

# **End-Stage Renal Disease Patient-Reported Outcomes Technical Expert Panel**

*Summary Report*

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*In-Person Meeting, Baltimore, MD  
May 23-24, 2017*

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# ***End-Stage Renal Disease Patient-Reported Outcomes Technical Expert Panel Summary***

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The Centers for Medicare & Medicaid Services (CMS) has contracted with The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to convene a Technical Expert Panel (TEP), including patients and experts with relevant experience, to evaluate and make recommendations regarding the development of patient-reported outcome (PRO) measures.

## ***TEP Objectives***

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The objectives of the End Stage Renal Disease (ESRD) Patient-Reported Outcomes (PRO) Technical Expert Panel (TEP) are described in the TEP charter provided (Appendix A) to TEP members prior to the in-person meeting. The TEP was tasked with the following: (1) Review existing health-related quality of life (HRQoL) measures and recovery time measures and the PROMIS set including evaluating evidence and usability for patients and providers; address existing testing or need for psychometric testing within the ESRD population; and data collection feasibility and (2) Make recommendations on the potential development of PRO measures including health-related quality of life, recovery time, and measures derived from PROMIS item banks/domains, or potentially other measures identified by the TEP.

## ***TEP In-Person Meeting***

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The in-person ESRD PRO TEP was convened in Baltimore, MD, on May 23, and 24, 2017.

The TEP consisted of individuals from the following areas of expertise or experience:

- Patients and consumers with experience with dialysis;
- Clinical treatment of ESRD;
- Dialysis organization operation;
- PRO measure expertise;
- Methodological expertise (including psychometric testing).

The TEP was tasked with discussing the following topic areas:

- Existing health-related quality of life (HRQoL) measures;
- Existing recovery time measures;
- PROMIS measure set;
- Address existing testing or need for psychometric testing within the ESRD population;
- Data collection feasibility;
- Future development of PRO measures including health-related quality of life, recovery time, and measures derived from PROMIS item banks/domains, or potentially other measures identified by the TEP.

**The following individuals participated in this TEP:**

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest Declared
<p>Jennifer Flythe, MD, MPH <i>TEP-co-chair</i></p> <p><i>Medical Director</i></p> <p><i>Assistant Professor and Research Fellow</i></p>	<p>University of North Carolina Hospitals Dialysis Services, Chapel Hill, NC</p> <p>University of North Carolina at Chapel Hill, Chapel Hill, NC</p>	<p>Research grant from Renal Research Institute (RRI) to develop a PRO related to fluid symptoms management.</p>
<p>Michelle M. Richardson, Pharm D. <i>TEP-co-chair</i></p> <p><i>Director of Dialysis Outcomes Programs, Director of Communications, and Assistant Professor of Medicine</i></p> <p><i>Director, Outcomes Monitoring Program</i></p>	<p>Tufts Medical Center, Boston, MA</p> <p>Dialysis Clinic Incorporated, Nashville, TN</p>	<p>Dialysis Clinic, Inc. has a contract with Tufts Medical Center to pay Dr. Richardson’s salary for directing the Outcomes Monitoring Program. Dr. Richardson is an employee of Tufts Medical Center and was a co-investigator on Chronic Kidney Disease-Computerized Adaptive Testing (CKD-CAT), a potential survey to be considered by this TEP.</p>
<p>Kerri Cavanaugh, MD, MS <i>Medical Director</i></p> <p><i>Associate Professor of Medicine</i></p>	<p>Vanderbilt Dialysis Clinic-Campus</p> <p>Division of Nephrology &amp; Hypertension, Department of Medicine, Vanderbilt University Medical Center Nashville, TN</p>	<p>None</p>
<p>Paul T. Conway, BA <i>President</i></p> <p><i>Board Member</i></p> <p><i>Board Member</i></p>	<p>American Association of Kidney Patients (AAKP)</p> <p>Mid-Atlantic Renal Coalition (MARC)</p> <p>Polycystic Kidney Disease Foundation (PKDF)</p>	<p>None</p>

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest Declared
<p>Lorien S. Dalrymple, MD, MPH <i>Vice President of Epidemiology and Research</i></p> <p><i>Volunteer Clinical Faculty, Associate Professor</i></p>	<p>Fresenius Medical Care North America (FMCNA)</p> <p>Department of Medicine, Division of Nephrology, University of California, Davis</p>	<p>Employed by Fresenius Medical Care NA, member of the Kidney Care Quality Alliance (KCQA) Steering Committee, and participates in a patient-reported outcomes initiative.</p>
<p>Derek Forfang <i>Board of Directors Member and Kidney Patient Advisory Council Chair</i></p> <p><i>Kidney Advocacy Committee Member and Public Policy Committee Member</i></p>	<p>National Forum of ESRD Networks</p> <p>National Kidney Foundation</p>	<p>None</p>
<p>Patrick O. Gee <i>Patient Advisory Committee Chair and Subject Matter Expert</i></p> <p><i>Kidney Advocacy Committee Member</i></p>	<p>Quality Insights Mid-Atlantic Renal Coalition Network 5</p> <p>National Kidney Foundation</p>	<p>None</p>
<p>Jennifer Geiger, MSW, LSW, NSW-C <i>Regional Lead Social Worker</i></p> <p><i>Medical Review Board Member</i></p>	<p>Fresenius Medical Care North America (FMCNA)</p> <p>Quality Insights Renal Network 3</p>	<p>None</p>
<p>Amanda Grandinetti, MPH <i>Senior Specialist, Performance Measures and Analysis</i></p> <p><i>Kidney Action Committee Member</i></p>	<p>American Academy of Dermatology</p> <p>National Kidney Foundation</p>	<p>None</p>

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest Declared
<p>Lori Hartwell <i>Founder and President</i></p> <p><i>Board of Directors Member</i></p> <p><i>NQF Renal Standing Committee Member</i></p>	<p>Renal Support Network</p> <p>Kidney Care Partners</p> <p>ESRD National Quality Forum</p>	None
<p>Daniel Iniguez <i>Secretary of the Board of Directors</i></p>	<p>Dialysis Patient Citizens</p>	None
<p>Jacqueline Javier-Burns, RN <i>Director of Patient Care Services</i></p>	<p>Queens Long Island Renal Institute, New Hyde Park, NY</p>	None
<p>Michael "Jack" Lennon, MBA <i>Program Manager</i></p> <p><i>Medical Advisory Committee Member</i></p>	<p>Division of Nephrology and Hypertension, Cincinnati Children’s Hospital Medical Center, Cincinnati, OH</p> <p>National Kidney Foundation of Greater Cincinnati, OH</p>	None
<p>Klemens Meyer, MD <i>Director of Dialysis Services</i></p> <p><i>Professor of Medicine</i></p> <p><i>Medical Director</i></p>	<p>Tufts Medical Center, Boston, MA</p> <p>Tufts University School of Medicine, Boston, MA</p> <p>Boston, Walden Pond, and Somerville clinics, Dialysis Clinic, Incorporated</p>	<p>Dr. Meyer’s employer, the Tufts Medical Center Physician Organization receives payments from Dialysis Clinic Inc. (DCI) a dialysis provider, for his services as the medical director of DCI facilities; and for his services as DCI’s national Medical Director for Information Technology. DCI also pays for meeting fees, travel, accommodations, and meals and meetings at which Dr. Meyer represents the organization; for travel undertaken on their behalf; Dr. Meyer receives no consulting fees from DCI; he has worked with Investigators including John Ware, PhD and Michelle Richardson, PharmD to develop a computer adaptive tool to evaluate quality of life across the stages of chronic kidney disease. The first has not been published.</p>

Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest Declared
<p>Sherry Rivera, DNP, APRN, ANP-C <i>Nurse Practitioner</i></p>	<p>New Orleans Nephrology Associates, Marrero, LA</p>	<p>None</p>
<p>Brigitte Schiller, MD <i>Chief Medical Officer and Vice President of Scientific Affairs</i></p> <p><i>Consulting Associate Professor</i></p>	<p>Satellite Healthcare, Inc., San Jose, CA</p> <p>Department of Medicine, Division of Nephrology, Stanford University, Palo Alto, CA</p>	<p>None</p>
<p>Nancy L. Scott <i>President</i></p> <p><i>Chairperson of the Board of Directors</i></p>	<p>Dialysis Patient Citizens Education Center</p> <p>Henrietta Johnson Medical Center, Wilmington, DE</p>	<p>None</p>
<p>Francesca Tentori, MD, MS <i>Medical Director</i></p> <p><i>Adjunct Instructor in Medicine</i></p> <p><i>Medical Advisory Board Member</i></p>	<p>Outcomes Research, DaVita Clinical Research, Minneapolis, MN</p> <p>Department of Internal Medicine, Division of Nephrology, Vanderbilt University Medical Center, Nashville, TN</p> <p>American Association of Kidney Patients</p>	<p>Dr. Tentori is a current employee of DaVita Clinical Research. She has received research grants from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Patient-Centered Outcomes Research Institute (PCORI) and a consortium of industry sponsors that support the Dialysis Outcomes and Practice Patterns Study (DOPPS) (see <a href="http://www.dopps.org">www.dopps.org</a> for more details).</p>



Name and Credentials	Organizational Affiliation, City, State	Conflicts of Interest Declared
<p>John E. Ware, Jr., PhD <i>President, Founder, and Chief Science Officer</i></p> <p><i>Professor and Division Chief</i></p> <p><i>Research Professor</i></p>	<p>John Ware Research Group, Watertown, MA</p> <p>Quantitative Health Sciences, University of Massachusetts Medical School, Worcester, MA</p> <p>Department of Medicine, Tufts University School of Medicine, Boston, MA</p>	<p>Dr. Ware is a major shareholder in John Ware Research Group, Inc., an NIH SBIR grant and medical products industry supported corporation, affiliated with University of Massachusetts Medical School, that develops computerized adaptive outcome measures for use in health care research and practice. Dr. Ware was the principal developer and first author of the SF-36, SF-12, and SF-8 Health Surveys and articles documenting their development and evaluation during the Medical Outcomes Study; and, he is a co-author of articles documenting the development and evaluation of PROMIS physical functioning and other domain item banks.</p>

\*Note: One TEP member was unable to attend the in-person TEP meeting.

**Additional Disclosures**

- Dr. Tentori disclosed that she previously worked at Arbor Research Collaborative for Health on projects funded by various industry organizations.
- Dr. Dalrymple disclosed that she is going through the re-appointment process for volunteer faculty at UC Davis.
- Dr. Meyer disclosed that he attended a Kidney Care Quality Alliance (KCQA) meeting related to Patient Reported Outcomes. Dr. Meyer disclosed that he along with Dr. Richardson worked with Dr. Ware on two of Dr. Ware’s Small Business Innovation Research (SBIR) grants.
- Dr. Ware disclosed that he is a co-founder of the Medical Outcomes Trust, which is a nonprofit trust that holds trademarks for many widely used survey tools in this field of PROs. Dr. Ware stated that many of these tools are used commercially under licenses. Dr. Ware disclosed that he has received several grants from the National Institute of Health (NIH). Dr. Ware has consulted with medical product companies that use these tools.
- Dr. Flythe disclosed that she has received research funding from Fresenius Medical Care (FMC) and has received honorarium from various other entities.
- Dr. Richardson disclosed that she and Dr. Meyer have worked with Dr. Ware on two of Dr. Ware’s SBIR grants.

- Prior to the in-person TEP meeting, Dr. Flythe disclosed she had a Research grant from Renal Research Institute (RRI) to develop a PRO related to fluid symptoms management. After the In-person TEP meeting, Dr. Flythe updated her disclosure to reflect that she recently created a steering committee as part of the RRI funded project to develop a PRO related to fluid symptoms management. This committee includes the following PRO TEP members: Derek Forfang, Dr. Lorien Dalrymple, and Dr. Francesca Tentori. Their inclusion on the steering committee came as a result of discussions at the ASN Kidney Health Initiative annual stakeholder meeting and was not related to their TEP participation.

<b>Contractor Staff</b> University of Michigan Kidney Epidemiology and Cost Center (UM KECC)
Claudia Dahlerus, PhD, MA, <i>Principal Scientist</i>
Joseph Messana, MD, <i>Swartz Collegiate Professor of Nephrology, University of Michigan Health System and Interim Director, UM-KECC</i>
Richard Hirth, PhD, <i>Professor of Health Management and Policy</i>
Lan Tong, MPH, <i>Lead Research Analyst</i>
Casey Parrotte, PMP, <i>Project Manager/ Research Analyst</i>
Jennifer Sardone, PMP, <i>Project Manager/ Research Analyst</i>
Jordan Affholter, BA, <i>Research Analyst</i>
Mimi Dalaly, MPH, <i>Research Analyst</i>

# ***1. Introduction***

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This report summarizes the discussions and recommendations of the End Stage Renal Disease (ESRD) Patient-Reported Outcomes (PRO) Technical Expert Panel (TEP).

The in-person ESRD PRO TEP was convened on May 23, and 24, 2017 in Baltimore, MD, as well as two pre-TEP teleconference calls that were conducted on April 24, 2017 and May 5, 2017. Two post-TEP teleconference calls were conducted on July 19, 2017 on August 30, 2017 (see Appendix H and I for the final post-TEP teleconference call minutes).

## ***2. Overview***

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The TEP was tasked to review existing PRO measures for potential future implementation and to provide recommendations on the potential development of PRO measures. The TEP was asked to consider existing health-related quality of life (HRQoL) measures; recovery time measures; and the PROMIS measure set. On the second teleconference, the TEP identified additional measure topics (described later in this report) to be further discussed at the in-person meeting. The TEP also addressed existing testing for the KDQoL-36 as well as the need for psychometric testing of PROMIS and other generic PRO instruments within the ESRD population. The TEP also briefly considered data collection feasibility of PROs.

## ***3. Preliminary Activities***

### ***3.1 Environmental Scan and Literature Review***

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Prior to the in-person meeting, the TEP was provided relevant materials related to Patient-Reported Outcomes:

- Report on Patient-Reported Outcomes (PROs) that UM-KECC produced for the Centers for Medicare and Medicaid Services (CMS) (January 2017);
- Patient-Reported Outcomes (PROs) in Performance Measurement report by the National Quality Forum (NQF) from 2013;
- Results of Environmental Scan of NQF endorsed PRO Measures;
- Existing PRO Instruments: Kidney Disease Quality of Life-36 (KDQOL-36) survey, the 36-Item Short Form Health Survey (SF-36), Patient-Reported Outcomes Measurement Information System (PROMIS) Measure Set (See the appendices for Exhibit #3-5. The PROMIS Tools were downloaded on March 29, 2017 from the HealthMeasures.net website at the following link: <http://www.healthmeasures.net/explore-measurement-systems/promis/obtain-administer-measures>); and the one question Recovery Time measure (Lindsay et al, 2006);
- Patient-Reported Outcome TEP Overview of PRO Measures;
- Annotated Bibliography of studies and reviews of PROs;
- Select articles from the Annotated Bibliography.

## ***3.2 TEP Charter***

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The PRO TEP Charter was publicly posted with the nomination materials, and was distributed to the TEP members for review. The TEP Charter is included as Appendix A.

## ***3.3 Pre-TEP Teleconference Calls***

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Two 60-minute preliminary teleconference calls preceded the in-person TEP meeting. These calls were held on April 24, 2017 and May 5, 2017.

The first pre-TEP teleconference call focused on the introduction of the TEP members, the role of the TEP, the TEP Charter, the TEP objectives, and served as an overview of the Existing PRO Measures. The second pre-TEP teleconference call served as an opportunity for TEP members to provide feedback on the Patient-Reported Outcomes topics that are most important to patients from their perspective as patients and also what the clinicians thought would be most important to patients.

The pre-TEP teleconference minutes were provided to the TEP before the in-person meeting on May 23, and 24, 2017.

The pre-TEP teleconference minutes and public comments are included as Appendices C and D.

# ***4. TEP Meeting***

## ***4.1 Introductions***

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Claudia Dahlerus, PhD introduced herself as a Principal Research Scientist at the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC). Dr. Dahlerus (UM-KECC) welcomed everyone to the End-Stage Renal Disease (ESRD) Patient-Reported Outcomes (PRO) Technical Expert Panel (TEP) In-Person Meeting. The other members of the UM-KECC introduced themselves to the TEP: Joseph Messina, MD (Clinical Nephrologist, University of Michigan), Richard Hirth, PhD (Health Economist and Professor of Health Management and Policy, University of Michigan), Lan Tong (Lead Research Analyst, University of Michigan), Jennifer Sardone (Project Manager/ Research Analyst, University of Michigan) and Jordan Affholter (Research Analyst, University of Michigan).

Dr. Dahlerus, Dr. Messina, and Dr. Hirth are the TEP co-facilitators for the PRO TEP.

Jesse Roach, MD introduced himself as a nephrologist working for Centers for Medicare & Medicaid Services (CMS). Dr. Roach (CMS) thanked the TEP members for their participation in this project. Later in the meeting, Joel Andress, PhD (CMS) and Elena Balovlenkov, RN (CMS) introduced themselves. Joel Andress, PhD (CMS) is the Project Contracting Officer's Representative (COR). Elena Balovlenkov, RN, (CMS) is the Dialysis Facility Compare (DFC) Lead for Public Reporting.

Dr. Dahlerus asked TEP members to introduce themselves and provide any updates to their conflict of interest disclosure originally provided when they applied for the TEP. The TEP Members introduced themselves and disclosed their conflicts of interest. The TEP member affiliations and conflicts of interests are documented in the TEP In-Person Meeting section of this document.

## ***4.2 “Overview of Measure Development Process” Presentation, Claudia Dahlerus, PhD (UM-KECC)***

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Dr. Dahlerus (UM-KECC) began with an overview of the In-Person TEP Meeting agenda and provided an overview of the measure development process. Dr. Dahlerus explained that CMS uses the Measures Manager Blueprint (Centers for Medicare & Medicaid Services, 2016) to guide measure development and implementation. Quality measures are developed based on expert opinion and stakeholder input through TEPs; measures go through stakeholder review and input through the public comment period and through review by the National Quality Forum (NQF). Developed measures are proposed for public reporting through the Dialysis Facility Compare (DFC) Program and/or the ESRD Quality Incentive Program (QIP).

Dr. Dahlerus explained the objective of the PRO TEP is to provide preliminary recommendations on candidate measure concepts in area of PROs.

Dr. Dahlerus explained that NQF evaluates quality measures based on the following criteria (National Quality Forum, 2017):

- Importance to Measure and Report: Evidence, Performance Gap, and Priority (Impact);
- Scientific Acceptability: Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care;
- Feasibility: Data that are readily available or could be captured without undue burden;
- Usability: Stakeholders (e.g., consumers, purchasers, providers, policy makers) can use measure performance results for both accountability and performance improvement.

Additionally, Dr. Dahlerus noted that NQF also considers Comparison to Related or Competing Measures (harmonization) when there are two or more similar quality measures.

As additional background, Dr. Dahlerus explained that in response to increased attention on PROs, NQF produced a report in January 2013 on “Patient Reported Outcomes (PROs) in Performance Measurement” (National Quality Forum, 2013). Dr. Dahlerus provided the NQF definition of patient reported outcomes which is: “Any report of the status of a patient’s (or person’s) health condition, health behavior, or experience with healthcare that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else” (U.S. Food and Drug Administration, 2009).

Dr. Dahlerus went on to explain the NQF PRO Report outlines recommendations on PRO measure development. Dr. Dahlerus presented the “Figure 2. Pathway from PRO to NQF-endorsed PRO-PM” from the NQF PRO Report (National Quality Forum, 2013). Dr. Dahlerus briefly went through the main steps in Figure 2 illustrating the process for developing PRO Measures, noting PROs are also evaluated for scientific acceptability (reliability and validity testing) by using the same basic criteria that NQF applies to other types of measures.

Dr. Dahlerus provided a brief overview of the TEP objectives (see the TEP objectives section). At this point Dr. Dahlerus handed over discussion to the TEP co-chairs.

## ***4.3 “Brief Summary of What We Know About Health-Related QOL and How to Measure It” Presentation, John E. Ware, Jr., PhD (TEP Member)***

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### **4.3a Presentation**

The TEP co-chairs explained they wanted to make sure everyone had a conceptual understanding of health related quality of life (HRQoL) and a basic understanding of PRO measurement science which will help inform the discussions over the course of the in-person meeting. To provide this background, another TEP member (Dr. John Ware) delivered a presentation on measurement of HRQoL.

Dr. Ware’s full presentation slide set is provided in the ESRD PRO TEP In-Person Presentation, located in Appendix J.

Dr. Ware began the presentation explaining that health has multiple domains or components, which should include the well-being of a patient. Dr. Ware explained that QoL is one of the best predictors of the many important outcomes in health care. QoL predicts various outcomes such as future health, return/ability to work, and mortality in addition to capturing outcomes that are among the most important to most patients.

Dr. Ware provided a brief overview of measurement science in this field, including conceptual and psychometric advances, standardization of QoL content and metrics, and Computerized Adaptive Testing (CAT) methods.

Dr. Ware explained the difference between generic Quality of Life (QoL) measures and disease specific QoL measures (see slide 28 in the ESRD PRO TEP In-Person Presentation, Appendix J). Generic QoL components attributes certain health-related outcomes to general health status, while the disease specific QoL component attributes symptoms/outcomes to a specific disease. Dr. Ware stated this increases the ability of individual questions to provide specific measurement information about outcomes related to the disease. Dr. Ware explained that for a single item (in a measure) disease specific attribution is important because it shifts focus to that disease as opposed to other diseases, or to health in general.

Dr. Ware explained some survey instruments only measure a negative outcome, for example if a patient feels fatigue or other bothersome symptoms. Often QoL survey instruments do not include items that ask about the positive range of health-related QoL, for example, questions asking the patient if they feel they have a lot of energy, feel positive about life, and so forth.

Dr. Ware explained that in the general population measures of patient-reported outcomes (PROs) have problems with ceiling effects, i.e., most people scoring high on an item(s). For example, if the upper end of a physical functioning scale is the ability to walk several flights of stairs without any difficulty or problem, most respondents in a general population will achieve the highest score, and the scale will not effectively differentiate among them. Dr. Ware went on to give some examples to demonstrate how items can be scaled in order to provide more information at higher levels of functioning. Dr. Ware displayed a physical functioning question that allowed some respondents to score an item from “Not at all” to “Extremely” difficult. Dr. Ware then explained that in his work with PROMIS and other item banks in the physical domain, rescaling responses to this item (on functioning) from “very easy” to “very

difficult” raised the ceiling to enable respondents to score higher on the item range and to provide more useful information (Liegel et. al, 2017). Additionally, this scale was easier for patients to interpret.

Next, Dr. Ware described Computer Adaptive Testing (CAT) methodology which reduces the number of questions needed in a survey. Adaptive testing does not ask redundant items or items not appropriate given the respondent’s level of health. The psychometric basis for the CAT method is Item Response Theory (IRT). The method enables comparison (cross-walk) of scores for respondents who answer different items including those derived from different QoL instruments for the same domain. Once the IRT model estimates where a patient is likely to score based on an initial question item, survey items are then matched to that patient’s level. Thus, CAT scores responses and selects follow-up questions based on the initial scoring of the preceding item(s). CAT can also compute the reliability of a patient’s score. Other static surveys, such as the KDQoL-36, administers all items to every patient regardless of their contribution to score precision and does not estimate the reliability of each patient’s score.

For the visual example of how CAT works, please see Dr. Ware’s full presentation in Appendix J.

Dr. Ware summarized other advantages of CAT: more accurate risk screening; less respondent burden; manages ceiling and floor effects; and allows data quality and precision monitoring in real time. Dr. Ware stated the CAT alone does not solve the respondent burden problem. Because QoL has multiple domains, e.g., physical, vitality, mental health and social health domains, a CAT for every domain may not be enough to sufficiently reduce total respondent burden.

### **4.3b TEP Questions on Dr. Ware’s Presentation**

The TEP co-chair opened up the discussion to any TEP questions for Dr. Ware.

One TEP member asked whether using the CAT would allow one to see improvement in patients’ (HRQoL) scores over time. For example, if a patient was getting better, would the questions be different for them the next time they take the survey. Dr. Ware explained that even though people may answer different questions (each time), the psychometric method enables scores to be meaningfully compared. Dr. Ware explained that each item is an unbiased estimate of the domain score and that CAT does not ask inappropriate and redundant questions.

The TEP member asked how attributing symptoms to a disease adds information (i.e., impact on a person’s QoL). Dr. Ware explained that no measures are so specific that any change in a measure can be interpreted automatically as an outcome of a particular disease or symptoms. Dr. Ware explained that a QoL survey with a disease-specific attribution or focus has been shown to give a better signal about changes in patient quality of life that may be attributed to the disease (and symptoms), but to attribute causality requires a good measure and an experimental design.

## ***4.4 Discussion: Patient and Provider Perspectives on current HRQoL measures***

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### **4.4a Patient Perspectives on current HRQoL measures**

The TEP co-chair asked the patient TEP members to share their experience on taking the KDQoL (or other HRQoL) surveys; whether they get their results or if they are discussed, and how they feel it

impacts patient care. A range of perspectives was shared. Note, where needed to illustrate the patient perspective, we indicate responses from patient TEP members.

Patient TEP members all stated there is a need for the HRQoL surveys to impact care and for patients to hear back from their providers on the HRQoL survey results and how they were used. Some patients stressed the importance of facilities explaining the purpose of the HRQoL survey to patients which may give patients incentive for filling out the surveys. It should be explained to patients that the purpose of the HRQoL survey is to improve quality of life. Several patients explained they want to complete the HRQoL surveys if it contributes to the common good or well-being for patients. However, many patients feel that currently HRQoL survey administration is a “check-box” process that facilities have to complete but that the HRQoL survey does not impact their care. Many patients stated it was unclear if anyone was reviewing the HRQoL surveys they completed.

