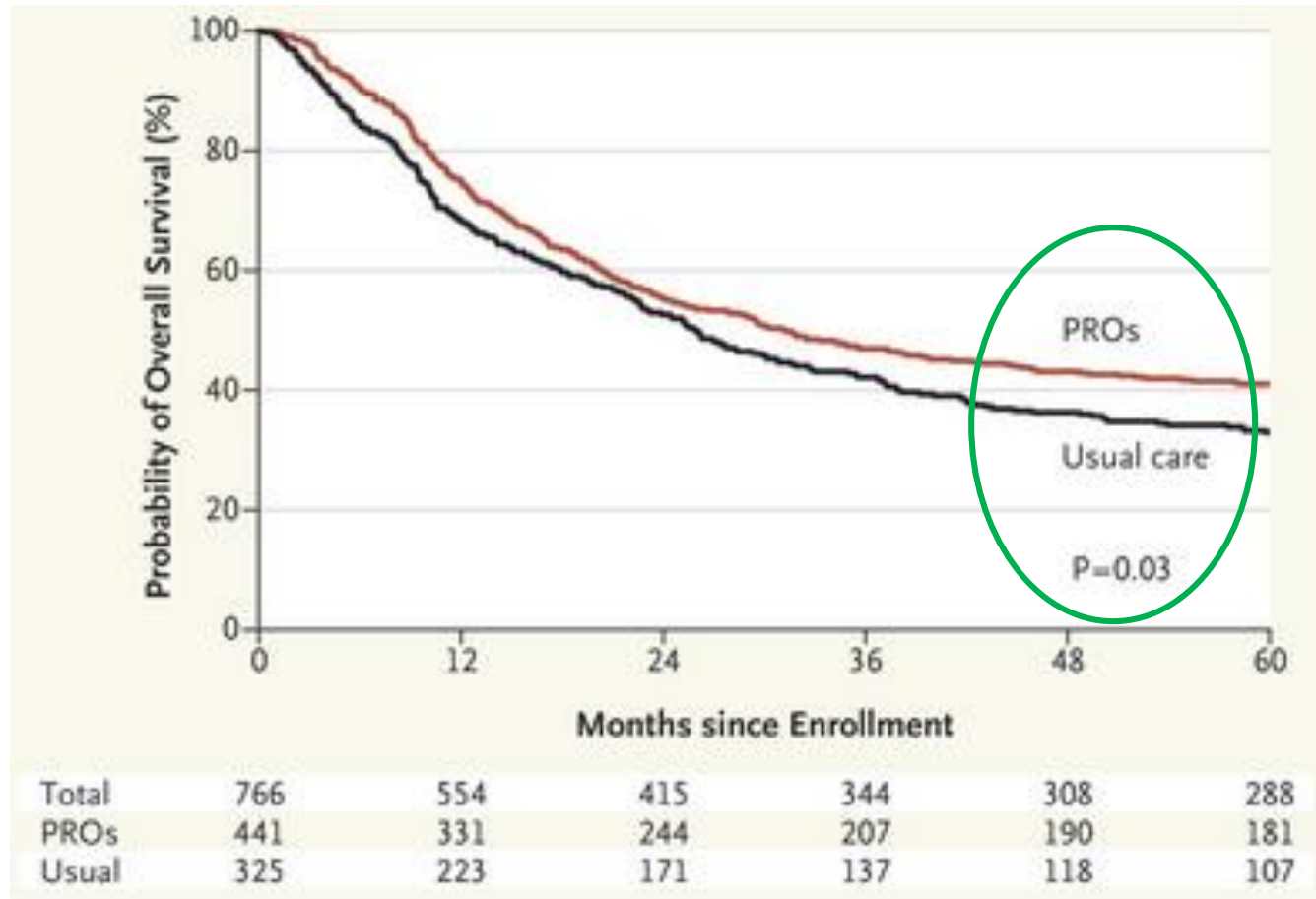
• *PROs are a type of PRM*



# Assessing PRMs along Stage of Provider-Patient Encounter



# Successes Administering PRMs in Clinic (1)



Basch. *N Eng J Med.* 2017.