The patient TEP members shared their perspectives on burden. Several patients stated the HRQoL surveys are burdensome when they do not amount to anything. However, if patients hear back about the HRQoL survey results they will often not view completion as burdensome if it contributes to their patient care. Specifically, one patient stated that in their organization they have not heard much concern about survey burden, but have heard that patients are interested in contributing to something that makes an impact on care.

One patient TEP member stated patients are interested in giving feedback to their providers and facilities but there is not a great tool right now for providing such feedback.

Another patient TEP member stated they were in favor of an experience of treatment measure from the patient’s perspective, which would be more relevant than a HRQoL PRO measure. The patient TEP member stated that sometimes the HRQoL survey is burdensome for a patient, for example, if they are completing it in the dialysis chair during their dialysis treatment. The patient TEP member referenced that they had received health care in a different setting where patients provided answers to several questions about their treatment experience right as they left the center. The TEP member felt this was less burdensome.

One patient TEP member provided a personal experience where they had a major treatment issue related to acute hospitalization care and provided that feedback on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. In that situation, the patient had no follow-up despite the fact they reported a major treatment issue. The patient TEP member felt that no follow-up from providers discourages patients from completing the surveys.

Another patient TEP member stated there are HRQoL metrics that may be applicable to the dialysis setting.

One patient TEP member stated they did not mind receiving the HRQoL survey when they are in the chair receiving dialysis treatment; another patient TEP member stated most patients in the chair on dialysis do not want to do anything other than to sleep or to watch television.

One provider TEP member stated the patients that fill out the HRQoL surveys on their own (i.e., without social worker assistance) often do not get follow-up from the social worker, but patients who do not fill it out on their own get one on one time with the social worker to go through the HRQoL survey. The TEP member explained that unfortunately those patients who are engaged (and complete the survey on their own) do not get that extra attention. TEP members also noted that often social workers have to



split their time between multiple facilities, which can reduce the time they have available for all patients.

One patient TEP member stated that the patients on the TEP are very engaged (and may not be representative of all patients) but it may be difficult to reach patients who are not engaged in their care.

#### **4.4b Provider Perspectives on current HRQoL measures**

One provider TEP member stated that when they used the SF-36 (i.e., Medical Outcomes Study Short Form-36) in the past they went through the results with their patients. The TEP member stated they found going through the survey was very helpful for learning about and understanding patients. The provider stated that the next step (after completing a HRQoL survey) is to identify how to address the patient's problems or symptoms. For example, the provider stated there are challenges in coordinating care such as trying to refer a patient to a physical therapist. The provider also stated that getting a mental health referral for a patient is very difficult because of the insurance coverage limitations. The TEP member stated that it would be important for the survey to be really meaningful at the individual patient level in order for the survey to be successful.

Several provider TEP members presented information on their dialysis organization's experience with HRQoL.

The TEP co-chair stated that their organization started using the SF-36 in the 1990s. The program's goals were to use the surveys to improve patient care, facilitate survey administration, educate clinic staff on how to use results, process data, produce reports, and help implement results into patient care. The TEP co-chair stated their organization uses both the KDQoL-36 and the "SF-36+24" survey (which includes the 24 kidney disease specific questions from the KDQoL-36) for adult patients and the PedsQL (Pediatric Quality of Life Inventory™) for pediatric patients. The facility social worker is responsible for facilitating the HRQoL survey completion. The TEP co-chair stated when patients take time to complete the survey, their results should be used in care.

The next provider TEP member shared information about their organization's survey distribution. The provider stated their organization's patients complete several surveys including the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems Survey (ICH CAHPS), KDQoL-36, and a depression screening tool. The TEP member stated their organization does have concerns about patient burn out (from filling out a lot of surveys), and often the (KDQoL-36) survey is filled out as a "favor" to the social worker. They felt patients are discouraged because they often do not hear back after taking the KDQoL-36 survey. The provider stated the expectation is that social worker is supposed to go back and speak with the patients (about the results) once the survey has been completed. The provider stated it is expected the survey results are taken to the care team for review. The provider did state that the social workers follow-up with patients based on the depression screening. The provider further reported their organization has done some work on the recovery time, that is, they have been asking their patients how long it takes them to recover from dialysis and that patients were very appreciative when they were asked this question. The provider also presented initial results showing a distribution of how long it takes patients to recover from dialysis.

A third provider TEP member presented information on their organization's experience with KDQoL-36. The TEP member stated the social workers are responsible for administration of the KDQoL-36 survey. The TEP member stated their organization's social workers hear that patients are interested in having the conversation around HRQoL (i.e., KDQoL-36 survey results) with their social worker. The TEP

member stated the patients who fill out survey tend to be a younger, healthier, and have less comorbidity burden. The TEP member presented KDQoL-36 scores which showed they were similar across different modalities.

The TEP co-chair opened up the discussions for any follow-up questions or comments.

One TEP member stated that even if the facility is not getting back to patients, the facility staff is reviewing the survey.

## ***4.5 Discussion: Prioritization of Patient-Reported Outcomes***

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### **4.5a Introduction to the Prioritization of Patient-Reported Outcomes Discussion**

The TEP co-chair gave a brief review of the charter objectives explaining what the TEP was tasked to do, including the review of existing quality of life measures and the PROMIS set (of measures). The TEP co-chair explained that the particular measures identified in the charter were based on stakeholder input UM-KECC received last year as part of their information gathering on PROs for the PRO Report prepared for CMS.

The TEP co-chair briefly described the framework for the prioritization of patient-reported outcomes (PROs) discussion which included these steps: 1) Prioritization of PROs based on patient/stakeholder feedback regardless of facility practices or influence, 2) Identification of the prioritized PROs that are attributable to facility practices/influence, 3) Identification of PROs from steps 1 and 2 that meet criteria for evidence and actionability, and 4) Identifying any existing PRO-Measures that capture topics or domains highlighted in the previous steps.

The TEP co-chair explained this was just a framework and could be changed but the first part of discussion was the prioritization of PROs based on patient and other stakeholder feedback. Furthermore, the co-chair explained that facility influences (attributability) and practices would be a separate point of discussion. The TEP co-chair recognized there is lack of evidence in this area of attributability, but there should be discussion of what the evidence is to inform prioritization, develop measures and make the measure actionable. The TEP co-chair explained that after prioritizing topics the TEP can determine which among these topics/PROs facilities can influence or improve.

The TEP co-chair presented a list of topics that were identified from the 2<sup>nd</sup> teleconference call (see appendix F). To facilitate discussion, the items were grouped under different topic areas. The TEP co-chair stated all items mentioned on teleconference #2 were included. A TEP member asked if the TEP should concentrate more on health status/health-related quality of life or health services (i.e., patient experience of care). The TEP co-chair answered that although they do relate to each other (e.g., poor experience of care may impact on HRQoL), the TEP was not charged with focusing on health services. There was a question for CMS from a TEP member, regarding if the focus of the discussion should be on existing measures (i.e., feedback on ICH CAHPS). CMS responded it should not be the focus of the TEP. Additionally, CMS indicated there would be an opportunity (separately) to share feedback with the ICH CAHPS team.

Note that throughout this session of the TEP, discussion frequently shifted among multiple topics, specifically HRQoL, patient experience of care at the facility, life goals, and symptoms, as several felt

these topics are related. To maintain clarity, the discussion summaries are organized by the main topic groupings in the subsequent section summarizing this session of the TEP discussion. Additionally, where needed to illustrate the patient perspective we indicate responses from patient TEP members.

#### **4.5b Patient Experience of Care**

The first topic area discussed was *Patient Experience of Care*. There was TEP discussion on what qualifies as patient experience of care. The TEP co-chair explained that some items (such as cramping) may fall under symptoms or symptom management. The TEP co-chair explained patient experience of care items could include items such as interactions with staff and patients. The TEP co-chair asked the TEP to verify if they were in agreement with the presented grouping of the patient experience of care topics (see slide 86 on Appendix J) and if these could be put aside for now to allow for further discussions on the other groupings which were the focal point of the TEP charter objectives. The TEP co-chairs explained that several of the items related to patient experience of care are captured by the existing ICH CAHPS instrument. The TEP co-chairs and TEP agreed to set aside the items related to patient experience of care items during this part of the discussion and move onto the next grouping section.

One TEP member brought up the point that they consider experience of care as their experience with the (dialysis) treatment. They suggested focusing on the actual experience of treatment and how it effects the patient's health. For example "did I cramp on dialysis", "feel nauseous?" They stated that focusing on the patient's treatment gives the physician a tool to address/improve their treatment (symptoms). They felt if a patient is feeling better, then that can improve the patient experience with care and interactions with staff.

Another TEP member felt patient experience of care does not entirely capture all the topics listed in the grouping. The TEP co-chair acknowledged that and stated the grouping presented allows for grouping of the range of topics that came up. The other co-chair supported the distinction made by the TEP member between the patient's experience of the treatment (versus staff interactions).

Another TEP member stated that standardized surveys do not apply to all kinds of patients (e.g., pediatric patients who do not fill out surveys; or very sick and old patients that are not cognitively or physically able to respond to surveys). They felt this was an important point to recognize because it leaves out a subpopulation of patients.

During further discussion, TEP members gave examples of the range of patient experiences and how that may relate to aspects of HRQoL (e.g., loss of hope). TEP members acknowledged it is difficult to define and capture the relationship between patient experience of care and HRQoL. There was further acknowledgement that patient experience of care is related to HRQoL, but the TEP co-chairs restated the goal should not be to come out with something that measures patient experience of care, because that is already captured in an existing measure (i.e., in the ICH CAHPS). The TEP co-chairs stated that although patient experience of care is already being captured (i.e., in the ICH CAHPS), that does not exclude that topic from being important, but the charge of the TEP is to capture PROs not captured in ICH CAHPS.

In relationship to HRQoL measurement, a few TEP members discussed how general (non-disease specific) survey instruments may not fit for various patients with ESRD.

## 4.5c Patient Education and Engagement

TEP members discussed the importance of patient empowerment and navigating their own care through patient engagement and patient activation. Furthermore, modality education and disease knowledge were also identified as important by TEP members.

## 4.5d HRQoL

Next, the topics grouped as Health-Related Quality of Life (HRQoL) were discussed.

There was TEP discussion on whether facilities are responsible for a patient's HRQoL. One TEP member stated facilities cannot be held accountable for a patient's HRQoL. The TEP member referenced that other factors outside of the facility's control (such as poverty; other social or economic factors) also impact quality of life. The TEP member stated it was therefore important to focus on (dialysis) treatment which is something the facility can influence and has control over.

In response, several TEP members disagreed and stated they believe facilities are accountable for a patient's HRQoL. One TEP member stated that they felt many things on the list (patient experience of care) helps improve their HRQoL.

There was TEP discussion around defining HRQoL as having both social and physical role functioning aspects. For example, poor care at the dialysis facility, and dialysis treatment can all affect a patient's quality of life in general (e.g., social aspects and physical aspects). The TEP noted that the facility plays a large role in health-related quality of life and that facility care and overall facility "service" impacts a patient's life.

One TEP member stated that the disease specific tools are more actionable than the generic (or general) tools. The TEP member compared disease specific tools to a clinically useful barometer that could warn clinicians when something is wrong. The TEP member stated the importance of using a PRO that is as actionable as possible. The TEP member stated that functional items and outcomes may be actionable items that could improve a patient's life. The TEP member stated that while environmental factors may play a large role in a patient's HRQoL, the focus of a patient's health or HRQoL should be individual bodily health, which is more directly actionable by dialysis facilities.

TEP co-chair responded that what the TEP member described is a disease specific measure, noting there is an existing one, KDQoL-36, but that the community has identified short comings in the KDQoL-36. The TEP co-chair asked whether there needed to be discussion about what can be done to improve the existing disease specific QoL measure (i.e., KDQoL-36). There was no direct response but one TEP member proposed a broader question for CMS about how CMS intends to use PROs (i.e., in CMS' public reporting programs).

CMS explained that PROs could be used for public reporting or potentially for the Quality Incentive Program (QIP). CMS provided some additional context on how facilities can get more immediate feedback that is facilitated by patient-reported data. CMS stated PROs allow for collection by a facility (or third party vendor) which in effect gives facilities more timely feedback (in this case from patients) about care and related outcomes. This in turn can support quality improvement through the more direct feedback loop, i.e., patient-reported data.

One TEP member identified other HRQoL topics as important: energy, vitality, and fatigue, anxiety, depression, and resilience. A few TEP members also mentioned the importance of social functioning

and role functioning and also being able to distinguish where the dialysis treatment contributes to HRQoL outcomes versus the disease impacting HRQoL.

The TEP identified potential topics for health-related quality of life which could include symptoms (including fatigue, cramping, lack of appetite, and recovery time), care burden, mental health (including depression and anxiety), physical functioning, social functioning, sexual function, and sleep (see section 4.5h Summary of Afternoon Discussion for the complete list of important PRO topics the TEP identified during the afternoon discussion).

Physical functioning, sexual function, and social functioning were acknowledged as important but some TEP members stated these are things that may be difficult for the facility to impact. These items were marked as having lower priority.

### **4.5e Life Goals and Aspirations**

The discussion of HRQoL transitioned into a discussion of life goals, as well the relationship between the two. TEP members discussed patient-defined life goals as a potential area for quality measure development. Several TEP members felt that achieving life goals (and QoL) can be influenced by dialysis treatment at the facility. One TEP member explained that many patients are not engaged or have not thought about what their life goals and aspirations are, therefore, it is important to get those patients engaged. This can be approached as a partnership between patients and their providers. For example, it is important to have set times where conversations take place between patients and their providers about life goals. Several TEP members referenced the importance of modality choice in achieving life goals and aspirations.

The TEP co-chair stated the importance of facilities and patients having conversations on how to meet life goals while also meeting treatment goals.

One TEP member reinforced the point that patient aspiration needs to be identified in order for patients to *put dialysis (or treatment options) in service* to their aspirations and not have *dialysis determine their aspirations*. That is, discussion of goals (and aspirations) is critical and requires substantive communication among the care team and with the patient. This directly impacts the choices patients make, patient care, trajectory of care, and the options that patients choose and their ability to aspire.

One TEP member stated they felt it is the responsibility of the facility to make sure the dialysis treatment makes patients feel good so they can then go out and pursue what matters to them, but that it is not the facility's responsibility to help patients achieve their goals.

Another TEP member responded that their experience with their facility is that they were not offered treatment (modality options) that might have been better tailored to their own goals (e.g., ability to work or go to school). The TEP member made the point the facility was responsible for helping them achieve their goals as a patient.

Several TEP members felt that HRQoL and achieving their goals are intricately related. The TEP co-chair stated that for the sake of prioritization they would keep life goals and HRQoL as separate topics for now and then consider if there are measures that capture both (topics) when they get to that part of the discussion. The TEP accepted that direction.

Other points made about life goals is how to reach patients that are not activated. One TEP member noted they were not originally an activated patient until they became frustrated with their treatment.

They felt it was important that patients be asked about their goals. TEP co-chair asked how should patients be asked about their goals: e.g., as a reporting measure, process measure, and some kind of documentation that the conversation happened? One TEP member responded that the report needs to come directly from the patient and should reflect that something happened where patients feel the facility is supporting them (in their life goals).

#### **4.5f Symptom and Symptom Management**

Next, there was a discussion of topics within the broader category of symptom and symptom management. The TEP co-chairs gave an example of certain symptoms such as cramping, which is a symptom of treatment (versus overall symptoms which may not be related to treatment). One TEP member stated concerns about a cramping measure, because in order to avoid cramping, it could have an unintended consequence of patients completing dialysis treatment with too much fluid left in their system. Nutrition, appetite, and diet were also briefly mentioned as topic areas under symptoms.

Discussion led off with one TEP member suggesting that they think it is important that patients are able to report specific symptoms that impact whether the patient experiences a bad treatment (e.g., crashing and cramping on dialysis). Reporting whether they had a bad treatment places responsibility on the provider/facility to monitor how many bad dialysis sessions the patient experienced (based on their reporting) and then modify treatment accordingly. The TEP member explained it is important for a doctor to be able to react to the patient's symptoms (during treatment) in order to intervene. They felt this can have an important impact on how patients experience treatment.

One of the TEP co-chairs asked whether it would be helpful to re-frame this question (about whether the patient had a bad treatment) to focus on a positive experience, for example, what a good treatment looks like. The TEP member agreed and gave an example, "How was your treatment, was it tolerable?" A similar question could be the patient reporting if they feel their access is being properly managed or if there is a problem. Another TEP member gave an example question of "How long does it take you to feel back to normal?" This allows the patient to report to their provider how treatment effects them.

One TEP member stated that staff skill and competence matter (because it can affect their ability to address symptoms and treatment effects). They also stated the type of provider matters, because patients are often more willing to listen to doctors (nephrologists) than staff, for example.

In discussing recovery from treatment, some TEP members emphasized measuring this in real time, for example, ask the patient how their last treatment went, rather than asking about how the last three treatments went. In the latter, the recall is harder to distinguish what treatment was bad and the potential reason. TEP members also said recovery time is important for providers to evaluate at regular intervals as a way to keep assessing health after treatment.

Other TEP members agreed. One TEP member said they prefer this question (about how the last treatment went) be asked after every treatment so the provider could respond. They felt this was important because otherwise patients give up when they continually experience bad treatments.

One TEP member described their experience with patients keeping calendars of how they feel and that this has positively impacted their care. The TEP member also felt this can impact HRQoL.

One of the TEP co-chairs summarized the discussion to this point, noting it started very broad in discussing HRQoL and shifted to very specific things such as symptoms. The TEP co-chair asked TEP members how they felt about a symptom-related PRO measure, for example, post-dialysis fatigue and

recovery time, but not defined by a specific recall period. One TEP member responded there could be drawbacks in terms of how the measure would be used to make broader comparisons of facility performance.

Another TEP member stated the goal of a measure is to impact facility quality. For example, measuring how a facility performs in taking into account the patient's health and tailoring treatment and modality to best keep the patient healthy and achieve their goals. To do this, a measure needs to be broad enough so that it drives discussions between the patient and provider.

The TEP co-chair noted that based on the discussion it sounded like a possible measure would be a disease specific measure that addresses specific symptoms but also helps providers to address broader HRQoL issues. Based on the discussion the co-chair stated there seems to be consensus on the importance of the broad topic of HRQoL. The co-chair reinforced that the TEP is not being asked to choose one topic but rather is still considering several topics (as presented at the beginning of the afternoon session).

Another TEP member stated they felt life goals is an important topic. The co-chair responded there was a lot of interest in life goals as being very important and this topic has not been taken off the table.

#### **4.5g Discussion on PRO Measurement**

There was further discussion on attributability of the PROs and topics discussed in the previous session (see section 4.5f Symptoms and Symptom Management), and the ability to accurately measure changes or improvement, e.g., in HRQoL. TEP members discussed the concern over variability among clinics and the importance of using appropriate methods to measure PROs in order to detect true differences (in care quality) between dialysis facilities, especially in domains/topic areas such as physical functioning. Specifically, the TEP discussed that case-mix adjustment may need to be considered (for any future HRQoL measure) in order to appropriately attribute HRQoL outcomes to facility care. There was TEP discussion about the topic of Patient Safety, specifically the importance of patients feeling safe in the facility.

The TEP briefly returned to the topic of life goals. Several stated measurement should be tailored to the individual (patient) because patients will have different levels of life goals and aspirations. The TEP also recognized HRQoL and life goals are related to each other. With respect to HRQoL, one of the TEP co-chairs discussed the importance of measurement at the individual patient-level versus the current instruments that assess HRQoL at the population-level. There was also TEP discussion about whether HRQoL outcomes can be attributed to differences in facility performance.

#### **4.5h Summary of Afternoon Discussion**

Throughout the afternoon discussion, the TEP members and TEP co-chairs produced a list of important PRO topics.

Note, at certain points in the discussion summary and where needed to illustrate the patient perspective we indicate responses from patient TEP members.

The TEP felt both HRQoL and specific symptoms should be on the list. The TEP also felt life goals and patient activation and engagement should be included.

The co-chair set-up the discussion to consider what information exists to support these measure topics. The TEP co-chair opened the discussion on HRQoL topics. One TEP member asked about patient education. The TEP co-chair responded that came up as part of patient engagement and that patient engagement can be added to the list.

Another TEP member asked about adding mental health; another asked about including energy, vitality, and fatigue.

One TEP member said that in becoming specific the TEP should not throw out the possibility of having a generic measure of HRQoL. TEP co-chair responded that the possibility of a generic HRQoL measure is not being thrown out, but that topics are just grouped this way to make sure these topics are included for discussion when the TEP gets to the measure evaluation stage.

One TEP member noted the list has symptoms that are specific and general. The TEP member asked whether the TEP wants to include broader or specific symptoms. For example, mental health is a broader category and encompasses other topics like sleep because it relates to depression.

There was further discussion among TEP members about the importance of sleep and how it impacts other HRQoL outcomes such as anxiety.

The TEP co-chair stated that they heard that physical function was important to the TEP. Additionally, appetite (lack of appetite) was identified as important. Other TEP members suggested adding fear. There was TEP discussion about fear of treatment and feeling safe. One of the co-chairs stated this falls under patient experience of care and that per the earlier discussion the TEP agreed to set aside for the time being patient experience of care. The TEP co-chair stated that the TEP can have a separate call specifically about what works and what does not work about ICH CAHPS, which may include a discussion on patient safety.

The other TEP co-chair returned to the topic of patient safety stating patients are the only ones that can report this. The TEP co-chair stated it is very important that patients can report their feeling of safety. Several TEP members agreed. The TEP co-chair proposed this being its own topic on the list. There was a TEP question on if there is anything in the ICH CAHPS related to patient safety. One TEP member responded there is one question related to safety on the ICH CAHPS.

The TEP co-chairs asked the TEP whether they felt comfortable with the list of topics. One TEP member noted that finances and sexual problems are also important HRQoL topics; others agreed stating that sexual issues/problems is a topic that has come up in other patient focus groups. One TEP co-chair stated they are not ruling out any specific topics while also allowing for evaluation of attributability (to facility care) to help define the list of topics. Discussion to this point has focused on broad HRQoL. The TEP co-chair stated these specific topics (i.e., sexual issues) could be listed under symptoms.

Another TEP member returned to the topic of patient safety noting there is not a specific question about this in the ICH CAHPS survey, rather there was a question asking the patient about safety practices at the facility. One TEP co-chair responded that identifying safe practices is not the same as “whether you feel safe”.

Next, discussion shifted to patients specifically commenting on the topics listed under HRQoL. One patient TEP member said that being on dialysis impacts social function, and therefore is attributable to kidney disease. One of the TEP co-chairs noted that social function is also related to recovery time. A long recovery time (from dialysis) impacts social function and other things that can impact HRQoL. The



other TEP co-chair gave an example of how social functioning is also related to life goals. If one is limited in what they can do (because of how long it takes them to recover from treatment), that can constrain life goals. There may be ways to address this (long recovery times) through treatment modification. The TEP co-chair noted that this can vary by patient.

Another TEP member made the point that social functioning and what is important to each person is informed by one's cultural and other values. They felt this introduces subjectivity (versus objectivity) of what is being measured. Another TEP member agreed this is an important measurement issue.

In response, one TEP co-chair asked the TEP how to objectively define social function. One TEP member responded saying it could be a general question, such as "are you meeting your activities"; "are you able to do your activities." Another TEP member said these concepts fall under the domains of social and role function under HRQoL. Therefore, a way to avoid the issue of subjective perception (of social function) is to rely on the health attribution. For example, ask "is it hard to work or do the things you want to because of your health condition."

TEP co-chair noted that dialysis treatment effects attribution (to the facility/provider), and asked if a (PRO) question about how the treatment effects your HRQoL or how does kidney disease effect HRQoL should be considered. One TEP member responded that is an empirical question and asked patient TEP members what they think. One patient TEP member responded they agree that a possible focus would be "how does dialysis treatment effect HRQoL." Another TEP member stated one could not compare HRQoL (scores) across different dialysis modalities as some symptoms (from treatment) may not apply. The main discussion came down to whether it is the treatment or the disease impacting HRQoL. One TEP co-chair stated both constructs could be potentially considered, the symptom effect on HRQoL and then broader HRQoL.

The TEP co-chair stated based on the discussion it appeared there was no clear indication what PRO topics can be taken off the table (e.g., symptoms) and the general sense of the TEP is that these are all important. The next step then is to start looking at existing measures and see whether they capture what is important. They also noted it may be difficult to try and take any topics off the list or to prioritize them because many were regarded as important (based on the TEP discussion).

The TEP co-chair then asked if there are any topics the TEP would be comfortable taking off the list, based on the preceding discussion. For HRQoL, the ultimate goal is to have some measure that is a judgement of the quality of care of the facility. The discussion then moved to discussing attribution (i.e., attributing HRQoL outcomes to the care quality of the facility).

One TEP member felt there are some HRQoL-related things the facility can do to intervene on certain outcomes (physical functioning, sexual function, social functioning) but not on others.

One TEP co-chair restated that the lack of strong evidence for HRQoL (and whether facilities can impact patients' HRQoL) may make HRQoL a not very good PRO measure to move forward on.

Another TEP member asked for a general definition of life goals (as a separate measure). A TEP member responded that life goals could for example, be part of the care plan, it could be measured at the beginning of dialysis and then checked periodically. They further stated that their goal as a provider is to help patients achieve their life goals whatever they may be.

One TEP member raised a concern that a requirement for facilities to educate patients about renal replacement treatment options already exists (in the CMS Conditions for Coverage), therefore, does it

make sense to create a measure that is capturing a process that already exists. The TEP co-chair responded by making the distinction that what is being captured is discussion about modality that helps patients to achieve their goals. But there needs to be discussion about how to measure this, for example, would it be a check-box? The TEP co-chair further noted that the discussion has now moved away from HRQoL to life goals and there is a need to further discuss how to measure life goals, saying that it might be possible to define a measure about how patients feel their life goals are responded to (by the facility).