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# Successes Administering PRMs in Clinic (2)

## Systematic review of administering PRMs in clinics:

- ❖ 65% found evidence of PROs improving processes of care
- ❖ 47% found evidence of PROs improving outcomes of care

Valderas, et al. *Qual Life Res.* 2008



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# PRMs in Dialysis

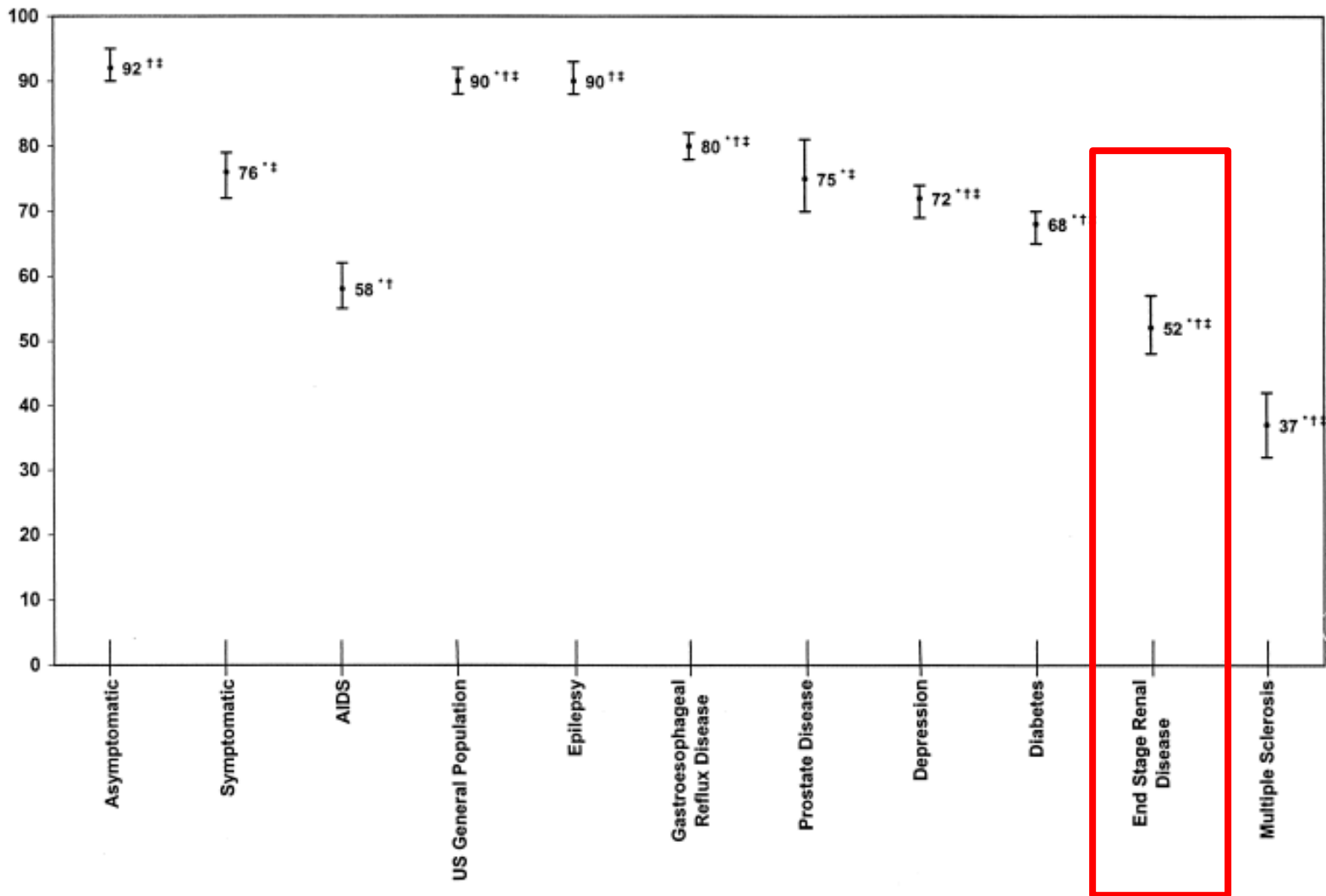
## Used as performance measures

- 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™)-36 incorporated into care plans





Hays, et al. *Am J Med.* 2000



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# Kidney Care Quality Alliance Commissioned Report on Methodological Issues in PRMs



**CJASN**

Clinical Journal of the  
American Society of Nephrology

## Using Patient-Reported Measures in Dialysis Clinics

*John D. Peipert\* and Ron D. Hays<sup>†</sup>*



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# Objectives

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



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# I. Identifying PRMs Relevant to Dialysis Patients

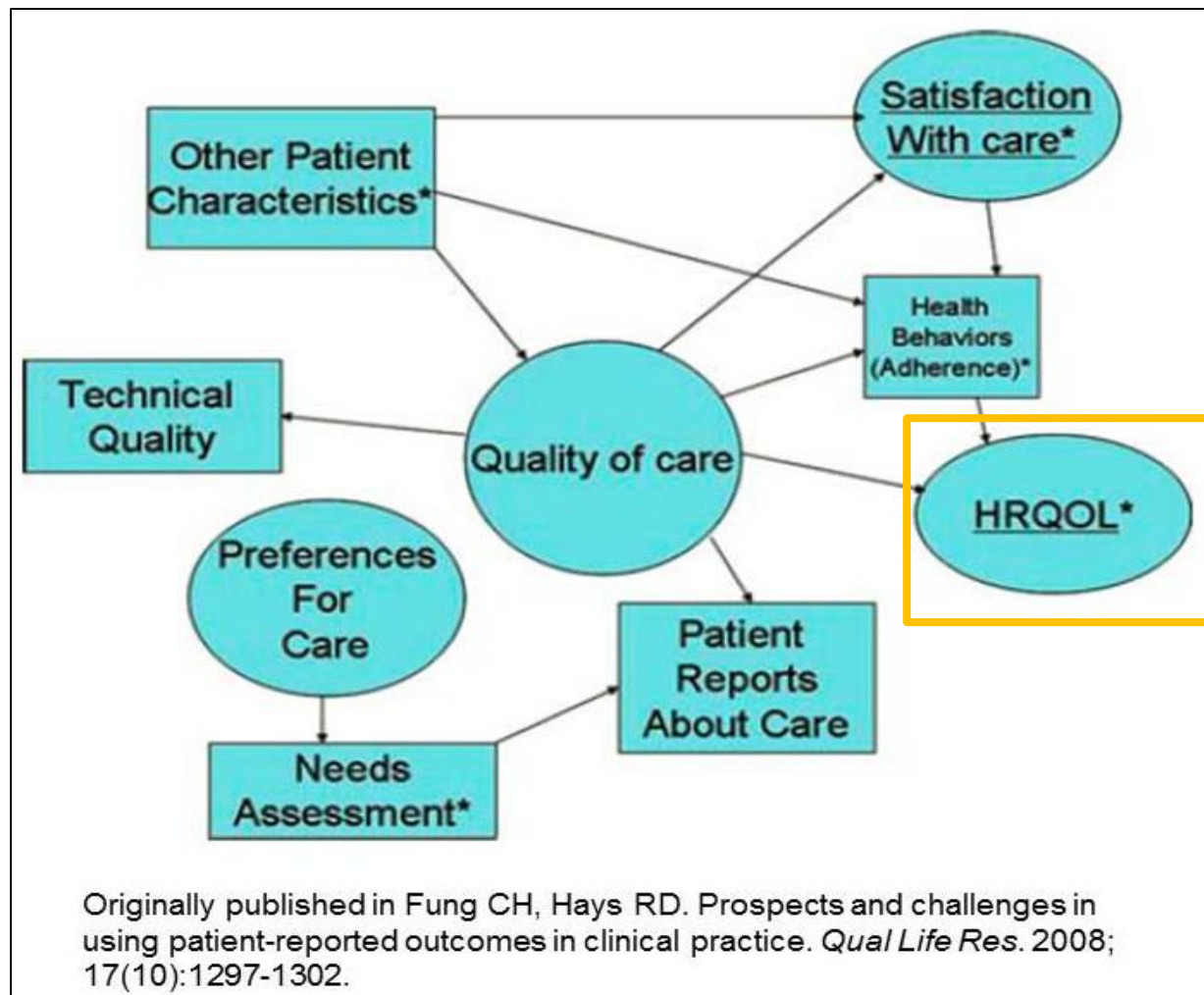


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# Fung & Hays Framework





- 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



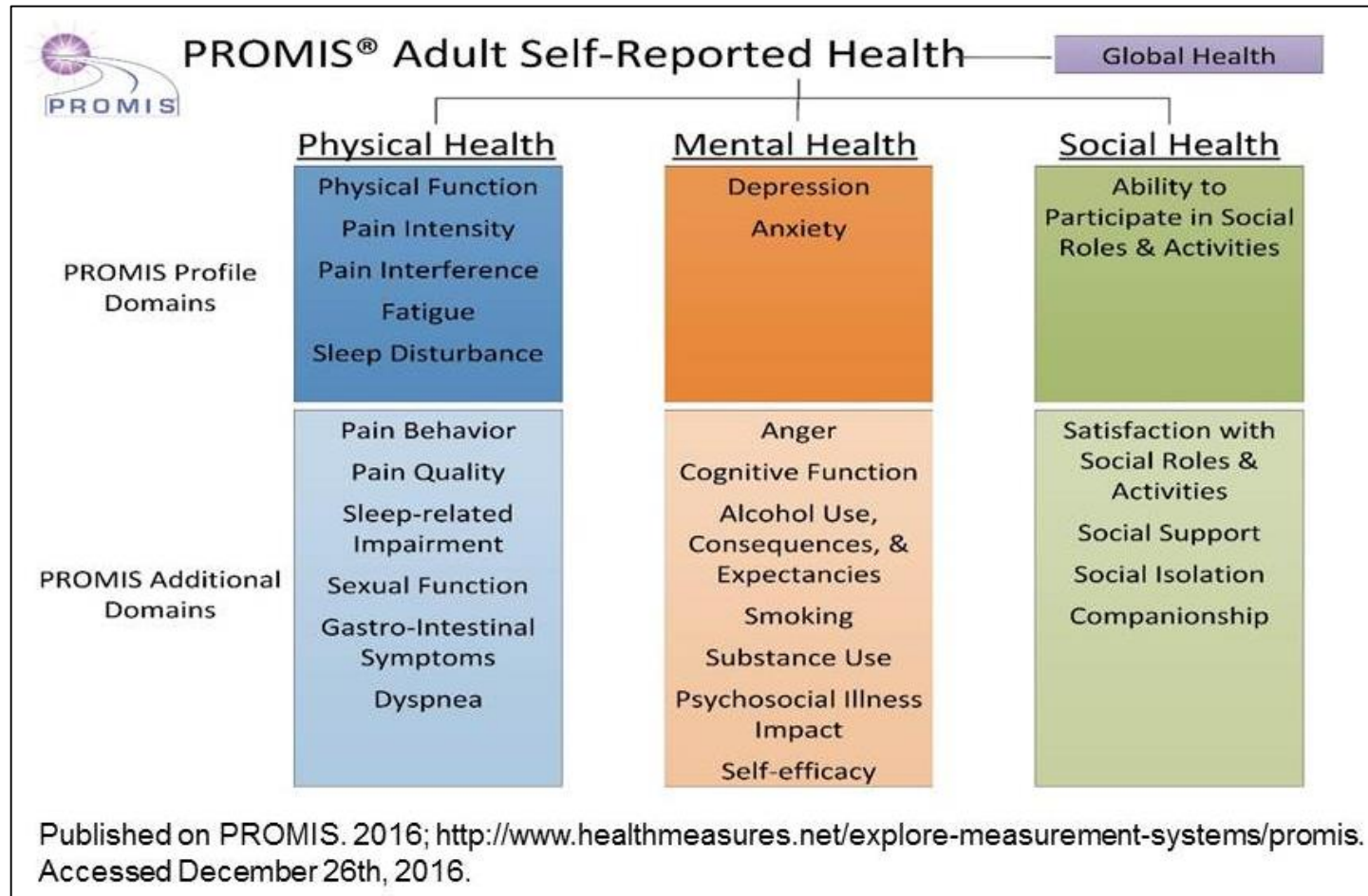


- Measures for both adult and pediatric patients
- **PROMIS-29: Multi-domain profile measure:**
  - Physical function
  - Anxiety
  - Depression
  - Fatigue
  - Sleep disturbance
  - Ability to participate in social roles and activities
  - Pain interference
  - Pain intensity