The TEP co-chair briefly summarized the preceding discussion about what concept captures what is most important (to patients) and that HRQoL may not be it.

One TEP member stated life goals will be different for each patient based on what stage they are in, in their life. The co-chair responded that a life goals measure does not need to be standardized but rather the focus is “did you meet your life goals.” Another TEP member responded there needs to be discussion about the actionability of a life goals measure. For example, some life goals may be unachievable. Another TEP member replied that the life goals question just needs to be asked (and asked periodically of the patient), and that the intent of the measure is it is based on what is important to the patient (i.e., life goals and aspirations as defined by the patient) and that treatment must be in service to what patients want. Such a PRO can transform how dialysis care is delivered on the basis of using direct patient-reported data.

Another TEP member responded that if a patient does not feel good after a treatment then they do not have any goals. The TEP member understood the importance of having life goals but felt the starting point should be about the treatment and how that makes patients feel. One of the TEP co-chairs responded and asked, “Could that patient’s life goal be to feel good”? The TEP member responded that what was most important was measuring what the facility can respond to (i.e., regarding treatment). They felt that if the life goal (of a patient) is only they do not want to, for example, cramp anymore, then that does not offer much as a life goal. Another TEP member stated it is important that life goals be identified at the start of dialysis which in turn can result in patients having symptom-free treatment that allows them to achieve their goals.

At this point, one TEP member clarified a point made earlier about HRQoL. They stated that HRQoL is not actionable because of how it is being measured, but that the construct itself is not problematic. The point is it may be measurable but it has not been measured appropriately.

Another TEP member made the point that HRQoL and life goals inform one another and are not that separate in terms of functioning as PRO measures. The TEP member posed the question if there can be valid PRO measures developed based on PRO qualitative data.

One TEP co-chair responded that previous PRO measures developed and implemented have not met measurement criteria, for example, the KDQoL was developed for use as a population level measure but is used at the individual patient level. The TEP co-chair stated that PROs must be high quality and meet measurement criteria. The TEP member then asked how the FDA approaches this issue in development of PROs (used in testing of new drugs and devices). The TEP member made the further point whether the same criteria (FDA) can be applied to the PROs being discussed at this TEP.

With regard to future development of a PRO measure, one TEP member asked who would be responsible for developing the measures the TEP recommends. UM-KECC responded that would be a separate stage of work (outside this TEP) either under the current ESRD measure development contract or another contract, and would involve measure testing.

The TEP co-chair briefly summarized the afternoon discussion, which resulted in a list of un-prioritized topics (listed below and also provided on slide 93 in the ESRD PRO TEP In-Person Presentation, Appendix J).

### **Un-Prioritized Topics Identified**

- Life Goals
- HRQOL
  - Symptoms/Recovery Time, Fatigue, Cramping, Lack of Appetite
  - Care Burden
  - Mental Health
    - Depression, Anxiety
  - Physical Functioning
  - Sexual Function
  - Social Functioning
  - Sleep
- Patient Activation/Engagement
  - Education on Modality
- Patient Safety

The TEP co-chairs stated that the topics of life goals and HRQoL would be the focus of the Day Two Discussion as these were the top two topics of greatest interest identified by the TEP, with potentially greater enthusiasm for life goals. The TEP co-chairs acknowledged the other topics discussed on Day One were not considered as unimportant, but given the discussion, life goals and HRQoL rose to the top in terms of interest. The TEP co-chairs asked the TEP if they were comfortable with life goals and HRQoL as the focus and starting point of the Day Two Discussions. The TEP stated they were.

The discussion concluded for the day and the meeting moved to the public comment period.

## ***4.6 Public Comments Period (Day One)***

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There were no public comments received during the public comment period on day one of the PRO TEP.

## ***4.7 Day Two Discussions on PROs***

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### **4.7a Summary of Day One Discussions**

The TEP co-chair provided a summary of the PRO measure topics that had been identified on the first day of the TEP. The TEP co-chair stated that the idea of a measure that captures life goals or life aspirations as a way to individualize what is important to patients was identified. A potential life goals measure could potentially incentivize the facility to respond to what is important to patients. The TEP co-chair stated there may not be an existing measure that addresses this topic. The TEP co-chair stated that the second main topic (which may have been identified to be slightly lower priority) is health-related quality of life. The TEP identified potential domains for Health-related quality of life which could include symptoms (including fatigue, cramping, lack of appetite, and recovery time), care burden, mental health (including depression and anxiety), physical functioning, social functioning, sexual

function, and sleep. The TEP co-chair summarized that many members of the TEP believed that no existing measure currently effectively captures the domains that the TEP identified as most important. The TEP co-chair stated that the topics of life goals and HRQoL will be the primary topics of the second day's discussion. The TEP co-chair stated there were two other (un-prioritized) topics that came up which were the concept of patient safety (and patient activation/engagement such as education on modality); and the concept of treatment tolerance that was considered as related but potentially outside the immediate construct of HRQoL.

Among the topics discussed, the TEP co-chair stated some were more short-term and narrow in scope, such as treatment tolerance and patient safety, meaning they would be easier to implement in the short-term but not able to be as transformative to (improve) patient care in the long term. The TEP co-chair asked for TEP members to comment on the summary provided. The TEP members had no dissenting comments on the summary. One TEP member added that some patients are not actively engaged in their care therefore it is important PRO measures take into account all types of patients, i.e., both those that are active and those patients who are not as active in their own care. A patient TEP member also responded it is important to take into account the broad variability of what life goals may be to individual patients. For example, for some patients their life goal may be the absence of pain. The TEP member felt it was important that life goals allow for what is ultimately important to the individual patient whether that is absence of pain or being able to participate in or continue a specific hobby or activity, whatever that may be.

#### **4.7b Discussion of Life Goals and Aspirations**

From the TEP discussion on life goals, several topics were discussed. One of the main topics discussed was the lack of patient-centered care. Many patient TEP members expressed that they believe that facilities are delivering a "cookie-cutter" (or formulaic) approach to manage care for their patients. Several patient TEP members expressed the concern that the conversations of life goals between patients and providers (and their care team) are not occurring. Often, patients just accept what they are told in their care team meetings and often do not have the opportunity to speak up, e.g., share what are their goals for treatment. Several TEP members provided feedback about the importance for physicians to be involved in the topic of patient life goals and in one-on-one interactions with patients. Several TEP members agreed that the life goals themselves do not have to be achieved in order to qualify as a measure, but that the conversation of life goals needs to happen between patients and providers.

One TEP member reinforced their point (made earlier in the initial discussion about life goals and aspirations) that patient aspiration needs to be identified so that patients can *put dialysis (or treatment options) in service* to their aspirations and not have *dialysis determine their aspirations*.

Another TEP member stated that it is important to ensure that a patient-provider conversation takes place in order to discuss what patients want from their treatment and it is important for the fact that the conversation happened to be documented (similar to a process measure). The TEP member recommended that the follow-up check-in could happen at intervals (30 days, 90 days, etc.). The TEP co-chair stated that the goal of this TEP would be to identify a more patient-centered measure that can motivate facilities to meet patient individualized needs, e.g., discussion of life goals. There was also TEP discussion about restructuring the care plan in order to address the topic of life goals.

The TEP discussed how to potentially measure life goals and how the functioning of that measurement would work. Several TEP members stated concerns about dialysis patients who may not be able to provide their life goals, e.g., because they have never been asked or have not really had a chance to

think about what their goals might be. Several TEP members stated it will be important for the measure to be relevant to those patients. There was some TEP discussion on the statement that reimbursement and payment structure determines approaches to patient care and in turn outcomes, so an effective measure would need to be part of QIP or the payment system in order to incentivize the desired outcome. One TEP member brought up other concerns such as how to make the measure actionable by the facility. One TEP member stated that the TEP should identify something that is narrower and more specific if the concept is to be measurable. Several TEP members identified that the data collection process will be important for any PRO.

The TEP also discussed which provider should be responsible, for example, the social worker or the physician. One TEP member responded that it needs to be the physician, because they are the lead of the care team. The TEP co-chair asked about whether the discussion of life goals could be incorporated into the care plan. Several responded that incorporating the discussion of life goals into the care plan could be one approach. It also assumes there needs to be effective and regular communication among all the members of the care team (i.e., RN, social worker, dietician) and the physician. The TEP co-chair summarized what they heard from the discussion and that the patient care plan for now seemed like a possible setting for asking the patient about life goals.

One TEP member stated that life goals are very unique to each individual and it will be challenging to define them. The TEP member asked that the following be reflected in the minutes (i.e., summary report): for some patients, a life goal will mean stopping dialysis, which is a difficult conversation that providers should be prepared to discuss with patients.

There was TEP discussion on what a more specific measure would look like, for example a battery of questions, or documentation that discussion happened (patient-reported), specifically that the patient was asked “did the following things happen in a meaningful way to you?”

Another TEP member requested that the following be reflected in the TEP summary report: for the TEP to consider a patient or a caregiver reported outcome (i.e., to allow for a proxy respondent). For patients who cannot respond to the questionnaires, caregivers could provide a response.

There was some TEP discussion on the trade-off between patient anonymity and patients receiving follow-up (from the facility). If a PRO is based on anonymous reporting by patients, there may not be an opportunity for physician/provider follow-up if there is a problem occurring. One TEP co-chair made the point that an individual patient reporting about their goals (or problems at the unit) should be treated as similar to other patient-level data that facilities have access to and can act on (e.g., patient lab results). They felt that patient reporting of goals makes it distinct from the patient-reported experience of care that is captured by the ICH CAHPS survey, which is collected by a third party vendor. Facilities do not get the individual patient results from the ICH CAHPS survey.

Several TEP members stated it was important for a life goals measure to be actionable, i.e., making the measure results something the facility can act on. The TEP co-chair stated that there are some similar life goal measures in other settings/other patient populations, but some are open-ended measures. Therefore, there is a broad variety of these types of measures. The TEP co-chair stated that more literature research under the topic of life goals will be necessary as well as the need to have a later follow-up TEP call to discuss results of a literature search.

Several TEP members offered ideas for broad measure content, for example, the patient would be asked questions or indicate if goals were met. Overall, the TEP was in agreement that much more and longer term work would be needed to identify specific question content.

The TEP co-chair wrapped up the current discussion stating the discussion would now move to HRQoL and what may or may not be supported by existing instruments such as the KDQoL-36.

#### **4.7c Discussion on Health-related Quality of Life**

One of the TEP co-chairs stated that several health-related quality of life (HRQoL) domains were identified by the TEP on Day One as important. The TEP co-chair asked how the KDQoL-36 or other HRQoL measures address the domains identified by the TEP (and discussed during Day One). At this point, the KDQoL-36 form was presented to the group to review and discuss. The TEP members were also given hard copies of the KDQoL-36 to complete (if they chose to).

Several TEP members brought up a concern about how interpretable and actionable the KDQoL-36 Physical Component Summary (PCS) and Mental Component Summary (MCS) scores are. Several TEP members stated that the individual KDQoL-36 questions/items may be actionable. For example, one TEP member specifically stated that they found the symptoms, problems, and effects of kidney diseases questions useful.

One TEP member noted that what they heard in the Day One discussion is that patients felt there was not sufficient feedback from providers to patients about their HRQoL results. Another TEP member emphasized the importance of having follow-up (with the patient) on these survey results. Another TEP member stated the importance of using simple and understandable questions.

Several TEP members stated concerns about the ability to use KDQoL-36 to measure the quality of facility care.

Note, where needed to illustrate the patient perspective we indicate responses from patient TEP members.

One of the co-chairs posed the question to patient TEP members, do you feel you get feedback about the results? One provider TEP member further asked if patients want to hear the truth, that if a patient has a low PCS or MCS score, they have greater risk of hospitalization and mortality. A patient TEP member answered that some patients want to know the truth, but most patients do not want to hear anything. The other TEP co-chair asked for other reasons why patients may not be getting feedback from the facility about their results. Another TEP member more broadly responded that what they feel is important is how the facility is providing care in different domains, for example, practice changes that make sure patients feel safe. One of the TEP co-chairs indicated this may not fit with the HRQoL discussion versus patient experience of care. The other TEP co-chair recognized that patient safety may be distinct (from experience of care) and stated that topic will be pulled out for further discussion later in the day.

Regarding treatment experience, the TEP co-chair stated that the KDQoL-36 has some questions about symptoms, such as “In the past four weeks have you had any cramps?” The TEP co-chair asked if that question addressed one TEP member’s concern about treatment tolerance, the topic that TEP member brought-up on Day One (i.e., about including items about how the facility was addressing symptoms patients care about). One TEP member stated that patients do not generally respond to specific timeframes, but that patients generally respond to what is bothering them (at the time). The TEP co-chair posed the question to the TEP about how symptoms (within the broad HRQoL domain) could be captured in terms of frequency of asking about bothersome symptoms. However, discussion then shifted to broader issues about use of KDQoL-36, for example, for individual patient assessment versus facility level assessment of care quality.

One TEP member said that they do not believe any of the existing HRQoL instruments can be used to effectively measure or compare facilities, i.e., as a performance measure. The TEP member stated that something new without ceiling and floor effects would be necessary in order to measure or compare facilities. A ceiling effect was defined as when many respondents score very high on a measure and a floor effect was defined as when many respondents score very low on a measure, making it impossible to differentiate between those respondents at the ceiling or floor. The TEP member stated that some of the existing instruments (such as HRQoL short forms) can be effectively used for individualized care, but that is distinct from using it to compare the performance of facilities.

The TEP co-chair explained that the KDQoL-36 items are combined into the PCS and MCS (described earlier). The TEP co-chair highlighted that symptom questions (such as itching and cramping) on the KDQoL-36 may be useful individually but not as part of a composite scale because the symptoms and problems are so varied (e.g., chest pain and itching). The TEP co-chair stated their opinion that parts of the KDQoL-36 are not psychometrically sound because scale items are not associated conceptually or psychometrically. The TEP co-chair stated concerns that the summary scores may not be actionable, i.e., the summary score does not allow a provider to respond to a specific clinical symptom. The TEP co-chair stated that many of the important HRQoL domains and topics that were identified by the TEP (on Day One) are not included in the KDQoL-36 instrument. Overall, there was concern that patients are being asked a lot of questions (i.e., the 36 questions on the KDQoL) that may not be validated or actionable.

Given the discussion and concerns raised about the KDQoL-36, the TEP co-chairs proposed the question to the TEP: Is the KDQoL-36 an appropriate measure for comparing quality among facilities? The TEP co-chairs stated that an anonymous vote would be taken at the end of this discussion section.

One TEP member said some of the individual scales are useful for supporting individual patient care (e.g., symptoms, problems, burden and effects of disease).

Another TEP member asked about the original intent of the KDQoL survey. The TEP co-chair provided background information about the two intentions of the survey based on their understanding. First, the KDQoL was used for individual patients in their psycho-social plan of care and was also used in Quality Assurance & Performance Improvement (QAPI). Second, the TEP co-chair stated there was an intent (at an earlier point in time) that the PCS and MCS scores would be reported in CROWNWeb to CMS, but that did not happen. The TEP co-chair stated that recently, the NQF did not re-endorse the KDQoL-36 reporting measure.

One TEP member asked the TEP co-chairs whether or not the initial intention of the KDQoL survey was for comparison of facilities. The TEP co-chair responded that based on their understanding (but not as a developer of the survey) the original KDQoL measure was developed for use in clinical trials. The TEP member stated to the TEP that they felt it is important to understand the distinction about the intent of the KDQoL-36, and its use for individual patient assessment versus its use for a different purpose, i.e., comparing performance of facilities.

There was TEP discussion around case-mix considerations for the KDQoL-36 measure, e.g., other clinical and demographic factors that may also influence HRQoL outcomes and in turn assessment of facility performance.

One TEP member said the difficulty with quality of life measures is that HRQoL outcomes are determined by many factors. The TEP member asked if the TEP is being asked to vote on the use of this tool in monitoring outcomes or monitoring the quality of care process (i.e., was it administered).

Another TEP member responded that the question is about the outcome, that is measuring and monitoring the quality of care process (i.e., at the facility-level).

One TEP member stated concern about facilities being punished (e.g., as part of a CMS quality reporting program) for having patients that have a low quality of life (i.e., low HRQoL scores). Several TEP members expressed concerns that using a HRQoL measure to compare facilities may lead to potentially cherry-picking of patients.

At the end of the discussion, the TEP co-chairs called for the TEP to vote anonymously on the following question: Is the KDQoL-36 score an appropriate measure for comparing dialysis facility quality of care?

After the break, the TEP co-chairs presented the results of the KDQoL-36 vote. The results are in the table below.

**PRO TEP Voting Table (anonymous, written votes provided by TEP members)**

Is the KDQoL-36 an appropriate measure for comparing quality among facilities?		
Response	Yes	No
# of TEP Member Votes	1	17

### **4.7d Discussion on Candidate Measure Concepts that can be Supported by Existing PRO-Measures**

The next part of the discussion focused on the candidate measure concepts and determining whether there were any existing PRO instruments that could support measurement of these concepts.

The TEP co-chair stated that the TEP would review a few of the Patient-Reported Outcomes Measurement Information System (PROMIS) measures (which measure several HRQoL domains) to see whether they apply to any of the topics discussed at the meeting over the last two days. The TEP co-chair stated that the comprehensive list of the PROMIS Items is available to TEP members to review (via the link UM-KECC provided earlier in the spring. The TEP co-chair presented the following PROMIS Items: PROMIS Scale v1.2 Global Mental Health 2a, PROMIS SF v 1.0 Fatigue 8a, and PROMIS-29 Profile v2.0 (See the appendices for Exhibit #3-5. The PROMIS Tools were downloaded on March 29, 2017 from the HealthMeasures.net website at the following link: <http://www.healthmeasures.net/explore-measurement-systems/promis/obtain-administer-measures>). The TEP co-chairs noted these do not include disease attribution but are generic HRQoL questions. The TEP co-chair said they would open it up for feedback and discussion on these measures. The other TEP co-chair further clarified the purpose is to get feedback whether these measures would rise to the level of being used to make comparisons in quality of care among facilities. That is, if the PROMIS items would be applicable for a future PRO metric. The TEP co-chairs explained that the PROMIS measures have gone through psychometric assessments and testing, but have not been validated for dialysis patients. The TEP co-chairs stated that there has been some validation work done in the Chronic Kidney Disease (CKD-ND) pediatric population.



The TEP generally provided two different opinions on the PROMIS measures. Some TEP members stated that they did not think the PROMIS measures may be applicable for a future PRO metric, while some other TEP members stated that the PROMIS measures could be used but it would depend on the context and how the PROMIS items (e.g., from different item banks and domains) would be combined into a PRO. Several TEP members stated that validity testing (in the dialysis population) would be needed for the PROMIS items.

There was a range of perspectives shared by the TEP. One TEP member felt that a patient's socioeconomic status heavily impacts HRQoL and that is something the facility cannot control. Another TEP member felt there is a bit of similarity in these questions with KDQoL-36 as both are measuring aspects of HRQoL.

One TEP member stated that the PROMIS items may be too broad; it would be beneficial to have more focused PRO items that are informative about the quality of care at a facility. The TEP co-chair asked if there were any disease specific items in PROMIS. Dr. Dahlerus (UM-KECC) stated that there are some disease specific items in PROMIS (e.g., for cancer), but none currently for kidney disease/patients on dialysis.

Another TEP member stated that PROMIS should not be rejected simply because the questions are about HRQoL. The TEP member stated that there are not many good process measures to distinguish the quality of care and that it is difficult to find objective measures. The TEP member felt that these may be appropriate but would require validity testing for the dialysis population.

There was discussion about case-mix adjustment that could be applied to allow for meaningful comparison of facilities. One TEP member re-emphasized the point made on Day One that a HRQoL measure should contain appropriate disease specific and health attribution in the outcomes captured in the measure.

One TEP member stated it is important to receive input from patients on what would be used to compare the quality of facilities. The TEP member further emphasized the importance of care that reduces risk of mortality while also in a meaningful way promotes a high quality of life.

In considering whether PROMIS was appropriate to use for the dialysis population/ESRD patients, another TEP member stated that the PROMIS items would need to be revised to include items specific to the dialysis experience. The TEP co-chairs stated that the PROMIS questions could be revised so that they are disease specific questions.

Next, the discussion moved to broader consideration of PROs. The TEP co-chair stated that a PRO should have a feedback loop (i.e., provide results back to providers for them to act on) which in turn can increase the quality of patient care. The TEP co-chair asked the TEP members to answer the question of what PRO measure could drive process changes and lead to better outcomes. The TEP co-chair asked if a PRO measure would need to be broad or specific.

A TEP member responded that items (in a PRO) may need to be a mix of broad and specific topic items. The other TEP co-chair asked whether the PRO can be used to compare facilities. A TEP member responded that a PRO could be used to compare facilities. As an example, that TEP member referenced that CMS convened two ESRD Star Rating TEPs where patient stakeholders provided feedback that patients want quality ratings of facilities and comparison to be driven by what patients want to see and what is important to patients. The TEP member stated that a PRO could be used in the star rating system.

Note, where needed to illustrate the patient perspective we indicate responses from patient TEP members.

Another patient TEP member stated that a PRO could measure if a facility was responsive to a patient's symptoms. Several other TEP members stated that the point of measurement for a PRO is an important consideration. The TEP co-chair asked what concept best fits the framework for PROs and provides valid comparison of facility quality.

The TEP discussion shifted to life goals/aspirations. One patient TEP member outlined a general framework for how facilities would be accountable for improving a specific metric, like life goals. For example, a measure could ask if a patient's needs are being met. Then it is up to the facility to choose strategies for how they are addressing life goals, or patient safety, for example. This approach begins with individualization to the patient with the longer term goal of a broad downstream measure. This would account for the heterogeneity of clinics and different strategies they may adopt to address patient life goals or patient perception of safety.

A patient TEP member stated that a patient's experience with treatment impacts the rest of a patient's life. The TEP member stated that the dialysis center is accountable for the "whole" patient. The TEP member stated that a HRQoL measure would be the best way to influence delivery of care that takes the "whole" patient into account. They stated their concern about holding facilities accountable for a patient's life aspirations as this is only a process. However, the facility can be held accountable for the impact on health-related quality of life, such as impact of hospitalizations, being fatigued, and missing social events.

Another patient TEP member responded that the facility is responsible for how the treatment makes patients feel, which can impact other aspects of their lives. The TEP co-chair summarized that this perspective of the TEP member suggests they hold the dialysis facility accountable for how the treatment makes you feel.

The TEP co-chair asked one of the patient TEP members if filling out PRO surveys would help facilities take better care of patients and help differentiate performance of facilities (assuming that the quality measure has been validated). The patient TEP member responded that facilities should be held accountable for an item like patient fatigue related to kidney disease because that is a symptom they can clinically address (e.g., through treatment). The TEP member stated that the facility's level of care could be elevated by the process of the facility discussing how to manage fatigue with the patient.

Another patient TEP member stated that by asking patients how they feel after treatment may lead to allowing patients to have longer dialysis or switch treatment options (which may improve how they feel after treatment). They suggested that as PRO, the number of people who have good experience with treatment could be reported on Dialysis Facility Compare (DFC). The TEP member emphasized that facilities can be held responsible for treatment.

Next, there was a broader discussion of patient life goals. For this discussion, there was some overlap between specific aspects of HRQoL and life goals. For example, an earlier patient TEP member's example about treatment tolerance; and similarly, another TEP member's example that a potential goal would be living without symptoms.

The TEP co-chair asked if there is value in patient goals being individualized or broad. The TEP co-chair stated that there may be overlap between a measure (of life goals) that are individualized or broader. A TEP member agreed there is overlap and provided an example. They said that the modality a patient

choices may help patients achieve aspirations and goals. One TEP member agreed there was overlap between treatment management related to the modality option that best addresses patient's individual goals. This may encompass addressing specific symptoms such as fatigue or other issues. But the construct moves the measure focus from being on one specific symptom. The ultimate purpose of the measure is to ask the patient questions that lead to answers that helps the facility address what is important to the patient. That is, is the facility doing well addressing the patient's goals?

Another TEP member stated that patients could be asked if their facility is helping patients achieve their (life) goals.

One TEP member stated patient goals should not be only a facility measure, but it should also measure the physicians' role in helping patients achieve their goals. In short, facilities alone cannot do this without the physician that is responsible for prescribing the treatment patients need.

#### **4.7e Discussion on Patient Safety**

The discussion then moved to the topic of Patient Safety (as a PRO). The TEP co-chair stated that they will open up TEP discussion to talk about patient safety and patient perception of safety.

The other TEP co-chair stated there could be two related meanings of safety, that is, does the patient feel safe versus does the facility adhere to safety practices, such as infection control.

Several TEP members discussed that patient perception of safety as a PRO might be related to a patient's emotional sense or perception of safety.

Note, where needed to illustrate the patient perspective we indicate responses from patient TEP members.

Patient TEP members highlighted several risk factors to patient safety in dialysis units such as inexperienced technicians, staff lacking sufficient skills, how the staff treat patients, staff respect/listening, bloodstream infections, and facility cleanliness practices.

One patient TEP member stated that some facilities seem safer than others. Another patient TEP member stated that more engaged patients are less likely to feel unsafe in their facility because they proactively raise concerns and take control of their care. The TEP member also felt that the general attitude of the provider can also impact patient's feeling of safety and security.

Another TEP member extended this point and said this feeling of not being safe is also tied to the vulnerable position dialysis patients are in. A patient TEP member further reinforced this point and stated that safety is also related to whether they feel the staff shows respect to patients.