# Generic Health-Related Quality of Life



# Kidney Targeted HRQOL: KDQOL-36 (1)

- ❖ 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

<sup>a</sup>Hays, et al. *Qual Life Res.* 1994



# KDQOL-36 (2)

Composite	Reliability	n of Items	Sample Item
Burden of Kidney Disease	0.85	4	“My kidney disease interferes too much with my life”
Symptoms/ Problems with Kidney Disease	0.83	12	“To what extent are you bothered by chest pain?”
Effects of Kidney Disease	0.85	8	“How much does fluid restriction from KD bother you?”

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

<sup>a</sup>Peipert, et al. *Am J Kid Dis*. Under Review.



# KDQOL-36 (3)

	KDQOL Burden	p-value	KDQOL Symptoms	p-value	KDQOL Effects	p-value
<b>Dialysis Type</b>						
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
<b>Diabetes</b>						
Yes	51	Ref	78	Ref	73	Ref
No	54	<0.001	80	<0.001	75	<0.001



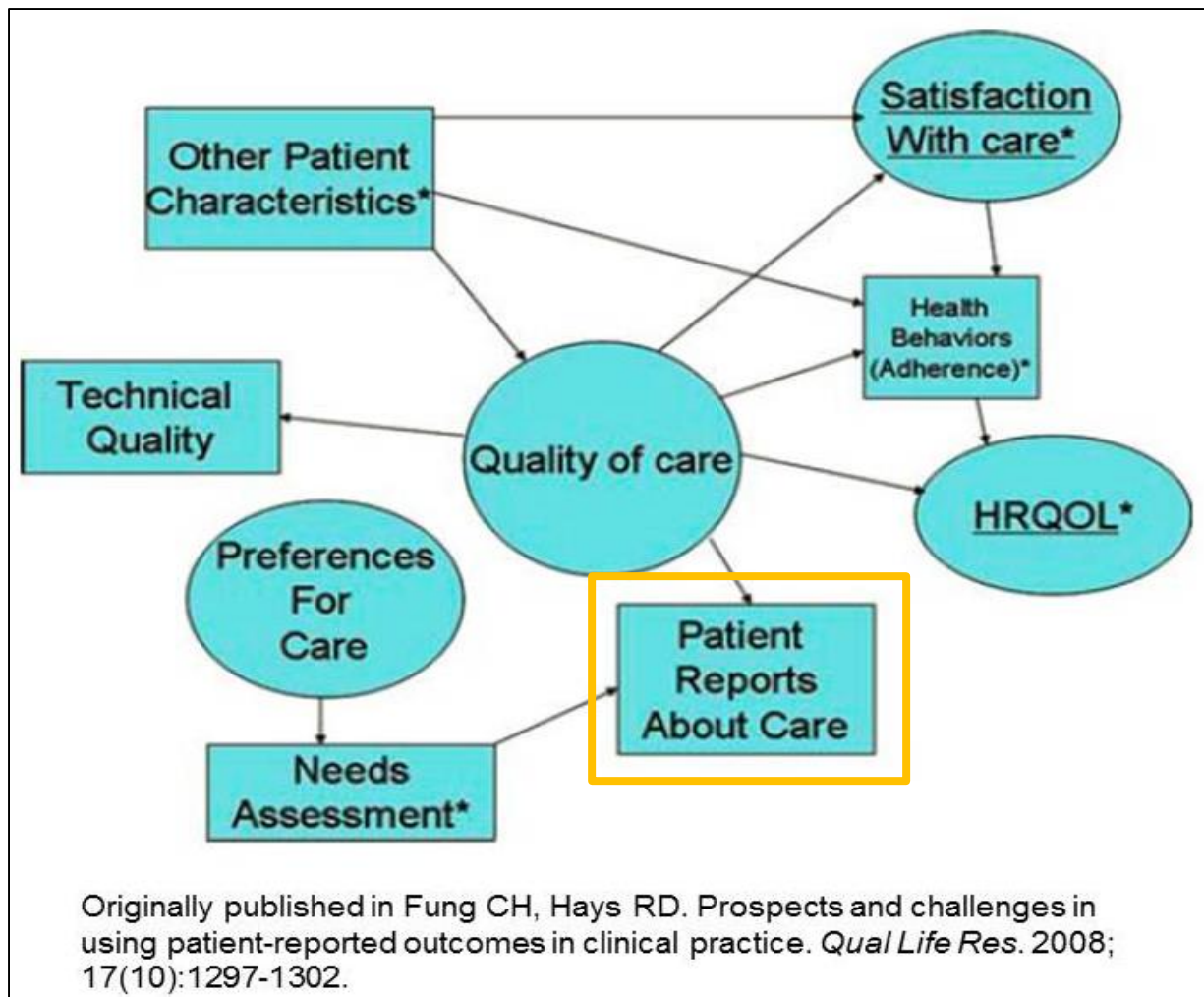
# Recommendation 1.1

*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 with PROMIS items*



# Fung & Hays Framework



# 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>



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# 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	Reliability	n of Items	Sample Item
Nephrologists Communication and Caring	0.89	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	0.93	9	“Did dialysis center staff at this center ever review your rights as a patient with you?”
Quality of Dialysis Center Care & Operations	0.75	17	“In the last 3 months, how often did the dialysis center staff show respect for what you had to say?”

+3 global items

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

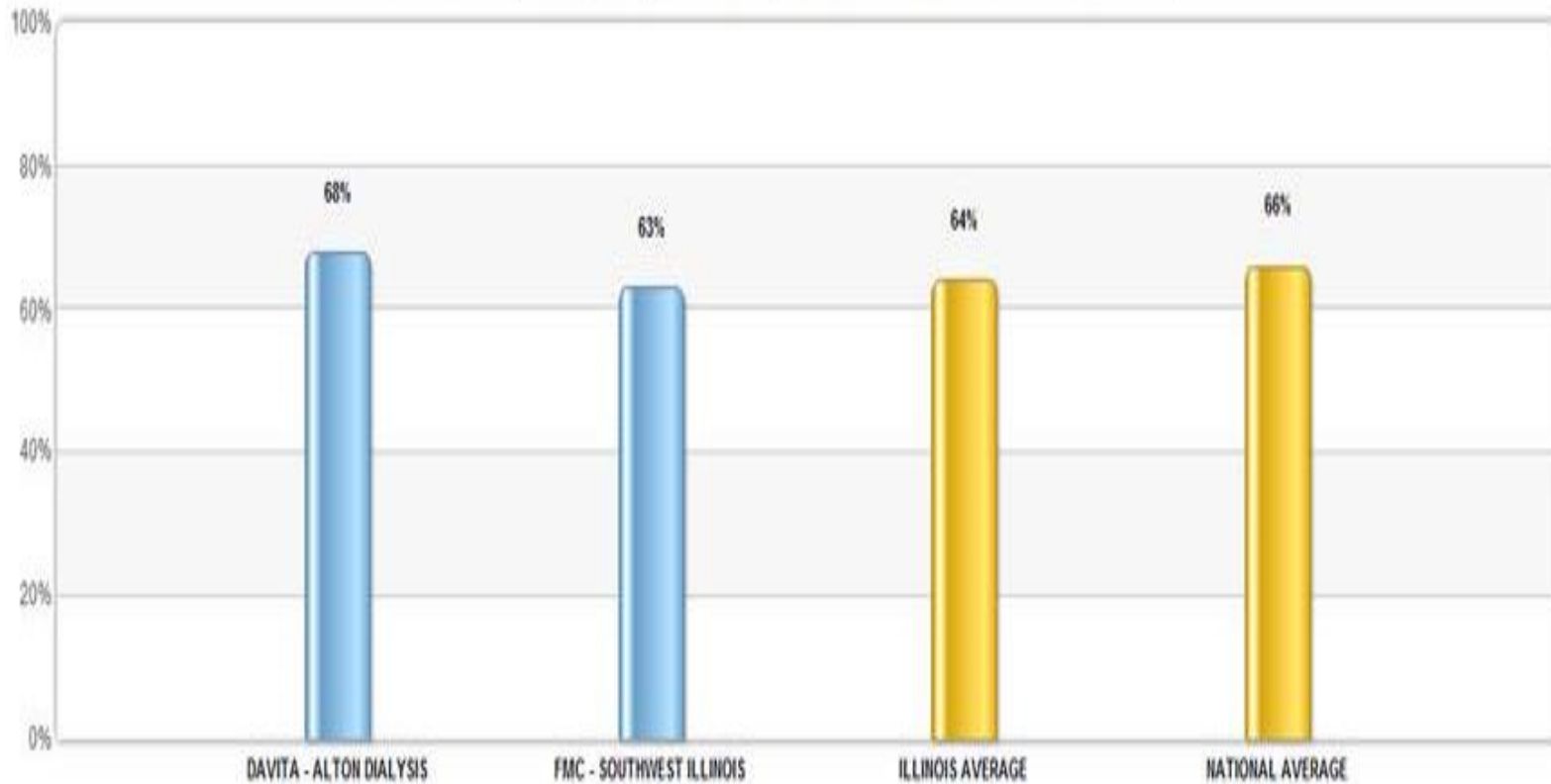


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# Inclusion in CMS QIP and Dialysis Facility Compare

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