The TEP co-chair stated that based on the discussion and specific examples brought up patient safety could fall under the topic of patient experience of care. The TEP co-chair additionally asked if it would be beneficial if ICH CAHPS incorporated questions or items about patient safety. A patient TEP member responded that it would be beneficial. They made the point that patient feeling of safety is impacted by many different things, some of which are concrete, like proper infection control practices.

The TEP co-chair stated that patient's feeling of being safe in a facility may go beyond the immediate process of (clinical) care. A patient TEP member stated that if patients cannot control things in their life and in their treatment, and need dialysis to stay alive, that impacts patients not feeling safe.

The TEP discussed many potential patient safety questions. For example, “does the dialysis center make you feel safe?” A patient TEP member asked a provider TEP member what would be a simple safety question. The provider TEP member stated that they were comfortable with a less detailed question that patients can define in their own ways. They further explained that measurement can range from very specific all the way to a very broad concept, but it is important for the measurement (of safety) to give providers the opportunity to improve care based on results of such a measure. The TEP member stated that the term “safe” is not on the ICH-CAHPS survey but there are other questions related to being comfortable at the clinic on the survey. The TEP member expanded on their comments, suggesting for example, a related and potential PRO question would be one that asks if patients are getting patient-centered care.

The TEP co-chair summarized that what they are hearing from the TEP is that a PRO needs to drive delivery of patient-centered care. All concepts discussed identified the importance of a measure that drives individualized patient care, for example, whether that is life goals or patient safety. They stated this would be a starting point for the wrap-up discussion and developing recommendations in the final session of the meeting. They reinforced this would not focus on picking concepts but rather prioritizing concepts. At that point the meeting adjourned for lunch.

## ***4.8 TEP Recommendations and meeting wrap-up***

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### **4.8a TEP Recommendations and meeting wrap-up**

At the beginning of this part of the in-person discussion, the TEP co-chairs explained that the goal was to reach consensus on a set of recommendations based on the conversation that took place over the last two days. They are also looking to develop a list of outstanding questions that would be needed to caveat some of the recommendations (where for example, there is a lack of evidence on the potential PRO topic). It was also noted that a follow up conference call is planned in order to get into some of the specifics of these recommendations.

The TEP co-chairs then reviewed a draft list of recommendations that they developed in order to initiate discussion among the TEP members. By the end of this discussion, a list of recommendations was developed with full TEP consensus. Consideration and discussion of each recommendation are in the next section.

### **4.8b Considerations for the Recommendations: Modality and Other Populations**

Prior to in-depth consideration of each recommendation there was a brief discussion on the related issues of modality and PRO measurement in various ESRD subpopulations.

Additionally, one TEP member clarified that their earlier points made throughout the meeting discussion about the importance of “patient experience of treatment” really were intended to mean “patient experience of the procedure,” and that they felt this is a sub-domain of HRQoL. Additionally, they felt patient experience of procedure is distinct from patient experience of care (i.e., topics captured in the ICH CAHPS). (Note: see the discussion in the following sections: 4.4a Patient Perspectives on current HRQoL measures, 4.5b Patient Experience of Care, 4.5e Life Goals and Aspirations, 4.5f Symptom and Symptom Management, and 4.7d Discussion on Candidate Measure Concepts that can be Supported by Existing PRO-Measures).

## Modality

One TEP member posed a broader question, asking if these recommendations apply to all (ESRD) patients, regardless of treatment modality. The TEP co-chair explained that the broad areas identified by the TEP (life goals and patient safety) are applicable to in-center and home therapy patients, although in different ways. The patient members of the TEP agreed that safety definitely applied to home patients (as well as in-center patients). Health-related quality of life may be considered an in-center specific subcategory when thinking about the “procedure” of dialysis, but some subsets (physical and mental functioning, sleep, etc.) have broad applicability across modalities.

The group discussed adding a recommendation that PROs be modality-sensitive. Dr. Messina (UM-KECC) asked the group to clarify whether they mean dialysis modalities or ESRD treatment modalities (which would include transplant). One TEP member noted the challenge with applying transplant patients is in defining the care team accountable for PRO outcomes. The TEP co-chair noted that they were uncomfortable expanding the recommendations to transplant given the lack of specific discussion about transplant patients by this TEP. They explained that their assumption was that the TEP had been speaking about dialysis patients. The group did however acknowledge that the broad topic of life goals would apply to transplant recipients. Another TEP member noted that the perspective of transplant patients is important given that patients are strongly encouraged to consider transplants. The TEP agreed to state explicitly that the TEP did not discuss transplant patients specifically, therefore the recommendations developed here cannot be extended to those patients without further discussion/consideration (by the TEP).

The group acknowledges that there can be differences in the focus or type of PROs by treatment modality, but there has been overall appreciation that PROs are important for patients across all modalities. One TEP member noted that it means measuring PROs would potentially require more than one instrument, or perhaps a toolkit of instruments depending on the treatment modality. CMS noted that while developing/testing tools or item sets, one thing that would be tested for is the applicability of the tool across modalities. CMS suggested that the TEP might want to specify testing across modalities and then let the testing results determine the path forward.

## Other Populations

One TEP member noted that pediatric patients and caregivers were two other populations that were not specifically discussed by the TEP as it pertains to PROs and measurement. Another TEP member noted that separate measures are often used that only include pediatric patients. The TEP co-chair asked if anyone in the group wanted to add a direct reference to pediatric patients or caregivers into the recommendations. Rather than specifically call these populations out in the specific recommendations, the group requested that the report reflect that it was acknowledged by the TEP that the pediatric population is important and that there needs to be more work done in that area. The TEP also discussed proxies and exceptions to being patient-reported versus caregiver reported.

## 4.8c TEP Recommendations and Discussion

**1. The TEP strongly recommends selecting PRO measures that capture and, ultimately drive, patient-centered care (individualization of care) for all dialysis modalities. The TEP adopted this principle as its guiding tenet for subsequent recommendations on specific PRO measures.**

One TEP member noted that this recommendation does not imply that such a measure already exists. The TEP co-chair explained that the intent of this recommendation was trying to capture the spirit of the discussion without being overly prescriptive. The next recommendation captures two topic areas that might help accomplish that.

The other TEP co-chair noted that the first recommendation might be better phrased as “patient-reported outcome measures that capture patient-centered care are important” as a mission statement to set up the rest of the recommendations. Similarly, one TEP member asked that the recommendation be strengthened from “support” to something stronger to indicate the strength of the TEP discussion on these issues. The TEP co-chair noted that the TEP was a diverse group (patients and clinicians) and it was significant that everyone strongly supported the fact that patient-reported outcome measurement is important.

Note, where needed to illustrate the patient perspective we indicate responses from patient TEP members.

One TEP member noted that they have a difficult time motivating patients to participate in their care. Another patient TEP member explained that the implementation of PRO measures has the effect of mobilizing patient advocacy groups to target patients specifically to educate them on how they can influence their own care. The TEP co-chair noted that there is a general feeling that some hard to reach patients are hard to reach because the clinician/facility is not doing enough/the right things to engage them, but it’s important to be introspective on the issue and accept some responsibility. A patient TEP member noted that if a patient is in denial, they won’t hear anything that anyone says so it might be hard to take-in information and be a proactive patient. Another patient TEP member emphasized that it is important to tailor communications (about care and other information) to the specific needs of the patient.

At the end of the discussion, the group re-affirmed their support that PRO measures must capture and ultimately drive patient-centered care (individualization of care) for all dialysis modalities and adopted this principle as the guiding tenet for subsequent recommendations on specific PRO measures.

**2. Two broad new topic areas of interest identified as the Highest Priority for PRO development: (1) Assessment of Patient Life Goals and (2) Assessment of Overall Patient Safety. The Topic Area of Health-Related Quality of Life was identified as important to explore but of lower priority compared to life goals and patient safety.**

The TEP discussed this recommendation, specifically whether to add health-related quality of life to the list of broad and prioritized topic areas of interest. The TEP co-chair explained that their understanding of the TEP’s discussion was that health-related quality of life did not fit as well with the first recommendation that PROs must capture patient-centeredness/individualized care. However, the case

could be made that health-related quality of life may be linked to patient life goals through its impact on the ability to achieve those goals. They asked for feedback from the group about how to approach this issue.

One TEP member noted they were concerned that the recommendations might not be consistent with each other, since another recommendation is to consider a disease-specific quality of life measure. One TEP member noted that patient safety and patient goals are two broad areas that are not currently represented adequately in the current HRQoL measures. As a result of the discussion and recognition of the importance of patient life goals and patient safety, the TEP decided to phrase the recommendation to emphasize that patient safety and patient goals were new areas that should be prioritized, but the existing area of health-related quality of life was also identified by the TEP as a topic of interest, albeit lower priority.

### ***3. The KDQoL-36 survey was not believed to be an effective PRO measure for comparing facility performance***

This recommendation reflects the TEP vote taken earlier in the meeting regarding the utility of the KDQoL-36 for comparing facility performance. One TEP member wondered whether it should be stronger to say that the KDQoL-36 is not a good measure of quality of life. The TEP co-chair pointed out that the vote taken was specific to comparing facility performance and the discussion may not have fully fleshed out the issue of general quality of life measurement (for individual patients). They further noted that the record would reflect the discussion/concerns raised about the KDQoL-36, but the formal recommendation should be limited to the vote that was taken.

### ***4. Other Generic and Disease Specific Health-related Quality of Life measures were not ruled out but additional considerations of important and actionable domains would drive clinic processes. The TEP recognized that additional work is needed before a HRQoL measure could be considered for this purpose.***

One TEP member noted that with regards to health-related quality of life, it is important to include a generic measure of quality of life, along with a disease specific measure. They felt it was important to always include a generic component in addition to a disease specific component.

### ***5. The Following Items were recognized as important but were tabled for discussion:***

- ***Patient Experience of Care***
- ***Transplant Recipients***

The TEP agreed to call attention to patient experience of care and transplant recipients as two important areas that were tabled for this particular discussion in order to focus on other items identified as the main TEP objectives in the Charter (Note: these topics may be potentially covered in a future follow-up call or future TEP).

#### ***6. It is critical for PROs to meet accepted current standards of measurement science.***

The TEP developed this particular recommendation to address a concern raised during the discussion. Specifically, one TEP member noted the TEP spent a lot of time discussing PRO measurement science, but that is not reflected in the recommendations. Dr. Messina noted that the TEP Summary Report will attempt to accurately summarize the two days of deliberation (so that discussion will be reflected there) and the TEP will be asked to review that report. The TEP co-chair felt that the issue of PRO measurement science should rise to the level of a recommendation, given that there are tools in use currently that have not been properly tested. Another TEP member noted that measurement science is advancing, and PRO measures should take advantage of those improvements. For example, in determining whether PRO measures should be generic or disease specific, or modality specific.

### **4.8d Wrap-Up and Next Steps**

One TEP member asked if recovery time needs to be addressed in the recommendations, given that it was specifically mentioned in the charter. The TEP co-chair clarified the TEP's charge per the Charter was to discuss PROs. The objectives in the Charter were intended to guide the TEP's discussion of PRO measures. They noted recovery time did not rise to a level of importance and priority to the TEP based on the day 1 TEP discussions. Given that recovery time did not emerge as a focus of TEP discussion or prioritization, the TEP agreed that it should not receive a separate recommendation.

Several outstanding questions were also identified by the TEP with regard to evidence for PROs. The TEP co-chair stated these may inform the topic of a follow-up teleconference. (Note a post-TEP teleconference call was conducted on July 19, 2017. A final post-TEP teleconference call is being scheduled. See Appendix H and I for the final post-TEP teleconference call minutes). The TEP co-chair noted that one outstanding question is about disease attribution – is the outcome attributed to kidney disease or to your dialysis treatment? One TEP member noted that in a recent study they worked on, they surveyed patients using both terms and did not observe significant differences.

One TEP member asked if there is a measure available for patient activation/engagement. It was noted that the Patient Activation Measure exists, but is very general. It was noted this measure was included in the environmental scan provided to the TEP (NQF# 2483 Gains in Patient Activation (PAM) Scores at 12 Months).

Another TEP member questioned what domains should be included in a future HRQoL (measure), and whether the same domains would be included for every patient, or could be selected. The TEP co-chair stated that this is likely a future question for CMS.

The TEP co-chair stated a next step is to explore if there are any existing PRO measures that capture life goals or patient safety. Existing measures of capturing life goals would be a point of discussion on a follow up teleconference with the TEP.

The meeting adjourned and moved to the public comment period.

## ***4.9 Public Comment Period (Day Two)***

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A 15-minute public comment period was held at the conclusion of the In-Person TEP Meeting on February 21, 2017. One public comment was received from Katherine Harris of IMPAQ.



“My comments are on the KDQoL bullet. Just two quick comments. I really appreciate the idea that the KDQoL can be improved, particularly with new computer assisted adaptive testing methodologies. I think it would help if there was a little more specificity perhaps about the problems with the KDQoL, I’m not sure whether it’s an evidence of absence or an absence of evidence issue. I work on a contract for CMMI kind of counterpart of CCSQ, and we’ve just collected thousands and thousands of KDQoL instruments so I think there are some opportunities to look at the psychometric properties of the instrument particularly in household survey type of contexts.”

## References

1. Cella et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. *J Clin Epidemiol*. 2010 Nov;63(11):1179-94.
2. Centers for Medicare & Medicaid Services (CMS). “Blueprint for the CMS Measure Management System”. Blueprint version 12.0 MAY 2016. Accessed May 11, 2017. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Downloads/Blueprint-120.pdf>
3. Cook et al. PROMIS measures of pain, fatigue, negative affect, physical function, and social function demonstrated clinical validity across a range of chronic conditions. *J Clin Epidemiol*. 2016 May;73:89-102.
4. Liegl G, Gandek B, Fischer FH, Bjorner JB, Ware JE, Rose N, Fries JF, and Nolte S. Varying the item format improved the range of measurement in patient-reported outcome measures assessing physical function, *Arthritis Research & Therapy* 2017;19: 66.
5. National Quality Forum (NQF). “Measure Evaluation Criteria”. 2017. Accessed May 17, 2017. [http://www.qualityforum.org/Measuring\\_Performance/Subsubmitting\\_Standards/Measure\\_Evaluation\\_Criteria.aspx](http://www.qualityforum.org/Measuring_Performance/Subsubmitting_Standards/Measure_Evaluation_Criteria.aspx)
6. 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](http://www.qualityforum.org/Projects/n-r/Patient-Reported_Outcomes/Patient-Reported_Outcomes.aspx)
7. Robert M. Lindsay, Paul A. Heidenheim, Gihad Nesrallah, Amit X. Garg, and Rita Suri; on behalf of the Daily Hemodialysis Study Group London Health Sciences Centre. “Minutes to Recovery after a Hemodialysis Session: A Simple Health-Related Quality of Life Question That Is Reliable, Valid, and Sensitive to Change.” *Clin J Am Soc Nephrol* 1: 952–959, 2006. doi: 10.2215/CJN.00040106
8. U.S. Food and Drug Administration. “Guidance for Industry, Patient-Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims.” *Fed Regist*. 2009; 74(35):65132–65133. Accessed August 12, 2016: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf>

## 5. Appendices

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### List of Appendices

Appendix A: Technical Expert Panel Charter

Appendix B: Technical Expert Panel Composition Form

Appendix C: PRO Pre-TEP Teleconference Call #1 Minutes

Appendix D: PRO Pre-TEP Teleconference Call #2 Minutes

Appendix E: TEP Survey on Patient Reported Outcomes

Appendix F: PRO TEP Topics Identified by Patients, Providers, or Measure Experts on the TEP call or survey (organized by TEP co-chair grouping of individual topics)

Appendix G: PROMIS Tools Inventory

Appendix H: PRO TEP Post TEP Teleconference Call #1 Minutes

Appendix I: PRO TEP Post TEP Teleconference Call #2 Minutes

Appendix J: TEP In-person Meeting Presentation Slides

Exhibit 1: NQF Report Figure

- Figure Title: “Figure 2. Pathway from PRO to NQF-endorsed PRO-PM” from the NQF PRO Report.
- Citation: 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](http://www.qualityforum.org/Projects/n-r/Patient-Reported_Outcomes/Patient-Reported_Outcomes.aspx)

Exhibit 2: KDQoL-36 Instrument

- Citation: Hayes et al. Development of the kidney disease quality of life (KDQOL) instrument. *Quality of life research*. 3(5) (1994). 329-38.

Exhibit 3: PROMIS Scale v1.2 - Global Health Mental 2a 09062016

- Citation 1: Cook et al. PROMIS measures of pain, fatigue, negative affect, physical function, and social function demonstrated clinical validity across a range of chronic conditions. *J Clin Epidemiol*. 2016 May;73:89-102.
- Citation 2: Liegl G, Gandek B, Fischer FH, Bjorner JB, Ware JE, Rose N, Fries JF, and Nolte S. Varying the item format improved the range of measurement in patient-reported outcome measures assessing physical function, *Arthritis Research & Therapy* 2017;19: 66.

Exhibit 4: PROMIS SF v1.0 - Fatigue 8a 5-16-2016

- Citation 1: Cook et al. PROMIS measures of pain, fatigue, negative affect, physical function, and social function demonstrated clinical validity across a range of chronic conditions. *J Clin Epidemiol*. 2016 May;73:89-102.
- Citation 2: Liegl G, Gandek B, Fischer FH, Bjorner JB, Ware JE, Rose N, Fries JF, and Nolte S. Varying the item format improved the range of measurement in patient-reported outcome measures assessing physical function, *Arthritis Research & Therapy* 2017;19: 66.

Exhibit 5: PROMIS-29 Profile v2.0 12-21-2016

- Citation 1: Cook et al. PROMIS measures of pain, fatigue, negative affect, physical function, and social function demonstrated clinical validity across a range of chronic conditions. *J Clin Epidemiol*. 2016 May;73:89-102.
- Citation 2: Liegl G, Gandek B, Fischer FH, Bjorner JB, Ware JE, Rose N, Fries JF, and Nolte S. Varying the item format improved the range of measurement in patient-reported outcome measures assessing physical function, *Arthritis Research & Therapy* 2017;19: 66.

## ***Appendix A: Technical Expert Panel Charter***

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### ***Project Title:***

End Stage Renal Disease (ESRD) Patient-Reported Outcomes (PRO) Technical Expert Panel (TEP)

### ***Dates:***

January – August 2017

***Project Overview:*** The Centers for Medicare and Medicaid Services (CMS) tasked the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop a white paper on Patient-Reported Outcomes (PRO) that explored existing End-Stage Renal Disease (ESRD) patient-reported outcome measures as well as other PRO measure areas of interest to ESRD patients and other stakeholders in the renal community. The white paper submitted in fall 2016 outlined several recommendations including potential measure development. As a next step, UM-KECC is convening a TEP to review a set of existing PRO measures and to make recommendations for development. This work is performed under the ESRD Quality Measure Development, Maintenance, and Support contract (HHSM-500-2013-13017I).

The TEP is a group of subject matter experts and stakeholders who provide input on the development and maintenance of measures for which the contractor is responsible. To develop a TEP that focuses on PROs, we adopt CMS' structured and standardized approach. The TEP is expected to represent a diversity of perspectives and backgrounds. Members will be selected based on one or more of the following: their experience as patients; caregivers; providers (e.g., physicians, nurses, other provider stakeholders); PRO measure expertise; and methodological expertise (including psychometric testing). The TEP will have ample representation from patients and patient advocates.

For this project, TEP members will (1) review the current quality of life and recovery time measure concepts; (2) provide recommendations on their potential development; and (3) review and provide recommendations on the Patient-Reported Outcome Measurement Information System (PROMIS) and potentially other PRO measures or measure concepts identified by the TEP.

We are seeking nominations from individuals with relevant experience, expertise, and a variety of perspectives to serve on this TEP. We anticipate that the in-person meeting will take place over one to two days and will likely include multiple pre-TEP teleconference calls and additional post-TEP teleconference calls as needed. The pre-TEP teleconferences will be working sessions that will focus on review and preliminary assessment of HRQoL instruments, the PROMIS catalog of PRO tools, a recovery time measure; and other potential PRO measures that should be considered for focused discussion at the in-person meeting. TEP members' attendance at all these meetings is required.

### ***Project Objectives:***

UM-KECC, through its contract with the Centers for Medicare and Medicaid Services (CMS), will convene a technical expert panel (TEP) to evaluate and make recommendations regarding the development of patient-reported outcome (PRO) measures.

### ***TEP Objectives:***

The TEP will be expected to:

1. Review existing health related quality of life (HRQoL) measures and recovery time measures and the PROMIS set including evaluating evidence and usability for patients and providers; address existing testing or need for psychometric testing within the ESRD population; and data collection feasibility.
2. Make recommendations on the potential development of PRO measures including health related quality of life, recovery time, and measures derived from PROMIS item banks/domains, or potentially other measures identified by the TEP.

### ***Scope of Responsibilities:***

The role of the TEP and each member is to provide advisory input to UM-KECC regarding patient-reported outcome measures.

*Role of UM-KECC:* As the CMS measure development contractor, UM-KECC has a responsibility to support the development of quality measures and public reporting for ESRD patients. The UM-KECC moderators will work with the TEP chair(s) to ensure the panel discussions are focused; during discussions, UM-KECC moderators may advise the TEP and chair(s) on the needs and requirements of the CMS contract and the timeline, and may provide specific guidance and criteria that must be met with respect to CMS requirements.

*Role of TEP chair(s):* Prior to the in-person TEP meeting, one or two TEP members are designated as the chair(s) by UM-KECC and CMS. The TEP chair(s) are responsible, in partnership with the moderator, for directing the TEP to meet the objectives of the TEP, including provision of advice to the contractor regarding the development of patient-reported outcome measures.

*Duties and Role of TEP members:* As defined by CMS in the Measure Management System Blueprint, TEPs are advisory to the measure contractor. In this advisory role, the primary duty of the TEP is to review existing patient-reported outcome measures and supporting materials, and provide feedback and make recommendations to UM-KECC, on these and other potential measures or measure concepts .

Attend 2-3 pre-TEP conference calls in March and April 2017. The pre-TEP teleconferences will be working sessions that will focus on review and preliminary assessment of HRQoL instruments, the PROMIS catalog of PRO tools, a recovery time measure; and other potential PRO measures that should be considered for focused discussion at the in-person meeting. TEP members are also expected to attend one in-person meeting in May of 2017 (dates are yet to be determined) in Baltimore, MD, and be

available to attend additional follow-up teleconferences and correspondence between May and September.

The TEP will review, edit (if necessary), and adopt a final charter at the first teleconference. The discussion will be on the overall tasks and objectives of the TEP.

During the in-person meeting: The TEP will review HRQoL, recovery time, and PROMIS item banks/domains; and potentially other measures or measure concepts identified by the TEP in the prior teleconference meetings. The key deliverables of the TEP in-person meeting include recommendations on measure development, and a summary report documenting the discussions and decisions that take place during the in-person meeting. The report will outline the preliminary TEP recommendations.

At the end of the in-person meeting the TEP chair(s) and TEP members will prepare a summary of recommendations. As necessary, the TEP chair(s) will have additional contact with UM-KECC moderators to work through further discussion of proposed recommendations. After the in-person meeting (approximately May –August, 2017): TEP members will review a summary report of the TEP meeting discussions, recommendations, and other necessary documentation forms.

### ***Guiding Principles:***

Potential TEP members must be aware that:

- Participation on the Technical Expert Panel is voluntary.
- Input will be recorded in the meeting minutes.
- Proceedings of the in-person meeting will be summarized in a report that is disclosed to the general public.
- Potential patient participants may keep their names confidential, if they wish to do so.
- If a TEP member has chosen to disclose private, personal data, that material and those communications are not covered by patient-provider confidentiality.
- All questions about confidentiality will be answered by the TEP organizers.
- All potential TEP members must disclose any current and past activities that may pose a potential conflict of interest for performing the tasks required of the TEP.
- All potential TEP members must commit to the expected time frame outlined for the TEP.
- All issues included in the TEP summary report will be voted on by the TEP members.
- Counts of the votes and written opinions of the TEP members will be included, if requested.

### ***Estimated Number and Frequency of Meetings:***

- TEP members should expect to come together for two to three teleconference calls prior to the in-person meeting held May 2017, in Baltimore, MD.
- The in-person meeting May 2017 (final date to be determined).
- After the in-person meeting, additional teleconference calls are planned.

### ***Date Approved by TEP:***

TBD

***TEP Membership:***

TBD

## ***Appendix B: Technical Expert Panel Composition Form***

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**Placeholder:** The Technical Expert Panel Composition Form is provided on the next several pages.

## TECHNICAL EXPERT PANEL COMPOSITION (MEMBERSHIP) LIST

**Project Title:**

*End Stage Renal Disease (ESRD) Patient-Reported Outcomes (PRO) Technical Expert Panel (TEP)*

**Dates:**

January – September 2017

**Project Overview:**

The Centers for Medicare & Medicaid Services (CMS) has contracted with The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC). The contract name is ESRD Quality Measure Development, Maintenance, and Support contract. The contract number is HHSM-500-2013-13017I. As part of its measure development process, CMS asks measure developers to convene groups of stakeholders and experts who contribute direction and thoughtful input to the measure developer during measure development and maintenance. The following individuals were selected and have agreed to serve as the Technical Expert Panel for this project.

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Consumer/Patient Perspective	Clinical Expertise	Performance Measurement	Coding and Informatics	Conflict of Interest Disclosure
Jennifer Flythe, MD, MPH <i>TEP-co-chair</i>  <i>Medical Director</i>  <i>Assistant Professor and Research Fellow</i>	University of North Carolina Hospitals Dialysis Services, Chapel Hill, NC  University of North Carolina at Chapel Hill, Chapel Hill, NC		X	X		Research grant from Renal Research Institute (RRI) to develop a PRO related to fluid symptoms management.



Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Consumer/ Patient Perspective	Clinical Expertise	Performance Measurement	Coding and Informatics	Conflict of Interest Disclosure
<p>Michelle M. Richardson, Pharm D. <i>TEP-co-chair</i></p> <p><i>Director of Dialysis Outcomes Programs, Director of Communications, and Assistant Professor of Medicine</i></p> <p><i>Director, Outcomes Monitoring Program</i></p>	<p>Tufts Medical Center, Boston, MA</p> <p>Dialysis Clinic Incorporated, Nashville, TN</p>		X	X		<p>Dialysis Clinic, Inc. has a contract with Tufts Medical Center to pay Dr. Richardson’s salary for directing the Outcomes Monitoring Program.” Dr. Richardson is an employee of Tufts Medical Center and was a co-investigator on Chronic Kidney Disease-Computerized Adaptive Testing (CKD-CAT), a potential survey to be considered by this TEP.</p>
<p>Kerri Cavanaugh, MD, MS <i>Medical Director</i></p> <p><i>Associate Professor of Medicine</i></p>	<p>Vanderbilt Dialysis Clinic-Campus</p> <p>Division of Nephrology &amp; Hypertension, Department of Medicine, Vanderbilt University Medical Center Nashville, TN</p>		X	X		None

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Consumer/Patient Perspective	Clinical Expertise	Performance Measurement	Coding and Informatics	Conflict of Interest Disclosure
<p>Paul T. Conway, BA <i>President</i></p> <p><i>Board Member</i></p> <p><i>Board Member</i></p>	<p>American Association of Kidney Patients (AAKP)</p> <p>Mid-Atlantic Renal Coalition (MARC)</p> <p>Polycystic Kidney Disease Foundation (PKDF)</p>	X				None
<p>Lorien S. Dalrymple, MD, MPH <i>Vice President of Epidemiology and Research</i></p> <p><i>Volunteer Clinical Faculty, Associate Professor</i></p>	<p>Fresenius Medical Care North America (FMCNA)</p> <p>Department of Medicine, Division of Nephrology, University of California, Davis</p>		X	X		Employed by Fresenius Medical Care NA, member of the Kidney Care Quality Alliance (KCQA) Steering Committee, and participates in a patient-reported outcomes initiative.
<p>Derek Forfang <i>Board of Directors Member and Kidney Patient Advisory Council Chair</i></p> <p><i>Kidney Advocacy Committee Member and Public Policy Committee Member</i></p>	<p>National Forum of ESRD Networks</p> <p>National Kidney Foundation</p>	X				None

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Consumer/Patient Perspective	Clinical Expertise	Performance Measurement	Coding and Informatics	Conflict of Interest Disclosure
Patrick O. Gee <i>Patient Advisory Committee Chair and Subject Matter Expert</i>  <i>Kidney Advocacy Committee Member</i>	Quality Insights Mid-Atlantic Renal Coalition Network 5  National Kidney Foundation	X				None
Jennifer Geiger, MSW, LSW, NSW-C <i>Regional Lead Social Worker</i>  <i>Medical Review Board Member</i>	Fresenius Medical Care North America (FMCNA)  Quality Insights Renal Network 3		X			None
Amanda Grandinetti, MPH <i>Senior Specialist, Performance Measures and Analysis</i>  <i>Kidney Action Committee Member</i>	American Academy of Dermatology  National Kidney Foundation	X		X		None

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Consumer/Patient Perspective	Clinical Expertise	Performance Measurement	Coding and Informatics	Conflict of Interest Disclosure
Lori Hartwell <i>Founder and President</i>  <i>Board of Directors Member</i>  <i>NQF Renal Standing Committee Member</i>	Renal Support Network  Kidney Care Partners  ESRD National Quality Forum	X				None
Daniel Iniguez <i>Secretary of the Board of Directors</i>	Dialysis Patient Citizens	X				None
Jacqueline Javier-Burns, RN <i>Director of Patient Care Services</i>	Queens Long Island Renal Institute, New Hyde Park, NY		X			None
Michael "Jack" Lennon, MBA <i>Program Manager</i>  <i>Medical Advisory Committee Member</i>	Division of Nephrology and Hypertension, Cincinnati Children's Hospital Medical Center, Cincinnati, OH  National Kidney Foundation of Greater Cincinnati, OH	X				None

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Consumer/Patient Perspective	Clinical Expertise	Performance Measurement	Coding and Informatics	Conflict of Interest Disclosure
<p>Klemens Meyer, MD <i>Director of Dialysis Services</i></p> <p><i>Professor of Medicine</i></p> <p><i>Medical Director</i></p>	<p>Tufts Medical Center, Boston, MA</p> <p>Tufts University School of Medicine, Boston, MA</p> <p>Boston, Walden Pond, and Somerville clinics, Dialysis Clinic, Incorporated</p>		X	X		<p>Dr. Meyer's employer, the Tufts Medical Center Physician Organization receives payments from Dialysis Clinic Inc. (DCI) a dialysis provider, for his services) as the medical director of DCI facilities; and for his services as DCI's national Medical Director for Information Technology. DCI also pays for meeting fees, travel, accommodations, and meals and meetings at which Dr. Meyer represents the organization; for travel undertaken on their behalf; Dr. Meyer receives no consulting fees from DCI; he has worked with Investigators including John Ware, PhD and Michelle Richardson, PharmD to develop a computer adaptive tool to evaluate quality of life across the stages of chronic kidney disease. The first has not been published.</p>
<p>Sherry Rivera, DNP, APRN, ANP-C <i>Nurse Practitioner</i></p>	<p>New Orleans Nephrology Associates, Marrero, LA</p>		X			None
<p>Brigitte Schiller, MD <i>Chief Medical Officer and Vice President of Scientific Affairs</i></p> <p><i>Consulting Associate Professor</i></p>	<p>Satellite Healthcare, Inc., San Jose, CA</p> <p>Department of Medicine, Division of Nephrology, Stanford University, Palo Alto, CA</p>		X	X		None

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Consumer/Patient Perspective	Clinical Expertise	Performance Measurement	Coding and Informatics	Conflict of Interest Disclosure
<p>Nancy L. Scott <i>President</i></p> <p><i>Chairperson of the Board of Directors</i></p>	<p>Dialysis Patient Citizens Education Center</p> <p>Henrietta Johnson Medical Center, Wilmington, DE</p>	<p>X</p>				<p>None</p>
<p>Francesca Tentori, MD, MS <i>Medical Director</i></p> <p><i>Adjunct Instructor in Medicine</i></p> <p><i>Medical Advisory Board Member</i></p>	<p>Outcomes Research, DaVita Clinical Research, Minneapolis, MN</p> <p>Department of Internal Medicine, Division of Nephrology, Vanderbilt University Medical Center, Nashville, TN</p> <p>American Association of Kidney Patients</p>		<p>X</p>	<p>X</p>		<p>Dr. Tentori is a current employee of DaVita Clinical Research. She has received research grants from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Patient-Centered Outcomes Research Institute (PCORI) and a consortium of industry sponsors that support the Dialysis Outcomes and Practice Patterns Study (DOPPS) (see <a href="http://www.dopps.org">www.dopps.org</a> for more details).</p>

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Consumer/Patient Perspective	Clinical Expertise	Performance Measurement	Coding and Informatics	Conflict of Interest Disclosure
<p>John E. Ware, Jr., PhD <i>President, Founder, and Chief Science Officer</i></p> <p><i>Professor and Division Chief</i></p> <p><i>Research Professor</i></p>	<p>John Ware Research Group, Watertown, MA</p> <p>Quantitative Health Sciences, University of Massachusetts Medical School, Worcester, MA</p> <p>Department of Medicine, Tufts University School of Medicine, Boston, MA</p>			X		<p>Dr. Ware is a major shareholder in John Ware Research Group, Inc., an NIH SBIR grant and medical products industry supported corporation, affiliated with University of Massachusetts Medical School, that develops computerized adaptive outcome measures for use in health care research and practice. Dr. Ware was the principal developer and first author of the SF-36, SF-12, and SF-8 Health Surveys and articles documenting their development and evaluation during the Medical Outcomes Study; and, he is a co-author of articles documenting the development and evaluation of PROMIS physical functioning and other domain item banks.</p>
<b>Contractor Staff</b>	University of Michigan Kidney Epidemiology and Cost Center (UM-KECC)					
Claudia Dahlerus, PhD, MA, <i>Principal Scientist</i>						
Joseph Messana, MD, <i>Swartz Collegiate Professor of Nephrology, University of Michigan Health System and Interim Director, UM-KECC</i>						

Name, Credentials, and Professional Role	Organizational Affiliation, City, State	Consumer/ Patient Perspective	Clinical Expertise	Performance Measurement	Coding and Informatics	Conflict of Interest Disclosure
Richard Hirth, PhD, <i>Professor of Health Management and Policy</i>						
Lan Tong, MPH, <i>Lead Research Analyst</i>						
Casey Parrotte, PMP, <i>Project Manager/ Research Analyst</i>						
Jennifer Sardone, PMP, <i>Project Manager/ Research Analyst</i>						
Jordan Affholter, BA, <i>Research Analyst</i>						
Mimi Dalaly, MPH, <i>Research Analyst</i>						



## ***Appendix C: PRO Pre-TEP Teleconference Call #1 Minutes***

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### **End Stage Renal Disease (ESRD) Quality Measure Development, Maintenance, and Support Project ESRD Patient Reported Outcomes (PRO) Technical Expert Panel (TEP)**

#### **Pre-TEP Teleconference Call #1 Minutes**

April 24, 2017 1:00pm – 2:00pm (ET)

<b>TEP Members</b>	<b>UM-KECC</b>	<b>CMS</b>
Jennifer Flythe	Claudia Dahlerus	Joel Andress
Michelle Richardson	Joseph Messana	Jesse Roach
Kerri Cavanaugh	Richard Hirth	
Paul Conway	Lan Tong	
Lorien Dalrymple	Casey Parrotte	
Derek Forfang	Jennifer Sardone	
Jennifer Geiger	Jordan Affholter	
Amanda Grandinetti	Mimi Dalaly	
Lori Hartwell		
Daniel Iniguez		
Jacqueline Javier-Burns		
Michael "Jack" Lennon		
Klemens Meyer		
Sherry Rivera		
Brigitte Schiller		
Nancy Scott		
Francesca Tentori		
John Ware		

#### **Introductions**

Claudia Dahlerus, PhD. from the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) welcomed everyone to the Patient Reported Outcomes (PRO) Pre-TEP conference call, and thanked the TEP members for their time and for serving on the TEP. Dr. Dahlerus stated the call was open to the public, being recorded, and that the last five minutes were set aside for public comments.

Dr. Dahlerus gave a basic overview of the pre-TEP call agenda. Dr. Dahlerus explained that during the nomination process, TEP members were asked to disclose any potential conflicts of interests. She explained that the purpose of disclosing conflict of interests is to maintain transparency during TEP discussions.

Dr. Dahlerus identified that Dr. Jennifer Flythe and Dr. Michelle Richardson were selected to serve as TEP co-chairs.

Other CMS representatives were also present for the call.

Each TEP member gave a brief introduction.

Dr. Jennifer Flythe: Dr. Jennifer Flythe, is a nephrologist and clinical investigator at the University of North Carolina Kidney Center. Dr. Flythe is the Medical Director of the University of North Carolina inpatient services dialysis center. She has research interests in patient preferences as well as patient reported outcomes.

Dr. Michelle Richardson: Dr. Michelle Richardson is the Director of the Outcomes Monitoring Program at Dialysis Clinic Incorporated (DCI) and works with patient reported outcomes information to improve dialysis facilities. She has also conducted patient reported outcomes research at Tufts Medical Center.

Dr. Kerri Cavanaugh: Dr. Kerri Cavanaugh is a health services researcher. Dr. Kerri Cavanaugh is the medical director of the Vanderbilt Dialysis Clinic-Campus unit, and is an Associate Professor of Medicine at Vanderbilt University.

Paul Conway: Paul Conway is the President of AAKP (American Association of Kidney Patients). In addition, he has experience in patient advocacy positions and has personal experience with ESRD.

Dr. Lorien Dalrymple: Dr. Lorien Dalrymple is a Nephrologist and is the Vice President of Epidemiology and Research for Fresenius Medical Care North America (FMCNA).

Derek Forfang: Derek Forfang volunteers with the ESRD network system. He has experience with patient advocacy, public policy, and has personal experience with ESRD.

Jennifer Geiger: Jennifer Geiger is a dialysis social worker with Fresenius Kidney Care. She is on the medical review board for Quality Insights Renal Network 3 in New Jersey.

Amanda Grandinetti: Amanda Grandinetti is a Kidney Action Committee Member from the National Kidney Foundation (NKF). She is also a Senior Measure Developer at the American Academy of Dermatology. Ms. Grandinetti has personal experience with ESRD.

Lori Hartwell: Lori Hartwell is the Founder and President of the Renal Support Network. Ms. Hartwell is an ESRD National Quality Forum (NQF) Renal Standing Committee Member, and has personal experience with ESRD.

Daniel Iniguez: Daniel Iniguez is on the Board of Directors for Dialysis Patient Citizens. Mr. Iniguez has personal experience with ESRD.

Jacqueline Javier-Burns: Jacqueline Javier-Burns is a nurse manager at Queens Long Island Renal Institute.

Michael "Jack" Lennon: Michael "Jack" Lennon is a program manager at Division of Nephrology and Hypertension, Cincinnati Children's Hospital Medical Center. Mr. Lennon has personal experience with ESRD.

Dr. Klemens Meyer: Dr. Klemens Meyer is a nephrologist at Tufts Medical Center and Dialysis Clinic Incorporated (DCI). Dr. Meyer added an additional potential conflict of interest, as he has been interviewed by the Kidney Care Quality Alliance (KCQA) and represents DCI on calls.

Sherry Rivera: Sherry Rivera is a nurse practitioner who works with New Orleans Nephrology Associates. Ms. Rivera has experience with the evaluation of recovery time in dialysis patients.

Dr. Brigitte Schiller: Dr. Brigitte Schiller is a nephrologist and Chief Medical Officer for Satellite Healthcare. Dr. Schiller is in charge of clinical and quality initiatives on improving life outcomes.

Nancy Scott: Nancy Scott serves as the President on the Dialysis Patient Citizens Education Center and is a retired nurse administrator. Ms. Scott has personal experience with ESRD. She is currently working on her doctorate in industrial organizational psychology.

Dr. Francesca Tentori: Dr. Francesca Tentori is a nephrologist with DaVita Clinical Research. She has conducted research in international dialysis practices has conducted research on best delivery in healthcare and understanding the experience of patients' perceptions.

Dr. John Ware: Dr. John Ware is a professor at the University of Massachusetts Medical School and at Tufts University School of Medicine. His research focus is on population surveys and in clinical applications. His work has recently focused on disease specific measures.

Dr. Fredric O. Finkelstein, and Mr. Patrick O. Gee were unable to attend the teleconference meeting.

Dr. Dahlerus stated she is with the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) and a political scientist by training. Dr. Joseph Messana introduced himself as a Clinical Nephrologist at the University of Michigan. Dr. Richard Hirth introduced himself as a Professor of Health Management and Policy at the University of Michigan. Drs. Dahlerus, Hirth, and Messana are the TEP facilitators for the Star Rating TEP.

Dr. Joel Andress (CMS) introduced himself as the Contracting Officer's Representative for CMS's Measures Project. Dr. Andress thanked all of the TEP members for volunteering their time to this project.

### **TEP Overview**

Dr. Dahlerus brought attention to the from the TEP charter. Dr. Dahlerus stated that UM-KECC assumes that TEP members accept the TEP charter as part of the process of agreeing to serve on the TEP. She encouraged any TEP members that had questions regarding the charter to contact UM-KECC. Dr. Dahlerus provided a brief overview of the TEP objectives (from the TEP charter) and TEP Member Role and Responsibilities. UM-KECC's responsibility is to listen to the TEP discussions and recommendations. Dr. Dahlerus encouraged for TEP members to share their opinions and experience. Dr. Dahlerus identified that UM-KECC has provided background materials to TEP members for review (provided to TEP members after the TEP teleconference call).

### **Overview of Existing PRO Measures**

The TEP co-chairs presented an overview of the existing Patient Reported Outcome (PRO) measures:

- Medical Outcomes Study (MOS), Short Form 36-item Survey (SF-36) on Health Related Quality of Life (HRQoL)
- Medical Outcomes Study (MOS), Short Form 12-item Survey (SF-12) on HRQoL,
- Kidney Disease Quality of Life (KDQoL-36) Survey on HRQoL
- Patient Reported Outcomes Measurement Information System (PROMIS®)
- Recovery Time from Dialysis (Lindsay et al. Minutes to recovery after a hemodialysis session: a simple health-related quality of life question that is reliable, valid, and sensitive to change. CJASN. 1(5). 952-9. 2006).

The TEP co-chair explained that the SF-36 and SF-12 are general health surveys. Both the SF-36 and the SF-12 can be used to calculate the physical component summary score (PCS) and mental component (summary score (MCS). Both the SF-36 and SF-12 have been extensively validated. The SF-36 and SF-12 has been tested in Hemodialysis (HD) and Peritoneal Dialysis (PD) populations.

Next, the TEP co-chair described the Kidney Disease Quality of Life (KDQoL-36) Survey that has been the survey used by many facilities as it is indicated in the CMS Conditions for Coverage. The KDQoL-36 contains 36 questions. Twenty-four of those questions are specific to kidney disease and dialysis patients; the 12 questions general questions are from the SF-12. There are no published validation studies using the KDQoL-36 in the U.S. dialysis population, but there is one published study that validated the English KDQoL-36 in hemodialysis patients in Singapore.

The other TEP co-chair described the Patient Reported Outcomes Measurement Information System (PROMIS®) measures. These measure patient reported outcomes such as depression, anxiety, physical conditions, and other domains. The TEP co-chair clarified that the PROMIS domains refer to areas of focus or interest for that specific patient reported outcome measure. Most of the PROMIS measures have short form versions as well as can be administered via computer adaptive testing (CAT). They have been validated in the general population and in select chronic disease populations; none of the measures have been validated in the dialysis population.

The TEP co-chair presented two examples of PROMIS measures: the respective anxiety and fatigue short forms. The TEP co-chair moved to an overview of the recovery time from dialysis measure. The TEP co-chair explained that this is a one question measure that assesses how long it takes for patients to recover from one dialysis session (in minutes and hours). The recovery time measure has been validated in the dialysis population and linked to outcomes in the dialysis setting. Recovery time is the time it takes to feel better or back to normal after having a dialysis treatment.

One TEP member provided a clarifying comment on the recovery time measure. They clarified that in the Lindsay study on recovery time, patients could respond in any time increment (that is, they were not asked specifically to report in minutes, hours, etc.). The TEP member further explained that in the DOPPS study (of which they were an investigator) DOPPS developed these categories as part of what was implemented and seemed appropriate categories, but these were not directly tested or validated.

The TEP co-chairs completed the overview and handed the call back to Dr. Dahlerus.

In reference to the overview of PROMIS, Dr. Dahlerus asked if everyone knew what computer adaptive testing (CAT) meant since this is a technical term. One TEP member (an expert in CAT and instrument development) gave a brief overview of CAT. They explained a computer adaptive test matches the items

to its current estimate of the patient's score. This allows respondents to answer fewer questions while still resulting in the ability to calculate a total score from the instrument. Although two different people are answering different questions, they are scored on the same underlying metric and scores can be directly compared. Computer adaptive testing also provides the confidence interval (CI) around the person's score. Computer Adaptive Testing can lower burden on the survey taker and has a high level of precision.

### **Wrap-Up and TEP Questions**

Dr. Dahlerus offered TEP members the opportunity to ask questions and share any comments they had.

One TEP member asked why the PROMIS measures were chosen for consideration by this TEP. The TEP member further asked if it was the only patient reported outcome database.

UM-KECC explained that it was not the only patient reported outcomes database, but it is one of the largest and that CMS has an interest in the TEP considering PROMIS as a potential source for patient reported outcomes as PROMIS is being considered by other post-acute care programs at CMS. Dr. Andress (CMS) further explained that CMS is looking at measures across quality programs and the goal is to standardize measures where possible and appropriate. Dr. Andress explained that PROMIS has a comprehensive set of up items that can address various quality of care issues. Dr. Andress explained that PROMIS is a toolkit and would need to be identified as appropriate for dialysis patients, i.e., through testing. Dr. Andress therefore explained that CMS wanted to get the TEP's input on if the PROMIS measures are appropriate for dialysis facilities and patients.

The TEP member further asked in which chronic disease settings has PROMIS been tested. Dr. Andress (CMS) stated that PROMIS has been used in the home health agency setting, skilled nursing facility setting, long-term care hospitals, and inpatient rehabilitation facilities. Dr. Andress explained that he is not aware if PROMIS has been used in the inpatient hospital setting.

Another TEP member asked for clarification on the goals of the PRO TEP. The TEP member stated that their understanding is that CMS wants a better understanding of the possible existing or future measures that may be used to address items like quality of life in ESRD. The TEP member asked CMS to confirm if their understanding was correct. Dr. Andress (CMS) confirmed that was an accurate statement. Dr. Andress further clarified that the goal of the TEP is consider what resources are currently available to support development of any existing PROs, and what PRO measures would be worth considering in the future. The TEP member asked if the goal is for these measures to be used for reimbursement issues or quality ranking. Dr. Andress stated that PROs could be used for a payment incentive program (such as the Quality Incentive Program), public reporting (such as for the DFC Star Ratings), and potential other programs, including payment programs.

One TEP member asked if there is an interest in potential measures that look at patient reported outcomes for patients on different modalities (i.e. in center hemodialysis, peritoneal dialysis, and home hemodialysis). The TEP member referenced the importance of patients being able to continue working while on dialysis. Dr. Andress stated that has not been a main focus of discussion to date, but that would be an appropriate topic area to consider for this TEP. Dr. Andress clarified that the measures presented today are not the only measures to be considered. Those measures were chosen as a place to start the discussion. The goal is to narrow down the options into a measure or a set of measures to be considered further for potential development.

Another TEP member asked if there is no link between dialysis processes and these PRO outcomes, then are the PROs still important to measure. They stated that recovery time may be influenced by care operations, but items like fatigue may be more difficult (to link to delivery of care). Dr. Andress clarified that for any outcome measure there needs to be good evidence that demonstrates the care that is being provided has an impact on the outcome being measured. Dr. Andress further stated that for an outcome measure to be endorsed by the National Quality Forum (NQF) it is necessary to demonstrate that the outcome can be impacted.

Dr. Dahlerus thanked the TEP members for their comments and questions and wrapped up the discussion. She stated that the second teleconference will be used as opportunity for TEP members to identify PROs they feel are important. Dr. Dahlerus stated that UM-KECC will send a survey form to the TEP members asking them to identify the top 5 patient reported outcomes that are important. These will help support the discussion on the next call. The TEP Survey and information on the next teleconference will help identify specific discussion topics for the in-person meeting. Dr. Dahlerus encouraged members to review the annotated bibliography. Furthermore, Dr. Dahlerus encouraged TEP members to take the PRO surveys (i.e., SF-36; KDQoL-36; PROMIS) to familiarize themselves with the questions on the surveys, and how long it takes to complete the surveys. Dr. Dahlerus reminded the TEP that the materials will be available on Box and that the TEP will be emailed that information.

#### **Public Comments**

There were no public comments received during this TEP call.

#### **Closing Questions and Remarks**

One TEP member asked if UM-KECC has considered if the TEP should familiarize themselves with the Standardised Outcomes in Nephrology (SONG) Initiative. The said the study associated with Hemodialysis (HD) patients has been completed and the SONG group is conducting one for PD and transplant patients. Dr. Dahlerus thanked the TEP member and stated that one of the SONG articles has been included in the annotated bibliography that will be provided to the TEP. In addition TEP members were invited to add any additional publications to the bibliography that would be useful for TEP members to review. TEP members were encouraged to send those to UM-KECC.

Dr. Dahlerus closed the call and thanked the TEP members for attending the teleconference. Dr. Dahlerus stated the next pre-TEP teleconference will take place on May 5, 2017.

## ***Appendix D: PRO Pre-TEP Teleconference Call #2 Minutes***

### **End Stage Renal Disease (ESRD) Quality Measure Development, Maintenance, and Support Project ESRD Patient Reported Outcomes (PRO) Technical Expert Panel (TEP)**

#### **Pre-TEP Teleconference Call #2 Minutes**

May 5, 2017 12:00pm – 1:00pm (ET)

<b>TEP Members</b>	<b>UM-KECC</b>	<b>CMS</b>
Jennifer Flythe	Claudia Dahlerus	Joel Andress
Michelle Richardson	Joseph Messana	Elena Balovlenkov
Kerri Cavanaugh	Richard Hirth	
Paul Conway	Lan Tong	
Lorien Dalrymple	Jennifer Sardone	
Derek Forfang	Jordan Affholter	
Jennifer Geiger		
Lori Hartwell		
Daniel Iniguez		
Jacqueline Javier-Burns		
Michael "Jack" Lennon		
Klemens Meyer		
Sherry Rivera		
Brigitte Schiller		
Nancy Scott		
Francesca Tentori		
John Ware		

### **Introductions**

Claudia Dahlerus, PhD from the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) welcomed everyone to the second Patient Reported Outcomes (PRO) Pre-TEP teleconference call. Dr. Dahlerus stated the call was open to the public, being recorded, and that the last five minutes were set aside for public comments. Dr. Dahlerus conducted an ordered roll call of the TEP members in attendance.