## Recommendation 1.2

*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 of their options?

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

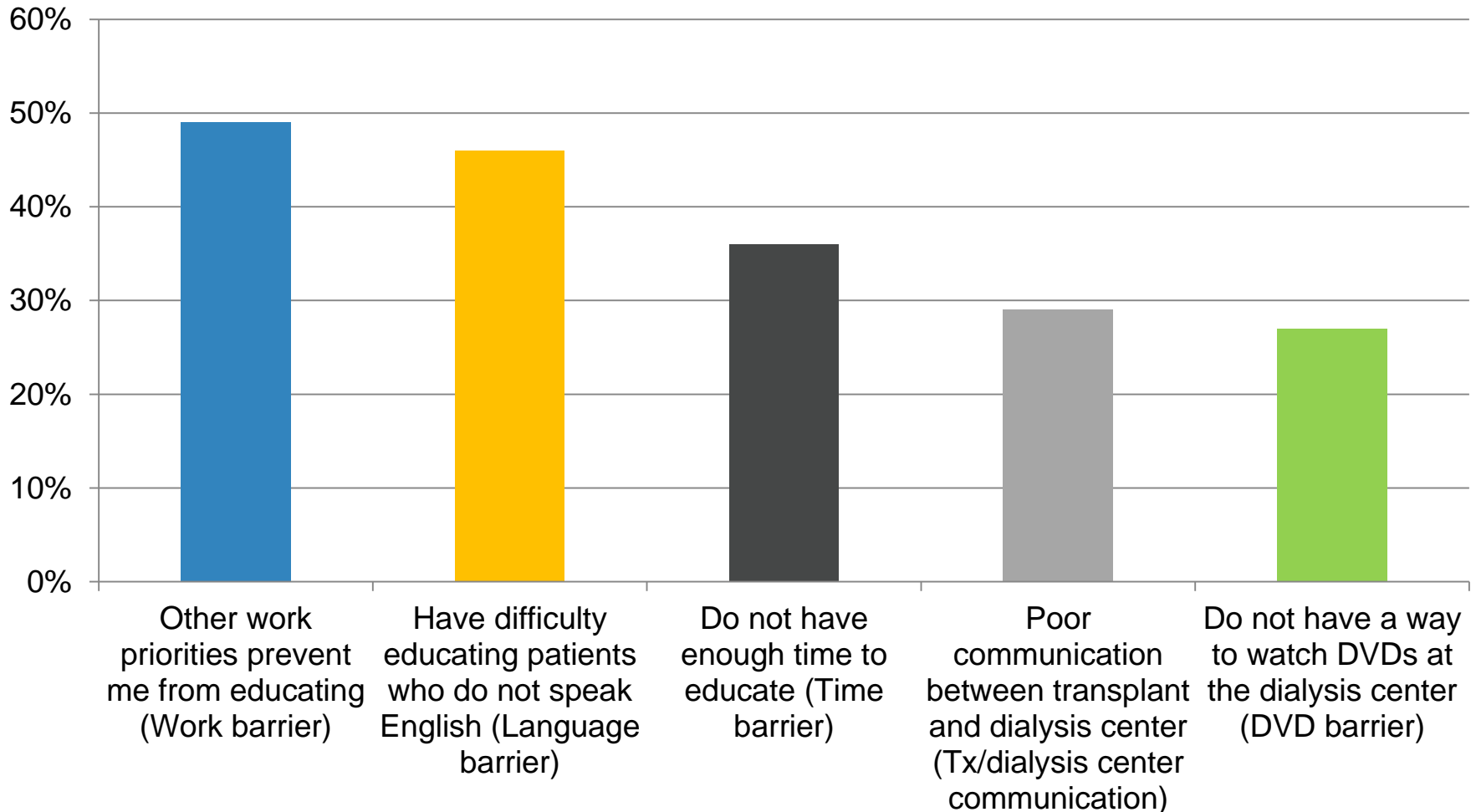
Patient-Reported KTPI	Provider-Reported KTPI		Total
	No	Yes	
No	30	108	138
Yes	32	218	250
Total	62	326	388

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. *J Am Soc Nephrol*. 2014.



# Transplant Education Barriers



Waterman, et al. *Am J Transplant*. Under Review.



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# Predictors of Using Intensive Transplant Education Strategies

Odds of Using 'Intensive Education' Strategy (>1 Practice)	Adjusted OR (95% CI)
Years of working with dialysis patients (dichotomized at median)	1.59 (1.26-2.01)
<b>Provider transplant knowledge (dichotomized at median)</b>	<b>1.27</b> <b>(1.01-1.60)</b>
<b>Tx/dialysis communication barrier</b>	<b>0.76</b> <b>(0.58-0.98)</b>
<b>Work priority barrier</b>	<b>0.66</b> <b>(0.52-0.84)</b>

Waterman, et al. *Am J Transplant.* Under Review.



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# Recommendation 1.3

*Adopt a PRM of whether patients have been informed about all their transplant and dialysis options*







## II. 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	



# Mode of Administration Matters: RCT of Mode on ICH-CAHPS Scores

Composites and Global Ratings	Mixed-Mail Model (n)	Mixed-Telephone Mode (n)	Telephone Only Mode (n)	p-value for difference in group means
Doctor Communication and Caring	77.4 (567)	76.4 (162)	75.6 (650)	0.47
Quality Dialysis Care/Operations	79.1 (567)	80.5 (162)	81.2 (650)	0.14
Providing Information to Patients	<b>78.0 (567)</b>	<b>69.6 (162)</b>	<b>73.4 (650)</b>	<b>&lt;0.001</b>
<b>Global Rating Items</b>				
<i>Q9 Global Doctor Rating</i>	82.1 (557)	87.4 (160)	81.9 (642)	<b>0.008</b>
<i>Q39 Global Staff Rating</i>	83.0 (561)	84.6 (159)	85.6 (647)	0.06
<i>Q43 Global Center Rating</i>	81.7 (561)	87.2 (161)	88.5 (646)	<b>&lt;0.001</b>

Peipert, et al. *In preparation*



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# 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
  - E.g., Updates to instructions and formatting



# Recommendation 2

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



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# III. Increasing Support for PRM Use in Dialysis



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# 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 3

*Launch new efforts to identify mechanisms for CMS, ESRD Networks, and other kidney organizations to reimburse 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 4

*Continue 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



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Thank You!  
Questions?



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