Dr. Dahlerus gave a basic overview of the pre-TEP call agenda. Dr. Dahlerus explained that the focus of the call was to obtain feedback from TEP members on PRO topics. Dr. Dahlerus provided background on the PRO Report that UM-KECC produced for the Centers for Medicare and Medicaid Services (CMS) in 2016 (the final report was released in January 2017). Dr. Dahlerus explained that as part of that effort, UM-KECC received feedback on topics that were identified as important patient reported outcomes by stakeholders. UM-KECC conducted calls with stakeholders and sent an email blast that requested information on ESRD patient reported outcomes that are meaningful to both patients and health care providers. UM-KECC included the list of PROs that were identified in the PRO report in the appendix of the TEP survey that was distributed after the first TEP teleconference call. Dr. Dahlerus explained that similar to the request for stakeholder input last year, on this teleconference call, the TEP co-chairs will request feedback from TEP members on what PROs are important to patients.

Dr. Dahlerus stated that UM-KECC sent a survey to the TEP asking TEP members to identify health-related outcomes that are important to patients. Dr. Dahlerus stated that for this call they would set aside specific definitions on what PROs are. That discussion can take place at the in-person meeting. Dr. Dahlerus explained that the focus for this call was for TEP members to identify specific PROs or PRO related topics that are important to patients. Dr. Dahlerus stated that it may be beneficial considering whether some of the PRO topics are important to new dialysis patients.

Dr. Dahlerus explained that the UM-KECC would be live taking notes during the call as TEP members provide feedback. Those notes were on display for the TEP members to view in order to stimulate discussion and give TEP members a chance to provide any corrections. The comprehensive list of PROs that were identified by TEP members during the call have been included in the appendix. Dr. Dahlerus handed the discussion over the TEP co-chairs.

### **TEP Feedback on Important Patient Reported Outcomes Topics**

The TEP co-chair explained they will go around and ask each TEP member to identify important health related outcomes that are most important to patients. The TEP co-chair stated that the goal of this call was to allow for a broad range of topics for this call regardless if these topics are actionable, feasible, or in the facility's control. The TEP co-chair explained that due to time constraints the co-chairs would ask each TEP member to identify their top three PRO topics. The TEP co-chair asked if there are any TEP member questions.

One TEP member asked if the TEP was being asked to provide feedback on the PROs that are most important or the PROs that are most important to patients. The TEP co-chair clarified that the question for this teleconference call is the PROs that are most important to patients. The other TEP co-chair agreed with this statement.

The TEP co-chair stated that they wanted to start the discussion by hearing from patient TEP members on the health related outcomes that are most important to patients. The TEP co-chair started the ordered roll call for feedback.

One TEP member provided their top three PRO topics which may fall under the theme of quality of life issues. The TEP member identified the importance of being able to meet life goals, work, and well-being. The TEP member stated that well-being could potentially be measured by recovery time, but well-being may involve other considerations such as dehydration, cramping, and fluid management.

The TEP co-chair thanked the TEP member for their feedback. The TEP co-chair stated that the TEP member provided a good example of what feedback they were looking for on this call.

The next TEP member first stated that many of the measures or topics may be covered on the CAHPS and asked if the CAHPS survey is no longer on the table (as a PRO quality measure). The TEP co-chair stated that the goal of the teleconference call is to hear from the TEP members on which items are important without considerations for actionability or availability at this moment. The TEP co-chair stated that if there is an item that a TEP member considers important that is covered in the CAHPS survey, they would like to hear that feedback.



The TEP member stated they are considering what the facility can impact. The TEP member identified patient experience of treatment as an important topic. Patient experience of treatment may include fluid management, how do patients feel after treatment and nutrition.

The TEP co-chair also asked to hear more items beyond what the facility could impact. The TEP member responded that while quality of life is important, for dialysis patients it is often already low because patients often do not feel well. The TEP member stressed the importance on focusing first on small specific items about how patients feel after dialysis. For example, whether patients feel good enough to go to work afterward. These are things the facility can make an impact on quickly.

Another TEP member identified that three topics would fall under the theme of quality of life. The TEP member identified psychological adjustment (if patients feel normal in society), continuity of care among providers, and psychological adjustment/gaining knowledge and education about the disease.

The next TEP member identified quality of care, trying to adjust to society (example: trying to figure out how to continue each day in a positive way), and diet (example: ensure the dietician is providing the correct information to patients) as important.

Another TEP member identified aspirations in both the medical and modality domain. The TEP member emphasized the importance of understanding what patients are aspiring to, such as if patients want to return to work, have a family, or other considerations. The TEP member stated it is important to educate patients on modality options to allow patients to have home dialysis treatment (such as home hemodialysis or peritoneal dialysis). The TEP member stated that the issues of fatigue, bloodstream infections, insomnia, gout, and nutrition are all of high importance.

The next TEP member identified quality of life (home life considerations) as important. The TEP member agreed with another TEP member that patient aspirations is of high importance. The TEP member identified recovery time as an important topic and stated that their company asks patients about recovery time as part of their quality of life screening. The TEP member also identified that depression is of high importance.

Another TEP member identified recovery time as important, which is connected to cramping and fatigue. The TEP member also identified the financial burden of care; the TEP member stated that patients will often avoid going to other providers to avoid the burdens of co-pays. The TEP member also identified that treatment experience (such as interaction with staff and patients) is important.

The TEP co-chair thanked the TEP members for their comments so far and stated that this was the type of feedback they were looking for.

The next TEP member stated that any treatment needs to maximize longevity (life) to pursue aspirations. The TEP member stated that getting a transplant is likely the best solution to maximize longevity. The TEP member also identified well-being (medical side effects such as cramping, etc.) and quality of life as important. The TEP member identified that worry, mental stress, and adjustment to social relationships (such as interactions with family, friends, and co-workers) are other important PRO topics.

Another TEP member stated that their list was influenced by potentially actionable items (things the facility can do). The TEP members identified safety, experience of treatment, patients being offered a full range of modalities, and symptoms being effectively addressed as important PRO topics.

The next TEP member identified recovery time, vitality (fatigue), and role functioning (physical and social). The TEP member also identified that the topic of worry as important.

Another TEP member identified the topic of patients being able to live as normal a life as possible including being able to have access to modalities and adjust dialysis treatment to life goals. The TEP member identified the importance of addressing symptom burden, which could include functional status, fatigue, and recovery time. The TEP member identified the importance of support services such as coordination of care and psycho-social emotional support.

The next TEP member identified the topics of healthy days at home (independence), patient empowerment (and engagement in care), and the level of comfort at a unit (temperature, cleanliness, noise) as important PRO topics.

Another TEP member identified the topic of patient experience, which would include safety, cleanliness, patient views on staff and clinician professional expertise, and handwashing as important PRO topics. The TEP member also identified the importance of clinician communication, caring, respect, and cultural competence. The TEP member also identified patient awareness of modality and patient understanding of current and future treatment that fits the patient life goals as important PRO topics.

The next TEP member identified the importance of generic health related quality of life. The TEP member stated that quality of life could be focused on health, disease burden, and functional health. The TEP member identified satisfaction with patient health care and services as important. The TEP member identified that disease specific biomarkers (specific symptoms) are also important, as well as the presence and burden of multiple conditions.

Another TEP member identified the importance of the treatment experiences of the patients and the competence level of technicians and nurses that are delivering care. The TEP member stressed the importance of educating patients which could increase patient independence. The TEP member stated that the option to decide whether to stop or continue dialysis should be included in the treatment options that are communicated to the patients.

The TEP co-chair provided their feedback on important PRO topics. The TEP co-chair stressed the importance of patients being able to do the things they want to do, have interactions they want to, and achieve the meaning in their lives that is important to them. The TEP co-chair stated that patients determine what is most important to them.

The other TEP co-chair identified the importance of patients living the life that they want to live. The TEP co-chair also identified fatigue and recovery time as important outcomes that have an impact on patient health.

The TEP co-chair asked if anyone else wanted to add to the list that had been compiled.

One TEP member identified the importance of increasing patient voice in clinics, which could help address all of the topics that have been identified. The TEP member stressed the importance of encouraging patients to make decisions about their healthcare.

The TEP co-chair thanked the TEP for providing their feedback. The TEP co-chair stated that the TEP co-chairs and UM-KECC will review the feedback. The TEP co-chair stated that during the in-person meeting the TEP will discuss actionability on these PRO items.

### **Wrap-Up and TEP Questions**

Dr. Dahlerus (UM-KECC) thanked the TEP members for providing their PRO topic feedback. Dr. Dahlerus stated that UM-KECC will send the PRO topic list (compiled during the call) to the TEP members to review and ask TEP members to ensure that their input was reflected accurately. The PRO topic list is provided in the appendix.

Dr. Dahlerus presented the general framework for the in-person TEP meeting:

- Step 1: Initial prioritization of PROs based on patient/stakeholder feedback about what is important, irrespective of facility practices/influence.
- Step 2: Identification of the prioritized PROs (from step 1) that patients/stakeholders believe are attributable to facility practices/influence.
- Step 3: Identification of PROs from first two discussion steps that meet criteria of evidence and actionability.
- Step 4: Identify if there are existing PRO-Measures that capture the topics/domains prioritized in steps 1-3.

Dr. Dahlerus stated that the TEP will be able to discuss the definition of PROs at the in-person meeting. Dr. Dahlerus stated that patient TEP members will be asked to share their experience with completing surveys. Dr. Dahlerus reminded TEP members to review the materials that were provided to the TEP through Box.com. Dr. Dahlerus highlighted that the annotated bibliography, select annotated bibliography articles, the PRO report, and a report prepared by the National Quality Forum (NQF) about patient reported outcomes have all been included in the supporting materials on Box.com.

One TEP member asked if the NQF report describes the level of evidence required for PROs. Dr. Dahlerus explained that it does not get in the details about the level of evidence required, but it uses the same level of evidence that NQF uses to evaluate other (clinical) measures. The report describes the NQF evaluation criteria, which will also be presented at the in-person meeting.

Another TEP member asked if it would be beneficial for the providers to share their experience with the surveys. Dr. Dahlerus agreed that it would be an important part of the discussion.

Jordan Affholter (UM-KECC) stated that TEP members should be all set with travel arrangements, but if they have questions to contact UM-KECC. Jordan Affholter reminded TEP members to complete the TEP survey on important PRO topics by close of business on May 9, 2017.

Several TEP members asked if they could be resent the TEP survey. UM-KECC stated that they would resend the TEP survey to the TEP. Dr. Dahlerus stated that UM-KECC would resend the list of PROs identified during the call as well to ensure that it accurately captured the TEP discussion.

### **Public Comments**

One public comment was provided by Chris Sarfaty.

“This is Chris Sarfaty, I actually participated in the two previous [DFC Star Rating] TEPs. I’m a clinical social worker, I worked in renal for twenty five years and I work in the area of patient-centered collaborative care coaching for health professionals. My comment is I just think this is an incredibly rich and valuable collection of contributions. This is a wonderful TEP that has been assembled. I would just underscore the value and importance of patient voice and level of worry. Both of which are related to the overarching umbrella of psychological safety. So if the patients know who to ask when they have questions. How do they know who to ask? Not just something posted on the bulletin board in the lobby about the network and not just one person or if you try to ask a question or if you are not comfortable with how staff responds to you. Actually, literally, in a functional, operational way- how do you go about that in a way where you feel a level of psychological safety? Do patients feel well regarded and supported in their efforts to share their patient voice and patient experience? I think everything flows from that aspect, patient psychological safety and all that has to go into that bucket. Thanks so much.”

### **Closing Questions and Remarks**

Dr. Dahlerus closed the call and thanked the TEP members for attending the teleconference. Dr. Dahlerus stated that UM-KECC will see the TEP members at the in-person meeting in Baltimore, MD (on May 23 and 24, 2017).

### **Appendix:**

Important Patient Reported Outcomes/Topic Areas Identified by TEP members:

- Quality of Life Issues
- Being able to meet life goals
- Work
- Well-being: (could be measured by recovery time potentially) may involve dehydration/cramping/fluid management.
- Patient Experience of Treatment (fluid management, how do they feel after treatment, nutrition)
- Psychological adjustment
- Continuity of care among providers
- Psychological adjustment/gaining knowledge about disease
- Quality of care
- Trying to adjust to society
- Diet (making sure dietician is getting right information to patient)
- Aspirations (medical, modality), understanding what patients are aspiring to. If patients want to back to work, have a family, other considerations
- Modality, if a patient wants to be in charge of healthcare, education on modality to allow patients to have treatment at home
- Fatigue
- Bloodstream Infections

- Nutrition
- Quality of Life (home life considerations)
- Recovery Time
- Depression
- Recovery Time (cramping, fatigue)
- Financial burden of care
- Treatment Experience (interaction with staff and patients)
- Treatment that maximizes longevity to pursue aspirations (transplant)
- Well-Being
- Quality of Life (worry, mental stress)
- Adjustment to social relationships (interactions with family, friends, co-workers)
- Safety
- Experience of Treatment
- Patients offered a full range of modalities
- Symptoms being addressed
- Recovery Time
- Vitality (Fatigue)
- Role Functioning (physical and social)
- Worry
- Patients being able to live as normal a life as possible (being able to have access to modalities, adjust dialysis to life plan)
- Symptom Burden (functional status, fatigue, recovery time)
- Coordination of Care and Psycho-social emotional support
- Healthy Days at Home (independence)
- Patient Empowerment and engagement in care
- Level of comfort at a unit (temperature, cleanliness, noise)
- Patient Experience (Safety, cleanliness, patient views on staff and clinician professional expertise, handwashing)
- Clinician communication/caring/respect/cultural competence
- Modality (patient awareness of modality, considerations for current and future treatment, fits life goals)
- Generic health related quality of life (focus on health and disease burden, functional health)
- Satisfaction with patient health care and services
- Disease specific biomarkers (patients can report biomarkers and specific outcomes, focus on symptoms)
- Presence and burden of multiple conditions
- Treatment experiences of the patients (how competent technicians and nurses are, education)
- Independence
- Treatment options (also include whether to stop dialysis or not)
- Patients be able to do the things they want to do, have interactions they want to, and achieve what is important to them
- Patients determine what is most important to them
- Living the life that patients want to live
- Fatigue
- Recovery Time
- Increasing patient voice in clinics

## ***Appendix E: TEP Survey on Patient Reported Outcomes***

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### TEP Survey on Patient Reported Outcomes

Name \_\_\_\_\_ Date \_\_\_\_\_

In the space below please identify the top 5 patient reported outcomes that are the most important to you. We are using this information to identify specific patient reported outcome topic areas for further discussion at the in-person meeting. For your reference, the attached appendix includes a list of topic areas identified by multiple stakeholders as part of information gathering on PROs in 2016. These are for reference only but you are not required to select topic areas from this list.

The top 5 patient reported outcomes that are most important:

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_

Comments:

Appendix: Table of Measures Identified by Stakeholders as Areas of Interest in the Patient Reported Outcomes White Paper

<b>Patient Reported Quality of Life/Symptom Topics</b>	<b>Related to existing measure, if yes, which?</b>
Health Related Quality of Life Surveys	KDQoL-36; SF-36; SF-12.
Fatigue/Energy/Washed out	KDQoL-36 (item 10, 25)

Ability for patients to travel	KDQoL-36 (item 32)
Impact on family	KDQoL-36 (item 16)
Ability to work	KDQoL-36 (items 5, 7, 8)
Anxiety/Stress	KDQoL-36 (items 9, 34)
Appetite issues	KDQoL-36 (items 24, 30)
Patient Experience of Treatment	KDQoL-36 (items 17-28)
Cramping (or Fluid Management)	KDQoL-36 (items 19, 29)
Patients being able to live the lives they want to live	KDQoL-36 (items 12-14, 29-32)
Normality/Independence	KDQoL-36 (items 12, 16, 31-36)
Overall symptom burden	KDQoL-36 (items 17-28); PROMIS (physical health item banks; global health)
Specific symptoms for CKD patients (itching, skin changes, loss of appetite, GI symptoms such as nausea, vomiting, shortness of breath, sleep disorders, restless legs, and sexual dysfunction)	KDQoL-36 (items 17-27, 34-36); PROMIS (physical health item banks)
Pain (Pain/Physical Discomfort)	KDQoL-36 (items 8, 17-27); RPA measure assessing pain control following invasive access intervention; ICH CAHPS (item 21)
Functional Status (physical functioning, includes the ability to ambulate, exercise capacity) ability to perform ADLs, dressing, eating, undressing, etc.)	KDQoL-36 (items 2, 3, 4, 5, 8, 31), and ICH CAHPS (items 53-55).
Depression Screening	Depression screening instruments: PHQ-2, PHQ-9, etc. KDQoL-36 (items 9, 10, 11), and ICH CAHPS (item 46).
McGill single-item question quality of life scale	This is an existing QoL measure.
CKD-QoL/QDIS prototype (summary disease specific QoL impact score)	Instrument developed by John Ware Research Group.
Sleep/Insomnia	PROMIS item banks/short forms on sleep disturbance
<b>Patient/Caregiver Assessed Experience of Care Topics</b>	<b>Related to existing measure, if yes, which?</b>
ICH CAHPS (In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems)	This measure is an existing measure
Measure that assesses if patients were offered a full range of modalities	ICH CAHPS (items 36, 39, 40)
Choosing modality that best fits patient's goals; Importance of the patient voice incorporated into patient's care plan	ICH CAHPS (item 40)
Emergency Preparedness (of facility and patients)	ICH CAHPS (items 30, 31)
Facility Cleanliness	ICH CAHPS (items 34)
Retaliation	ICH CAHPS (item 17)
Patient Education (general and specifically relating to transplant options)	ICH CAHPS (items 4, 11, 19, 26, 27, 28, 30, 31, 36, 38)

Palliative care and end of life planning measures	
Staff Attentiveness and other similar topics (staff caring/relationship of staff to patients/ open and non-judgmental communication and interactions, personalized care and attention, staff respect)	ICH CAHPS (items 5, 10,12-18, 22, 25, 41, 43)
Safety	ICH CAHPS (items 22, 23, 24, 30, 31), KDQoL-36 (item 28)
Temperature/Noise/Comfort	ICH CAHPS (items 15,21)
Wait time (at facility) for dialysis	ICH CAHPS (item 33)
Anticipating patient's needs before they become critical	ICH CAHPS (items 22,24, 30)
Cultural competency in patient/clinician/system interactions	no
Caregiver support; impact of treatment schedule, illness on caregiver	no
Patient empowerment	no
Patient activation	Measure developed by Judith Hibbert.
<b>Treatment Experience Topics</b>	<b>Related to existing measure, if yes, which?</b>
Recovery Time	One question instrument (Lindsay et al 2006)
Dialysis Free days/times; healthy days at home	existing MedPac measure (non-ESRD)
Symptoms being effectively addressed (such as symptomatic hypovolemia, Vomiting & nausea, Excessive itching, etc.)	no
<b>Staff and Facility Structure Topics</b>	<b>Related to existing measure, if yes, which?</b>
Staff are skilled/have appropriate training	no
Facility Staff Turnover; staff ratio	no
Consistent Staffing Availability	no
Social worker on the premises; availability of dietician	no
How many treatments are offered by the facility	no
Self-care (% of patients involved in self-care/home therapies)	no
Average treatment time	no
Flexible treatment time/getting shifts they want	no
Involuntary discharges (frequency)	no
Availability of transportation/Ease of transportation and travel to facility	no
<b>Patient Experience: Social</b>	<b>Related to existing measure, if yes, which?</b>
Support groups for ESRD patients	no
Access to social services	no
Patient living arrangements and independence	no
Return to work: An adult measure to assess whether individual is able to return to work	no



Return to school: A pediatric measure to evaluate whether patient is able to return to school	no
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## ***Appendix F: PRO TEP Topics Identified by Patients, Providers, or Measure Experts on the TEP call or survey (organized by TEP co-chair grouping of individual topics)***

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### **PRO TEP Topics Identified by Patients, Providers, or Measure Experts on the TEP call or survey (organized by TEP co-chair grouping of individual topics)**

#### **Patient Experience of Care at Dialysis Clinic**

- Treatment Experience (defined several ways)
  - interaction with staff and patients
  - staff competency, education and professionalism
  - on-time, smooth, streamlined clinic proceedings
  - clinic safety, cleanliness, hygiene practices
- Continuity of care among providers
- Coordination of care (medical services as well as psychosocial/ emotional support services)
- Clinician communication (caring, respect, cultural competence)
- Staff understanding of patient goals
- Quality of care (general)
- Satisfaction with patient health care and services
- Symptoms (non-specific) being addressed

#### **Patient Education and Engagement**

- Diet/ nutritional education
- Health risk behaviors
- Disease knowledge
- Patient empowerment
- Patient engagement (in care, in clinic) and patient activation (in care)
- Coping skills with chronic disease (via psychosocial-emotional support services)
- Adequate modality education and options (including option for conservative care without dialysis) so that “right patient has right modality”

### **Life goals\***

- Being able to meet life goals/ living the life that patients want to live
- Patients determine what is most important to them (work, family, other considerations)
- Independence (defined in several ways: personal living activities, medical aids, work capacity, dependence on medical substances, financial)
- Adjustment (societal, life)

\*life goals/ aspirations defined in multiple ways, including: to live as normal a life as possible, to have access to modalities that allow patients to adjust dialysis to their lives, to achieve what is important to them [patients], to facilitate desired social interactions, to maximize longevity to pursue aspirations (including transplant).

### **HRQoL**

- Quality of Life (general)
- Health-related quality of life (focus on health and disease burden, functional health)
- HRQoL - Role functioning (physical and social)
- Healthy days at home (independence)
  - HRQoL-Psychological/ Emotional
  - Psychological adjustment (worry and stress)
- Well-being
- Emotional issues (anxiety and depression)
- Energy/Vitality and Fatigue

### **Symptoms and Symptom Management\***

- Post-dialysis fatigue
- Time-to-recovery after dialysis
- Cramping
- Fluid management
- Sleep disruption
- Nutritional status

*\*Interest in symptoms as biomarkers but no specifics here*

### ***Clinical Outcomes***

- *Bloodstream Infections*
- *Presence and burden of multiple conditions*
- *Catheter rates for in the elderly population especially for those chronic units who has a high population*
- *Anemia Management issues on the elderly chronic setting*
- *Mortality and comorbidities*
- *Hospitalizations and readmissions*

## ***Appendix G: PROMIS Tools Inventory***

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### **PROMIS Tools Inventory**

(downloaded 3/29/2017)

#### **1) Adult Item Banks**

##### **a) Mental Health**

- i) PROMIS Bank v1.0 - Alcohol-Alcohol Use 4-26-2016.pdf
  - (1) One screening question and 37 statements about alcohol use from the user's perspective. The 37 statements are used if the answer to the screening question asking about use of any type of alcoholic beverage over the last 30 days is answered affirmatively.
- ii) PROMIS Bank v1.0 - Alcohol-Negative Consequences 4-25-2016.pdf
  - (1) One screening question and 31 statements about the negative consequences of alcohol use from the user's perspective. The 31 statements are used if the answer to the screening question asking about use of any type of alcoholic beverage over the last 30 days is answered affirmatively.
- iii) PROMIS Bank v1.0 - Alcohol-Negative Expectancies 4-25-2016.pdf
  - (1) Eleven statements describing potential negative opinions about drinking and drinkers with a five point scale for each statement spanning "not at all" to "very much".
- iv) PROMIS Bank v1.0 - Alcohol-Positive Consequences 4-25-2016.pdf
  - (1) One screening question and 20 additional statements about the positive consequences of alcohol use from the user's perspective. The 20 statements are used if the answer to the screening question asking about use of any type of alcoholic beverage over the last 30 days is answered affirmatively.
- v) PROMIS Bank v1.0 - Alcohol-Positive Expectancies 4-25-2016.pdf
  - (1) Nine statements describing potential positive opinions about drinking and drinkers with a five point scale for each statement spanning "not at all" to "very much".
- vi) PROMIS Bank v1.0 - Anxiety 4-27-2016.pdf
  - (1) Twenty nine statements (first person) about presence of specific feelings/emotions related to anxiety experienced within the last seven days with a 5 point scale from "never" to "always".
- vii) PROMIS Bank v1.0 - Applied Cog Abilities 4-25-2016.pdf
  - (1) Thirty three positive statements (first person) describing various cognitive tasks and the ability to perform them within the last 7 days with a five point scale from "not at all" to "very much".
- viii) PROMIS Bank v1.0 - Applied Cog General Concerns 4-25-2016.pdf
  - (1) Thirty four negative statements (first person) describing various cognitive tasks and the (in)ability to perform them within the last 7 days with five point scale from "not at all" to "very much".

- ix) PROMIS Bank v1.0 - Depression 4-27-2016.pdf
  - (1) Twenty eight statements (first person) describing the presence of various depression symptoms within the last 7 days with five point scale from “not at all” to “very much”.
- x) PROMIS Bank v1.0 - Self-Effic-ManagEmotions\_8-5-2016.pdf
  - (1) Twenty five positive statements (first person) describing the respondent’s confidence to control various emotions (e.g. anxiety, anger, stress, loss) within the last 7 days with 5 point scale from “I am not at all confident” to “I am very confident”.
- xi) PROMIS Bank v1.0 - Self-Effic-ManagMeds\_8-5-2016.pdf
  - (1) Twenty six positive statements (first person) describing the respondent’s confidence to perform various tasks related to medication management and supply within the last 7 days with five point responses from “I am not at all confident” to “I am very confident”.
- xii) PROMIS Bank v1.0 - Self-Effic-ManagSocial Int\_8-5-2016.pdf
  - (1) Twenty three positive statements (first person) describing the respondent’s confidence to manage their social situation through various specific tasks within the last 7 days with five point scale from “I am not at all confident” to “I am very confident”.
- xiii) PROMIS Bank v1.0 - Self-Effic-ManagSymptoms\_8-5-16.pdf
  - (1) Twenty eight positive statements (first person) describing the respondent’s confidence to manage their symptoms within the last 7 days with five point scale from “I am not at all confident” to “I am very confident”.
- xiv) PROMIS Bank v1.0 - Self-Effic-ManDaily Act\_8-5-2016.pdf
  - (1) Thirty five positive statements (first person) describing the respondent’s confidence to perform various activities of daily living within the last 7 days with five point scale from “I am not at all confident” to “I am very confident”.
- xv) PROMIS Bank c1.0 – Smoking\_Cop Expect All 12-8-2016.pdf
  - (1) Eleven (11) statements utilizing five-point response scales asking the respondent to rate first-person statements related to use of cigarettes to cope with emotional symptoms.
- xvi) PROMIS Bank c1.0 – Smoking\_Cop Expect Daily 12-8-2016.pdf
  - (1) Fifteen (15) statements questions utilizing five-point response scales asking the respondent to rate first-person statements related to use of cigarettes to cope with emotional symptoms.
- xvii) PROMIS Bank c1.0 – Smoking\_Cop Expect Nondaily 12-8-2016.pdf
  - (1) Eighteen (18) statements utilizing five-point response scales asking the respondent to rate first-person statements related to use of cigarettes to cope with emotional symptoms.
- xviii) PROMIS Bank c1.0 – Smoking\_Emo Sens Expect Daily 12-8-2016.pdf
  - (1) Sixteen (16) statements utilizing five-point response scales asking the respondent to rate first-person statements related to use of cigarettes to elicit positive emotional and sensory responses.
- xix) PROMIS Bank c1.0 – Smoking\_Emo Sens Expect Nondaily 12-8-2016.pdf
  - (1) Seventeen (17) statements utilizing five-point response scales asking the respondent to rate first-person statements related to use of cigarettes to elicit positive emotional and sensory responses.
- xx) PROMIS Bank c1.0 – Smoking\_Emo Sens Expect All 12-8-2016.pdf

- (1) Fifteen (15) statements utilizing five-point response scales asking the respondent to rate first-person statements related to use of cigarettes to elicit positive emotional and sensory responses.
- xxi) PROMIS Bank c1.0 – Smoking\_Health Expect All 12-8-2016.pdf
  - (1) Twelve (12) statements utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various medical complications (e.g. shorter lifespan, heart troubles) and development of impaired quality of life.
- xxii) PROMIS Bank c1.0 – Smoking\_Health Expect Daily 12-8-2016.pdf
  - (1) Nineteen (19) statements utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various medical complications (e.g. shorter lifespan, heart troubles) and development of impaired quality of life.
- xxiii) PROMIS Bank c1.0 – Smoking\_Health Expect Nondaily 12-8-2016.pdf
  - (1) Eighteen (18) statements utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various medical complications (e.g. shorter lifespan, heart troubles) and development of impaired quality of life.
- xxiv) PROMIS Bank c1.0 – Smoking\_Nicotine Dependence All 12-8-2016.pdf
  - (1) Sixteen (16) statements utilizing five-point response scales asking the respondent to rate first-person statements relating smoking-related behaviors to dependence behavior.
- xxv) PROMIS Bank c1.0 – Smoking\_Nicotine Dependence Daily 12-8-2016.pdf
  - (1) Sixteen (16) statements utilizing five-point response scales asking the respondent to rate first-person statements relating smoking-related behaviors to dependence behavior.
- xxvi) PROMIS Bank c1.0 – Smoking\_Nicotine Dependence Nondaily 12-8-2016.pdf
  - (1) Seventeen (17) statements utilizing five-point response scales asking the respondent to rate first-person statements relating smoking-related behaviors to dependence behavior.
- xxvii) PROMIS Bank c1.0 – Smoking\_Psychosocial Expect All 12-8-2016.pdf
  - (1) Fourteen (14) statements utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various negative psychosocial expectations (e.g. loss of control, decreased respect from others, feeling less attractive, etc).
- xxviii) PROMIS Bank c1.0 – Smoking\_Psychosocial Expect Daily 12-8-2016.pdf
  - (1) Eighteen (18) statements utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various negative psychosocial expectations (e.g. loss of control, decreased respect from others, feeling less attractive, etc).
- xxix) PROMIS Bank c1.0 – Smoking\_Psychosocial Expect Nondaily 12-8-2016.pdf
  - (1) Fifteen (15) statements utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various negative psychosocial expectations (e.g. loss of control, decreased respect from others, feeling less attractive, etc).
- xxx) PROMIS Bank c1.0 – Smoking\_Social Motivations All 12-8-2016.pdf

- (1) Seven (7) statements utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various positive social benefits (e.g. more relaxed with people, social bond with other smokers).
- xxxi) PROMIS Bank c1.0 – Smoking\_Social Motivations Daily 12-8-2016.pdf
  - (1) Twelve (12) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various positive social benefits (e.g. more relaxed with people, social bond with other smokers).
- xxxii) PROMIS Bank c1.0 – Smoking\_Social Motivations Nondaily 12-8-2016.pdf
  - (1) Twelve (12) statements utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various positive social benefits (e.g. more relaxed with people, social bond with other smokers).
- xxxiii) PROMIS Bank v1.1 - Anger 4-26-2016.pdf
  - (1) Twenty two statements (first person) describing the degree to which the respondent experienced various anger-related feelings within the last 7 days with 5 point responses from “never” to “always”.
- xxxiv) PROMIS Bank v2.0 – Cognitive Function 10-20-2016.pdf
  - (1) Thirty two (32) questions utilizing five-point response scales asking the respondent to rate negative first-person statements related to various cognitive abilities (e.g. thinking, tracking) over the past 7 days.
- xxxv) PROMIS Bank v2.0 Cognitive Function Abilities Subset 7-7-2016.pdf
  - (1) Thirty one (31) questions utilizing five-point response scales asking the respondent to rate positive first-person statements related to various cognitive abilities (e.g. sharpness, memory, thinking, tracking) over the past 7 days.
- xxxvi) PROMIS Ca Bank v1.0 - Anxiety 6-24-2016.pdf
  - (1) Twenty two statements (first person) describing the degree to which the respondent experienced various anxiety-related feelings within the last 7 days with 5 point responses from “never” to “always”.
- xxxvii) PROMIS Ca Bank v1.0 - Depression 6-24-2016.pdf
  - (1) Thirty statements (first person) describing the degree to which the respondent experienced various depression-related feelings within the last 7 days with 5 point responses from “never” to “always”.

**b) Physical Health**

- i) PROMIS Bank v1.0 - Erectile Function 7-8-2015.pdf
  - (1) 15 page sexual function and satisfaction measures user’s manual, including references and appendiceal validation data.
- ii) PROMIS Bank v1.0 - Global Satisfaction w Sex Life 7-8-2015.pdf
  - (1) 15 page sexual function and satisfaction measures user’s manual, including references and appendiceal validation data.
- iii) PROMIS Bank v1.0 - Interest in Sexual Activity 7-8-2015.pdf
  - (1) 15 page sexual function and satisfaction measures user’s manual, including references and appendiceal validation data.
- iv) PROMIS Bank v1.0 - Lubrication 7-8-2015.pdf
  - (1) 15 page sexual function and satisfaction measures user’s manual, including references and appendiceal validation data.



- v) PROMIS Bank v1.0 - Phys Func Samples w Mobility Aid 11-29-2016.pdf
  - (1) Two initial screening questions related to standing and walking 25 feet with three subsequent sections “A”, “B”, and “C”. Section A includes 92 specific questions about various activities of living that require performance of some physical task (e.g. “Are you able to shampoo your hair?”). Section B includes nine specific questions that define range of ambulation related physical functions. Section C includes eleven (11) specific physical function questions based on the assumption that you answered the screening question about the ability to stand in the affirmative. If you answered the walking screening question affirmatively, all three sub-banks (A, B, C) are to be answered. If you are able to stand but not walk, only sub-banks A and C are to be answered.
- vi) PROMIS Bank v1.0 - Sleep Disturbance 4-28-2016.pdf
  - (1) Twenty seven (27) questions asking the user to describe various aspects of sleep in the past 7 days. All questions on 5 point scale.
- vii) PROMIS Bank v1.0 - Sleep-Related Impairment 4-29-2016.pdf
  - (1) Sixteen (16) questions asking the user about symptoms and physical function impairment that could be a consequence of poor sleep. All questions on 5 point scale.
- viii) PROMIS Bank v1.0 - Vaginal Discomfort 7-8-2015.pdf
  - (1) 15 page sexual function and satisfaction measures user’s manual, including references and appendiceal validation data.
- ix) PROMIS Bank v1.0-Dyspnea Functional Limitations\_8-1-2016.pdf
  - (1) Thirty three (33) five-point response questions, in the context of “Considering your shortness of breath over the past 7 days, rate the amount of difficulty you had when doing the following activities:”, asking about a wide range of physical activities.
- x) PROMIS Bank v1.0-Dyspnea Severity\_8-1-2016.pdf
  - (1) Thirty three (33) five-point response questions (no SOB, mild SOB, moderate SOB, severe SOB, I did not do this in the past 7 days), in the context of “Over the past 7 days, how short of breath did you get with each of these activities...”, asking about a wide range of physical activities.
- xi) PROMIS Bank v1.1 - Pain Behavior 4-27-2016.pdf
  - (1) Thirty nine (39) questions on a 6 point response scale asking about physical and behavioral actions that were related to pain experienced in the last 7 days. An example question “When I was in pain I moved stiffly...”
- xii) PROMIS Bank v1.1 - Pain Interference 4-28-2016.pdf
  - (1) Forty (40) questions on a five-point scale generally asking about “How much did pain interfere or make it difficult to...” with the reporting timeframe being the past 7 days.
- xiii) PROMIS Bank v2.0 - Mobility - 11-29-2016.pdf
  - (1) Fifteen (15) questions on a five-point scale asking about various mobility tasks (including walking, running, standing for extended time, climbing and descending stairs, etc.) using the five-point scale bounded by “unable to do” through “without any difficulty”.
- xiv) PROMIS Bank v2.0 - Physical Function - 11-29-2016.pdf
  - (1) Extensive set (n=136) of questions describing a wide range of physical activities and asking the respondent’s ability to perform physical function elements using the five-point scale bounded by “unable to do” through “without any difficulty”. There are twenty seven (27) additional questions that ask how much the respondent’s current

health limits the ability to perform various physical tasks and two questions at the end of the bank ask global questions about physical activities and difficulty completing physical activities.

- xv) PROMIS Bank v2.0 - Upper Extremity - 10-16-2016.pdf
  - (1) Forty five (45) questions asking the respondent to grade the ability to perform various physical tasks that require use of the upper extremity, using the five-point scale bounded by “unable to do” through “without any difficulty”. There is one question that asks if the respondent’s current health now limits the ability to open a previously opened jar on a four-point scale from “not at all” through “quite a lot” with the fifth response point being “cannot do”.
- xvi) PROMIS Pool v1 0 - Dyspnea Activity Motivation 8 -1-2016.pdf
  - (1) Seven (7) questions are in this pool. Five questions ask the respondent’s preference about activity preferences, under the assumption that the respondent had no problem with dyspnea and assuming the respondent had the ability to do both, (attend a party by driving vs. walking, shop via catalog vs. walking through store, watching sporting event vs. participating in sporting event, listening to music at home vs. attending a concert, eating dinner at home vs. going out to dinner). The last two questions ask the respondent to rate on a five-point scale the two statements “I like to be active” and “I like to spend my day sitting quietly”.
- xvii) PROMIS Pool v1.0 - Anal Discomfort 7-8-2015.pdf
  - (1) 15 page sexual function and satisfaction measures user’s manual, including references and appendiceal validation data.
- xviii) PROMIS Pool v1.0 - Dyspnea Activity Requirements \_8-2-2016.pdf
  - (1) Four (4) questions asking about recent events (quit or retired, moved into new home with less stair use requirement, moved bedroom to ground floor of house) and an additional question asking about whether there is more than one story or level in the respondent’s living space. All questions are “no” or “yes” responses.
- xix) PROMIS Pool v1.0 - Dyspnea Airborne Exposure \_8-1-2016.pdf
  - (1) Six (6) questions with yes/no answer choices asking about respondent’s exposure to environmental respiratory irritants.
- xx) PROMIS Pool v1.0 - Dyspnea Assistive Devices and Resources \_8-1-2016.pdf
  - (1) Seven (7) questions asking if the respondent is using various environmental assistive devices or caregiver services. Questions are no/yes format.
- xxi) PROMIS Pool v1.0 - Dyspnea Characteristics \_8-18-2016.pdf
  - (1) Five (5) questions on a ten-point scale asking the respondent to grade the amount and character of shortness of breath experienced over the last 7 days.
- xxii) PROMIS Pool v1.0 - Dyspnea Emotional Response \_8-2-2016.pdf
  - (1) Seven (7) questions, all using a five-point response scale that asks the respondent to best describe the effect of their shortness of breath or oxygen need on emotional symptoms over the last 7 days.
- xxiii) PROMIS Pool v1.0 - Dyspnea Task Avoidance \_8-2-2016.pdf
  - (1) Three (3) questions, all using a five-point response scale that asks the respondent to best describe the effect of their shortness of breath on task avoidance over the last 7 days.

- xxiv) PROMIS Pool v1.0 - Dyspnea Time Extension\_8-2-2016.pdf  
 (1) Seven (7) questions asking respondents to rate the amount of time it has taken to complete several physical tasks associated with activities of daily living considering shortness of breath. Question response is “less time”, “same amount of time”, “more time”, or “does not apply” over the last 7 days relative to 3 months ago.
- xxv) PROMIS Pool v1.0 - Interfering Factors 7-8-2015.pdf  
 (1) 15 page sexual function and satisfaction measures user’s manual, including references and appendiceal validation data
- xxvi) PROMIS Pool v1.0 - Orgasm 7-8-2015.pdf  
 (1) 15 page sexual function and satisfaction measures user’s manual, including references and appendiceal validation data.
- xxvii) PROMIS Pool v1.0 - Sexual Activities 7-8-2015.pdf  
 (1) 15 page sexual function and satisfaction measures user’s manual, including references and appendiceal validation data.
- xxviii) PROMIS Pool v1.0 - Sexual Fx Screener Questions 7-8-2015.pdf  
 (1) 15 page sexual function and satisfaction measures user’s manual, including references and appendiceal validation data.
- xxix) PROMIS Pool v1.0 - Therapeutic Aids 7-8-2015.pdf  
 (1) 15 page sexual function and satisfaction measures user’s manual, including references and appendiceal validation data.
- xxx) PROMIS Sexual Function v1.0 - Profile-Female 6-23-2016.pdf  
 (1) Ten (10) question form with responses coded as five-point format (including a sixth option to indicate that the question does not apply to the last 30 days) asking respondents to rank various aspects of sexual function over the last 30 days (female sexual function).
- xxxi) PROMIS Sexual Function v1.0 - Profile-Male 6-26-2016.pdf  
 (1) Eight (8) question form with responses coded as five-point format (including a sixth option to indicate that the question does not apply to the last 30 days) asking respondents to rank various aspects of sexual function over the last 30 days (male sexual function).
- xxxii) PROMIS Sexual Function v1.0 - Profile-Male and Female 6-23-2016.pdf  
 (1) Thirteen (13) question form with responses coded as five-point format (including a sixth option to indicate that the question does not apply to the last 30 days) asking respondents to rank various aspects of sexual function over the last 30 days. Form includes a section with general sexual satisfaction questions (not specific to male or female sex) and specific questions for male and female sex.
- xxxiii) PROMIS-Ca Bank v1.0 - Fatigue 6-24-2016.pdf  
 (1) Fifty four (54) questions using a five-point response scale asking respondents to rate fatigue/energy in the last 7 days.
- xxxiv) PROMIS-Ca Bank v1.1 - Pain Interference 6-24-2016.pdf  
 (1) Thirty five (35) questions using a five-point response scale asking respondents to rate various effects of pain over the last 7 days.
- xxxv) PROMIS-Ca Bank v1.1 - Physical Function 6-24-2016.pdf

- (1) Forty five (45) questions using a five-point response asking respondents to rate their ability to perform various physical tasks and levels of physical activities (broad range of physical activities and levels of exertion).
- c) Social Health
  - i) PROMIS Item Bank v1.0 - Psychosocial Illness Impact Neg 8-4-2016.pdf
    - (1) Thirty two (32) questions, each with dual format asking for response about negative psychosocial symptoms/feelings “before your illness” and “now, since your illness”. Questions are formatted with five-point response scale.
  - ii) PROMIS Item Bank v1.0 - Psychosocial Illness Impact Pos 8-4-2016.pdf
    - (1) Thirty nine (39) questions, each with dual format asking for response about positive psychosocial symptoms/feelings “before your illness” and “now, since your illness”. Questions are formatted with five-point response scale.
  - iii) PROMIS Item Bank v1.0 - Social Sat DSA 4-28-2016.pdf
    - (1) Twelve (12) questions with five-point response scale asking the respondent to rate satisfaction with social/leisure activities over the last 7 days.
  - iv) PROMIS Item Bank v1.0 - Social Sat Role 4-28-2016.pdf
    - (1) Fourteen (14) questions utilizing a five-point response scale asking respondents to rate their satisfaction with the ability to fulfill social role responsibilities (ability to work, ability to perform household responsibilities, ability to meet the needs of those who depend on the respondent, etc).

## 2) Adult Profiles

- a) PROMIS-29 Profile v2.0 12-21-2016.pdf
  - i) Profile consists of twenty nine (29) questions. One question asks the respondent to rate pain intensity on a ten-point scale, four (4) questions about physical function, four (4) questions about anxiety symptoms in the last 7 days, four (4) questions about depression symptoms in the last 7 days, four (4) questions about fatigue, four (4) questions about sleep disturbance, four (4) questions about ability to participate in social roles, and four (4) questions about how much pain interferes with physical and social activities. Except for the one question about pain intensity, the remaining 28 questions utilize a five-point response scale.
- b) PROMIS-43 Profile v2.0 12-21-2016.pdf
  - i) Profile consists of forty three (43) questions. One question asks the respondent to rate pain intensity on a ten-point scale, six (6) questions about physical function, six (6) questions about anxiety symptoms in the last 7 days, six (6) questions about depression symptoms in the last 7 days, six (6) questions about fatigue, six (6) questions about sleep disturbance, six (6) questions about ability to participate in social roles, and six (6) questions about how much pain interferes with physical and social activities. Except for the one question about pain intensity, the remaining 42 questions utilize a five-point response scale.
- c) PROMIS-57 Profile v2.0 12-21-2016.pdf
  - i) Profile consists of fifty seven (57) questions. One question asks the respondent to rate pain intensity on a ten-point scale, eight (8) questions about physical function, eight (8) questions about anxiety symptoms in the last 7 days, eight (8) questions about depression symptoms in the last 7 days, eight (8) questions about fatigue, eight (8) questions about sleep disturbance, eight (8) questions about ability to participate in social roles, and eight (8)

questions about how much pain interferes with physical and social activities. Except for the one question about pain intensity, the remaining 56 questions utilize a five-point response scale.

### **3) Adult Short Forms**

#### **a) Global**

##### **i) Global Health Scale v1.2 08.22.2016.pdf**

(1) Ten (10) question form utilizing a five-point response scale asking respondents to rate general health, quality of life, physical and cognitive health, physical and social activities, social role, fatigue, emotional symptoms and pain.

##### **ii) PROMIS Scale v1.2 – Global Health Mental 2a 09062016.pdf**

(1) Two (2) question form utilizing a five-point response scale asking the respondent to rate satisfaction, in general, with mental health, (including mood and ability to think) and social activities/relationships.

##### **iii) PROMIS Scale v1.2 – Global Health Physical 2a 09062016.pdf**

(1) Two (2) question form utilizing a five-point response scale asking the respondent to rate, in general, physical health and ability to carry out everyday activities (e.g. walking, climbing stairs, carrying groceries, moving a chair).

#### **b) Mental Health**

##### **i) PROMIS SF v1.0 - Alcohol - Alcohol Use 7a 4-25-2016.pdf**

(1) One screening question, asking if the respondent drank any kind of alcoholic beverage in the last 30 days, followed by seven (7) questions utilizing a five-point response scale asking the respondent to rate various statements about alcohol use.

##### **ii) PROMIS SF v1.0 - Alcohol - Negative Consequences 7a 4-25-2016.pdf**

(1) One screening question, asking if the respondent drank any kind of alcoholic beverage in the last 30 days, followed by seven (7) questions utilizing a five-point response scale asking the respondent to rate various statements about whether they experienced specific negative consequences related to alcohol use in the last 30 days.

##### **iii) PROMIS SF v1.0 - Alcohol - Negative Expectancies 7a 4-25-2016.pdf**

(1) Seven (7) questions utilizing a five-point response scale asking respondents to rate various negative statements about people who are drinking.

##### **iv) PROMIS SF v1.0 - Alcohol - Positive Consequences 7a 4-25-2016.pdf**

(1) One screening question, asking if the respondent drank any kind of alcoholic beverage in the last 30 days, followed by seven (7) questions utilizing a five-point response scale asking the respondent to rate various statements about whether they experienced specific positive consequences related to alcohol use in the last 30 days.

##### **v) PROMIS SF v1.0 - Alcohol - Positive Expectancies 7a 4-25-2016.pdf**

(1) Seven (7) questions utilizing a five-point response scale asking respondents to rate various positive statements about people who are drinking.

##### **vi) PROMIS SF v1.0 - Applied Cog Abilities 4a 4-25-2016.pdf**

(1) Four (4) questions utilizing a five-point response scale asking the respondent to rate statements about “sharpness”, memory, thinking, task tracking over the last 7 days.

##### **vii) PROMIS SF v1.0 - Applied Cog Abilities 6a 4-25-2016.pdf**

- (1) Six (6) questions utilizing a five-point response scale asking the respondent to rate statements about “sharpness”, memory, thinking, task tracking, concentration and clarity of thinking over the last 7 days.
- viii) PROMIS SF v1.0 - Applied Cog Abilities 8a 4-25-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate statements about “sharpness”, memory, thinking, task tracking, concentration and clarity of thinking over the last 7 days.
- ix) PROMIS SF v1.0 - Applied Cog General Concerns 4a 4-25-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate concerns about, memory, thinking, and task tracking over the last 7 days.
- x) PROMIS SF v1.0 - Applied Cog General Concerns 6a 4-25-2016.pdf
  - (1) Six (6) questions utilizing a five-point response scale asking the respondent to rate concerns about, memory, thinking, concentration, attention span, and task tracking over the last 7 days.
- xi) PROMIS SF v1.0 - Applied Cog General Concerns 8a 4-25-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate concerns about, memory, thinking, concentration, attention span, and task tracking, as well as the impact of applied cognition difficulties on the respondent’s quality of life over the last 7 days.
- xii) PROMIS SF v1.0 - ED-Anxiety 4a 6-2-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate first-person statements about anxiety symptoms experienced in the last 7 days.
- xiii) PROMIS SF v1.0 - ED-Anxiety 6a 6-2-2016.pdf
  - (1) Six (6) questions utilizing a five-point response scale asking the respondent to rate first-person statements about anxiety symptoms experienced in the last 7 days.
- xiv) PROMIS SF v1.0 - ED-Anxiety- 7a 4-29-2016.pdf
  - (1) Seven (7) questions utilizing a five-point response scale asking the respondent to rate first-person statements about anxiety symptoms experienced in the last 7 days.
- xv) PROMIS SF v1.0 - ED-Anxiety 8a 6-2-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate first-person statements about anxiety symptoms experienced in the last 7 days.
- xvi) PROMIS SF v1.0 - ED-Depression 4a 6-26-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate first-person statements about depression symptoms experienced in the last 7 days.
- xvii) PROMIS SF v1.0 - ED-Depression 6a 6-26-2016.pdf
  - (1) Six (6) questions utilizing a five-point response scale asking the respondent to rate first-person statements about anxiety symptoms experienced in the last 7 days.
- xviii) PROMIS SF v1.0 - ED-Depression 8a 6-26-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate first-person statements about anxiety symptoms experienced in the last 7 days.
- xix) PROMIS SF v1.0 - ED-Depression 8b 5-2-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate first-person statements about anxiety symptoms experienced in the last 7 days. NOTE-significant content overlap with PROMIS SF v1.0 - ED-Depression 8a 6-26-2016.pdf.

- xx) PROMIS SF v1.0 - Self-Effic-ManagEmotions 4a\_8-5-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate first-person statements about current ability to handle various specific negative emotions.
- xxi) PROMIS SF v1.0 - Self-Effic-ManagEmotions 8a\_8-5-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate first-person statements about current ability to handle various specific negative emotions.
- xxii) PROMIS SF v1.0 - Self-Effic-ManagMeds 4a\_8-5-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate first-person statements about current ability to handle various medication self-management tasks.
- xxiii) PROMIS SF v1.0 - Self-Effic-ManagMeds 8a\_8-5-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate first-person statements about current ability to handle various medication self-management tasks.
- xxiv) PROMIS SF v1.0 - Self-Effic-ManagSocial Int 4a\_8-5-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate first-person statements about current level of social, cognitive, and emotional support. For some questions, the support is directed toward health condition, but not universally.
- xxv) PROMIS SF v1.0 - Self-Effic-ManagSocial Int 8a\_8-5-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate first-person statements about current level of social, cognitive, and emotional support. For some questions, the support is directed toward health condition, but not universally.
- xxvi) PROMIS SF v1.0 - Self-Effic-ManagSymptoms 4a\_8-5-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate first-person statements about current ability to manage symptoms.
- xxvii) PROMIS SF v1.0 - Self-Effic-ManagSymptoms 8a\_8-5-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate first-person statements about current ability to manage symptoms.
- xxviii) PROMIS SF v1.0 - Self-Effic-ManDaily Act 4a\_8-5-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate first-person statements about current ability to manage daily activities, including household chores, shopping, walking inside the house, and a regular exercise program.
- xxix) PROMIS SF v1.0 - Self-Effic-ManDaily Act 8a\_8-5-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate first-person statements about current ability to manage daily activities, including household chores, shopping, lifting/carrying groceries, walking inside the house, care of others, toileting, work-related activities, and a regular exercise program.
- xxx) PROMIS SF v1.0 – Smoking\_Cop Expect AllSmokers 4a 12-8-2016.pdf
  - (1) Four (4) questions utilizing five-point response scales asking the respondent to rate first-person statements related to use of cigarettes to cope with emotional symptoms.

- xxxix) PROMIS SF v1.0 – Smoking\_Cop Expect Daily 4a 12-8-2016.pdf  
 (1) Four (4) questions utilizing five-point response scales asking the respondent to rate first-person statements related to use of cigarettes to cope with emotional symptoms.  
 NOTE- Response options are identical to those contained in PROMIS SF v1.0 – Smoking\_Cop Expect AllSmokers 4a 12-8-2016.pdf
- xxxvii) PROMIS SF v1.0 – Smoking\_Cop Expect Nondaily 4a 12-8-2016.pdf  
 (1) Four (4) questions utilizing five-point response scales asking the respondent to rate first-person statements related to use of cigarettes to cope with emotional symptoms.  
 NOTE- Response options are identical to those contained in PROMIS SF v1.0 – Smoking\_Cop Expect AllSmokers 4a 12-8-2016.pdf
- xxxviii) PROMIS SF v1.0 – Smoking\_Emo Sensory Expect AllSmokers 6a 12-8-2016.pdf  
 (1) Six (6) questions utilizing five-point response scales asking the respondent to rate first-person statements related to use of cigarettes to elicit positive emotional and sensory responses.
- xxxix) PROMIS SF v1.0 – Smoking\_Emo Sensory Expect Daily 6a 12-8-2016.pdf  
 (1) Six (6) questions utilizing five-point response scales asking the respondent to rate first-person statements related to use of cigarettes to elicit positive emotional and sensory responses. NOTE- Response options are identical to those contained in PROMIS SF v1.0 – Smoking\_Emo Sensory Expect AllSmokers 6a 12-8-2016.pdf.
- xl) PROMIS SF v1.0 – Smoking\_Emo Sensory Expect Nondaily 6a 12-8-2016.pdf  
 (1) Six (6) questions utilizing five-point response scales asking the respondent to rate first-person statements related to use of cigarettes to elicit positive emotional and sensory responses. NOTE- Response options are identical to those contained in PROMIS SF v1.0 – Smoking\_Emo Sensory Expect AllSmokers 6a 12-8-2016.pdf.
- xli) PROMIS SF v1.0 – Smoking\_Health Expect AllSmokers 6a 12-8-2016.pdf  
 (1) Six (6) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various medical complications (e.g. shorter lifespan, heart troubles) and development of impaired quality of life.
- xlii) PROMIS SF v1.0 – Smoking\_Health Expect Daily 6a 12-8-2016.pdf  
 (1) Six (6) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various medical complications (e.g. shorter lifespan, heart troubles) and development of impaired quality of life. NOTE- Response options are identical to those contained in PROMIS SF v1.0 – Smoking\_Health Expect AllSmokers 6a 12-8-2016.pdf.
- xliiii) PROMIS SF v1.0 – Smoking\_Health Expect Nondaily 6a 12-8-2016.pdf  
 (1) Six (6) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various medical complications (e.g. shorter lifespan, heart troubles) and development of impaired quality of life. NOTE- Response options are identical to those contained in PROMIS SF v1.0 – Smoking\_Health Expect AllSmokers 6a 12-8-2016.pdf.
- xliiii) PROMIS SF v1.0 – Smoking\_Nicotine Dependence AllSmokers 4a 12-8-2016.pdf  
 (1) Four (4) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking-related behaviors to dependence behavior.



- xi) PROMIS SF v1.0 – Smoking\_Nicotine Dependence AllSmokers 8a 12-8-2016.pdf

(1) Eight (8) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking-related behaviors to dependence behavior.
- xli) PROMIS SF v1.0 – Smoking\_Nicotine Dependence Daily 4a 12-8-2016.pdf

(1) Four (4) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking-related behaviors to dependence behavior. NOTE- Response options are identical to those contained in PROMIS SF v1.0 – Smoking\_Nicotine Dependence AllSmokers 4a 12-8-2016.pdf
- xlii) PROMIS SF v1.0 – Smoking\_Nicotine Dependence Daily 8a 12-8-2016.pdf

(1) Eight (8) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking-related behaviors to dependence behavior. NOTE- Response options are identical to those contained in PROMIS SF v1.0 – Smoking\_Nicotine Dependence AllSmokers 8a 12-8-2016.pdf
- xliii) PROMIS SF v1.0 – Smoking\_Nicotine Dependence Nondaily 4a 12-8-2016.pdf

(1) Four (4) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking-related behaviors to dependence behavior. NOTE- Response options are identical to those contained in PROMIS SF v1.0 – Smoking\_Nicotine Dependence AllSmokers 4a 12-8-2016.pdf
- xliv) PROMIS SF v1.0 – Smoking\_Nicotine Dependence Nondaily 8a 12-8-2016.pdf

(1) Eight (8) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking-related behaviors to dependence behavior. NOTE- Response options are identical to those contained in PROMIS SF v1.0 – Smoking\_Nicotine Dependence AllSmokers 8a 12-8-2016.pdf
- xlv) PROMIS SF v1.0 – Smoking\_Psychosocial Expect AllSmokers 6a 12-8-2016.pdf

(1) Six (6) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various negative psychosocial expectations (e.g. loss of control, decreased respect from others, feeling less attractive, etc).
- xlvi) PROMIS SF v1.0 – Smoking\_Psychosocial Expect Daily 6a 12-8-2016.pdf

(1) Six (6) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various negative psychosocial expectations (e.g. loss of control, decreased respect from others, feeling less attractive, etc). NOTE- Response options are identical to those contained in PROMIS SF v1.0 – Smoking\_Psychosocial Expect AllSmokers 6a 12-8-2016.pdf
- xlvii) PROMIS SF v1.0 – Smoking\_Psychosocial Expect Nondaily 6a 12-8-2016.pdf

(1) Six (6) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various negative psychosocial expectations (e.g. loss of control, decreased respect from others, feeling less attractive, etc). NOTE- Response options are identical to those contained in PROMIS SF v1.0 – Smoking\_Psychosocial Expect AllSmokers 6a 12-8-2016.pdf
- xlviii) PROMIS SF v1.0 – Smoking\_Social Motivations AllSmokers 4a 12-8-2016.pdf

(1) Four (4) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various positive social benefits (e.g. more relaxed with people, social bond with other smokers).

- xlix) PROMIS SF v1.0 – Smoking\_Social Motivations Daily 4a 12-8-2016.pdf
  - (1) Four (4) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various positive social benefits (e.g. more relaxed with people, social bond with other smokers). NOTE- Response options are identical to those contained in PROMIS SF v1.0 – Smoking\_Social Motivations AllSmokers 4a 12-8-2016.pdf
- l) PROMIS SF v1.0 – Smoking\_Social Motivations Nondaily 4a 12-8-2016.pdf
  - (1) Four (4) questions utilizing five-point response scales asking the respondent to rate first-person statements relating smoking to various positive social benefits (e.g. more relaxed with people, social bond with other smokers). NOTE- Response options are identical to those contained in PROMIS SF v1.0 – Smoking\_Social Motivations AllSmokers 4a 12-8-2016.pdf
- li) PROMIS SF v1.1 - ED-Anger 5a 4-27-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate first-person statements about anger symptoms experienced in the last 7 days.
- lii) PROMIS SF v2.0 – Cognitive Abilities Subset 4a 10-20-2016.pdf
  - (1) Four (4) questions utilizing five-point response scales asking the respondent to rate positive first-person statements related to various cognitive abilities (e.g. sharpness, memory, thinking, tracking) over the past 7 days.
- liii) PROMIS SF v2.0 – Cognitive Function 4a 10-20-2016.pdf
  - (1) Four (4) questions utilizing five-point response scales asking the respondent to rate negative first-person statements related to various cognitive abilities (e.g. thinking, tracking) over the past 7 days.
- liv) PROMIS SF v2.0 – Cognitive Function 6a 7-7-2016.pdf
  - (1) Six (6) questions utilizing five-point response scales asking the respondent to rate negative first-person statements related to various cognitive abilities (e.g. thinking, tracking) over the past 7 days.
- lv) PROMIS SF v2.0 – Cognitive Function 8a 7-7-2016.pdf
  - (1) Six (6) questions utilizing five-point response scales asking the respondent to rate negative first-person statements related to various cognitive abilities (e.g. thinking, tracking, mathematical ability) over the past 7 days.
- lvi) PROMIS SF v2.0 – Cognitive Function Abilities Subset 6a 10-20-2016.pdf
  - (1) Six (6) questions utilizing five-point response scales asking the respondent to rate positive first-person statements related to various cognitive abilities (e.g. sharpness, memory, thinking, tracking, concentration, clarity) over the past 7 days.
- lvii) PROMIS SF v2.0 – Cognitive Function Abilities Subset 8a 7-7-2017
  - (1) Eight (8) questions utilizing five-point response scales asking the respondent to rate positive first-person statements related to various cognitive abilities (e.g. sharpness, memory, thinking, tracking, concentration, clarity) over the past 7 days.
- c) Physical Health
  - i) PROMIS Scale v1 0 - GI Belly Pain 5a 09-01-2016.pdf
    - (1) Five (5) question document utilizing five-point response scales to assess abdominal pain and discomfort in the last 7 days. There are two screening questions #1 and #5) asking the respondent to rate presence/frequency of “belly pain” (#1) and “belly discomfort”

- (#5). Questions 2-4 ask respondent to rate severity and how much belly pain limited day-to-day activities.
- ii) PROMIS Scale v1.0 - GI Bowel Incontinence 4a 09-01-2016.pdf
    - (1) Four (4) questions utilizing a five-point response scale asking the respondent about fecal incontinence occurring in the past 7 days.
  - iii) PROMIS Scale v1.0 - GI Constipation 9a 09-01-2016.pdf
    - (1) Nine (9) questions utilize a five-point response scale to assess constipation and rectal/anal pain. The scale includes three screening questions (#1 for constipation, #3 for straining at stool, and #6 for rectal/anal pain.
  - iv) PROMIS Scale v1.0 - GI Diarrhea 6a 09-01-2016.pdf
    - (1) Six (6) questions utilizing five-point response scale to evaluate diarrhea. Two screening questions are included. #1 inquires about the frequency of loose or watery stools. Question s#2 and 3 asses impact of diarrhea. Question #4 assesses tenesmus. If the respondent answers never, the survey is over. If any frequency, then questions #5 and 6 evaluate the impact of tenesmus on the respondent's day-to-day activities and symptom burden.
  - v) PROMIS Scale v1.0 - GI Disrupted and Swallowing 7a 09-01-2016.pdf
    - (1) Seven (7) questions utilizing a five-point response scale asking the respondent to rate the presence and severity of symptoms related to swallowing solids, semi-solids, liquids and pills in the last 7 days.
  - vi) PROMIS Scale v1.0 - GI Gas and Bloating 13a 09-02-2016.pdf
    - (1) Thirteen (13) questions utilizing a five-point response scale asking the respondent to rate the presence and severity of abdominal swelling, bloating, and gas-related symptoms over the past 7 days.
  - vii) PROMIS Scale v1.0 - GI Nausea and Vomiting 4a 09-01-2016.pdf
    - (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate the presence and severity of nausea, poor appetite, and vomiting symptoms over the past 7 days.
  - viii) PROMIS Scale v1.0 - GI Reflux 13a 09-01-2016.pdf
    - (1) Thirteen (13) questions utilizing a five-point response scale asking the respondent about the presence and severity of eructation, regurgitation, pain, hiccups, and burping over the past 7 days.
  - ix) PROMIS Scale v1.0 - Pain Intensity 3a 6-23-2016.pdf
    - (1) Three (3) questions utilizing a five-point response scale asking the respondent to rate the presence and severity of pain (peak, average, current) in the last 7 days.
  - x) PROMIS Scale v2.0 - Neuropathic Pain Quality 5a\_8-2-2016.pdf
    - (1) Five (5) questions utilizing a five-point response scale asking the respondent to rate the presence and severity of neuropathic pain symptoms (pins and needles, tingly, stinging, electrical, and numb) over the last 7 days.
  - xi) PROMIS Scale v2.0 - Nociceptive Pain Quality 5a\_8-2-2016.pdf
    - (1) Five (5) questions utilizing a five-point response scale asking the respondent to rate the presence and severity of nociceptive pain symptoms (sore, tender, achy, deep, and steady) over the last 7 days.

- xii) PROMIS SF v1.0-Dyspnea Functional Limitations 10a\_9-2-2016.pdf
  - (1) Ten (10) questions utilizing a four-point response scale asking the respondent to assess, considering the respondent's shortness of breath over the past 7 days, whether or not basic activities were performed and the amount of difficulty completing those activities of daily living, including walking ½ mile.
- xiii) PROMIS SF v1.0 - Dyspnea Severity 10a\_8-1-2016.pdf
  - (1) Ten (10) questions utilizing a four-point response scale asking the respondent to assess, considering the respondent's shortness of breath over the past 7 days, whether or not basic activities were performed and the severity of dyspnea associated with completion of those activities of daily living, including walking ½ mile.
- xiv) PROMIS SF v1.0 - Fatigue 4a 5-16-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate the presence and severity of fatigue in the last 7 days.
- xv) PROMIS SF v1.0 - Fatigue 6a 5-16-2016.pdf
  - (1) Six (6) questions utilizing a five-point response scale asking the respondent to rate the presence and severity of fatigue in the last 7 days, including single questions related to symptom burden and interference with physical function.
- xvi) PROMIS SF v1.0 - Fatigue 7a 5-2-2016.pdf
  - (1) Seven (7) questions utilizing a five-point response scale asking the respondent to rate the presence and severity of fatigue in the last 7 days, focusing on symptom burden and interference with physical function.
- xvii) PROMIS SF v1.0 - Fatigue 8a 5-16-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate the presence and severity of fatigue in the last 7 days, including frequency of fatigue-related interference with tasks and activities.
- xviii) PROMIS SF v1.0 - Pain Interference 4a 6-2-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate the degree to which pain interfered with day-to-day activities, household chores, and social activities.
- xix) PROMIS SF v1.0 - Pain Interference 6a 6-2-2016.pdf
  - (1) Six (6) questions utilizing a five-point response scale asking the respondent to rate the degree to which pain interfered with day-to-day activities, household chores, things usually done for fun, and social activities.
- xx) PROMIS SF v1.0 - Pain Interference 6b 5-2-2016.pdf
  - (1) Six (6) questions utilizing a five-point response scale asking the respondent to rate the degree to which pain interfered with day-to-day activities, household chores, things usually done for fun, and social activities. NOTE- Significant content overlap with PROMIS SF v1.0 - Pain Interference 6a 6-2-2016.pdf, but different questions used here.
- xxi) PROMIS SF v1.0 - Pain Interference 8a 6-2-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate the degree to which pain interfered with day-to-day activities, household chores, things usually done for fun, family life, enjoyment, and social activities.

- xxii) PROMIS SF v1.0 - Physical Func Samples w Mobility Aid 11-29-2016.pdf
- (1) Eleven (11) questions utilizing a five-point response scale asking the respondent about ability to walk, perform bathing/toileting functions, and other basic physical maneuvers. In addition, there is one screening question asking if the respondent can walk 25 feet on a level surface. If the respondent answers “yes” the first three main form questions are answered. If “no”, then those questions about extent of walking ability are skipped.
- xxiii) PROMIS SF v1.0 - Sleep Disturbance 4a 6-2-2016.pdf
- (1) Four (4) questions utilizing five-point response scales asking the respondent to rate first-person statements regarding sleep quality and effectiveness in the last 7 days.
- xxiv) PROMIS SF v1.0 - Sleep Disturbance 6a 6-2-2016.pdf
- (1) Six (6) questions utilizing five-point response scales asking the respondent to rate first-person statements regarding sleep quality and effectiveness in the last 7 days, including questions about difficulty falling asleep.
- xxv) PROMIS SF v1.0 - Sleep Disturbance 8a 6-2-2016.pdf
- (1) Eight (8) questions utilizing five-point response scales asking the respondent to rate first-person statements regarding sleep quality and effectiveness in the last 7 days, including questions about difficulty falling asleep and respondent’s satisfaction with sleep quality.
- xxvi) PROMIS SF v1.0 - Sleep Disturbance 8b 5-3-20126.pdf
- (1) Eight (8) questions utilizing five-point response scales asking the respondent to rate first-person statements regarding sleep quality and effectiveness, including questions about difficulty falling asleep and respondent’s satisfaction with sleep quality. NOTE- Substantive overlap with PROMIS SF v1.0 - Sleep Disturbance 8a 6-2-2016.pdf.
- xxvii) PROMIS SF v1.0 - Sleep Related Impairment 8a 5-9-2016.pdf
- (1) Eight (8) questions utilizing five-point response scales asking the respondent to rate first-person statements regarding awake time symptoms in the last 7 days related to lack of sleep effectiveness.
- xxviii) PROMIS SF v1.1 - Pain Behavior 7a 5-2-2016.pdf
- (1) Seven (7) questions utilizing five-point response scales asking the respondent to rate first-person statements regarding the effects of pain on several physical and psychological behaviors in the last 7 days.
- xxix) PROMIS SF v2.0 - Physical Function 4a 11-29-2016.pdf
- (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate statements about basic physical tasks (perform chores, ascend and descend stairs at normal pace, walk for at least 15 minutes, run errands and shop).
- xxx) PROMIS SF v2.0 - Physical Function 6b 11-29-2016.pdf
- (1) Six (6) questions utilizing a five-point response scale asking the respondent to rate statements about basic physical tasks (perform chores, ascend and descend stairs at normal pace, walk for at least 15 minutes, run errands and shop). In addition, there are two questions asking the respondent whether their health now limits the ability to do two hours of physical labor, or performing moderate work around the house (e.g. vacuuming, sweeping floors, carrying groceries).

xxxi) PROMIS SF v2.0 - Physical Function 8b 11-29-2016.pdf

- (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate statements about basic physical tasks (perform chores, ascend and descend stairs at normal pace, walk for at least 15 minutes, run errands and shop). In addition, there are two questions asking the respondent whether their health now limits the ability to do two hours of physical labor, or performing moderate work around the house (e.g. vacuuming, sweeping or scrubbing floors, lifting or carrying groceries, lifting/moving heavy furniture). NOTE- Nearly identical to PROMIS SF v2.0 - Physical Function 6b 11-29-2016.pdf, except for the addition of two additional questions that effectively raise the “ceiling” on difficulty of activities inquired about.

xxxii) PROMIS SF v2.0 - Physical Function 10a 11-29-2016.pdf

- (1) Ten (10) questions utilizing a five-point response scale asking the respondent to rate statements about limitations on both moderate and vigorous physical activities as well as five (5) questions asking the respondent to rate their ability to perform basic physical tasks (chores such as vacuuming or yard work, dressing oneself, shampooing your own hair, wash and dry body, toileting).

xxxiii) PROMIS SF v2.0 - Physical Function 10b 1-23-2017.pdf

- (1) Ten (10) questions utilizing a five-point response scale asking the respondent to rate statements about basic physical tasks (perform chores, get in and out of car, ascend and descend stairs at normal pace, run errands and shop, bend down and pick up clothing from floor, lift 10 lbs. over head). In addition, the form includes four questions asking the respondent if current health limits ability to perform vigorous activities, bathing/dressing, putting trash bag outside, or moderate activities.

xxxiv) PROMIS SF v2.0 - Physical Function 20a 11-29-2016.pdf

- (1) Twenty (20) questions utilizing a five-point response scale asking the respondent to rate six (6) statements about limitations on both moderate and vigorous physical activities as well as fourteen (14) questions asking the respondent to rate their ability to perform basic physical tasks (chores such as vacuuming or yard work, dressing oneself, shampooing your own hair, wash and dry body, toileting). NOTE- Significant overlap with PROMIS SF v2.0 - Physical Function 10a 11-29-2016.pdf, but this form includes a more extensive/detailed list of physical tasks.

xxxv) PROMIS SF v2.0 - Upper Extremity 7a 11-29-2016.pdf

- (1) Seven (7) questions utilizing a five-point response scale asking the respondent to rate statements about basic physical tasks requiring upper extremity function to complete (carry object weighing over 10 lbs., wash your back, put on or take off coat or jacket, carry shopping bag or briefcase, lift 10 lbs. above shoulder, change overhead lightbulb, pass a 20 lb. turkey or ham at dinner table).

d) Social Health

i) PROMIS SF v1.0 - Psychosoc Illness Impact-Neg 4a 8-4-2016.pdf

- (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate first-person perspective, negative statements about basic psychosocial items (worthlessness, disconnectedness, worry about the future, life meaning). Each question has two subparts, asking about accuracy of the statement before the illness and now, since the illness.

- ii) PROMIS SF v1.0 - Psychosoc Illness Impact-Neg 8a 8-4-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate first-person perspective, negative statements about basic psychosocial items (worthlessness, disconnectedness, worry about the future, life meaning), using an expanded list of items compared to PROMIS SF v1.0 - Psychosoc Illness Impact-Neg 4a 8-4-2016.pdf. Each question has two subparts, asking about accuracy of the statement before the illness and now, since the illness.
- iii) PROMIS SF v1.0 - Psychosoc Illness Impact-Pos 4a 8-4-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale asking the respondent to rate first-person perspective, positive statements about basic psychosocial items (comfortable with self, realize who my friends are, adjusting to things that cannot be changed, life meaning). Each question has two subparts, asking about accuracy of the statement before the illness and now, since the illness.
- iv) PROMIS SF v1.0 - Psychosoc Illness Impact-Pos 8a 8-4-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale asking the respondent to rate first-person perspective, positive statements about basic psychosocial items (comfortable with self, realize who my friends are, adjusting to things that cannot be changed, life meaning), using an expanded list of items compared to PROMIS SF v1.0 - Psychosoc Illness Impact-Pos 4a 8-4-2016.pdf. Each question has two subparts, asking about accuracy of the statement before the illness and now, since the illness.
- v) PROMIS SF v1.0 - Satisf w Partic in DSA 7a 6-26-2016.pdf
  - (1) Seven (7) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate satisfaction in the last 7 days with various aspects of discretionary social activity (fun activities at home, do things for friends, leisure activities, fun activities outside the home).
- vi) PROMIS SF v1.0 - Satisf w Partic in Soc Roles 7a 5-9-2016.pdf
  - (1) Seven (7) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate satisfaction in the last 7 days with the ability to work and work capacity as well as ability to perform daily routines and fulfill personal/household responsibilities. NOTE- Similar in all aspects to PROMIS SF v1.0 - Satisf w Partic Soc Roles 4a 6-6-2016.pdf and PROMIS SF v1.0 - Satisf w Partic Soc Roles 6a 6-6-2016.pdf, with slightly expanded question list.
- vii) PROMIS SF v1.0 - Satisf w Partic Soc Roles 4a 6-6-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate satisfaction in the last 7 days with the ability to work and work capacity as well as ability to perform daily routines and fulfill personal/household responsibilities.
- viii) PROMIS SF v1.0 - Satisf w Partic Soc Roles 6a 6-6-2016.pdf
  - (1) Six (6) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate satisfaction in the last 7 days with the ability to work and work capacity as well as ability to perform daily routines and fulfill personal/household responsibilities. NOTE- Similar in all aspects to PROMIS SF v1.0 - Satisf w Partic Soc Roles 4a 6-6-2016.pdf, with slightly expanded question list.

- ix) PROMIS SF v1.0 - Satisf w Partic Soc Roles 8a 6-6-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate satisfaction in the last 7 days with the ability to work and work capacity as well as ability to perform daily routines and fulfill personal/household responsibilities. NOTE- Similar in all aspects to PROMIS SF v1.0 - Satisf w Partic Soc Roles 4a 6-6-2016.pdf, PROMIS SF v1.0 - Satisf w Partic Soc Roles 6a 6-6-2016.pdf, and PROMIS SF v1.0 - Satisf w Partic in Soc Roles 7a 5-9-2016.pdf, with slightly expanded question list.
- x) PROMIS SF v2.0 -Informational Support 6a 6-23-2016.pdf
  - (1) Six (6) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate statements describing available sources of information and advice.
- xi) PROMIS SF v2.0 - Ability to Participate 4a 6-23-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate negative statements describing both work and leisure activity roles.
- xii) PROMIS SF v2.0 - Ability to Participate 6a 6-23-2016.pdf
  - (1) Six (6) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate negative statements describing both work and leisure activity roles. NOTE- Very similar in scope to PROMIS SF v2.0 - Ability to Participate 4a 6-23-2016.pdf, but with expanded question set that doesn't fundamentally add to the topics being assessed.
- xiii) PROMIS SF v2.0 - Ability to Participate 8a 6-23-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate negative statements describing both work and leisure activity roles. NOTE- Very similar in scope to PROMIS SF v2.0 - Ability to Participate 4a 6-23-2016.pdf, but with expanded question set that doesn't fundamentally add to the topics being assessed
- xiv) PROMIS SF v2.0 - Companionship 4a 6-23-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale, asking the respondent to rate statements describing companionship (e.g. someone with whom to have fun, someone with whom to relax).
- xv) PROMIS SF v2.0 - Companionship 6a 6-23-2016.pdf
  - (1) Six (6) questions utilizing a five-point response scale, asking the respondent to rate statements describing companionship (e.g. someone with whom to have fun, someone with whom to relax). NOTE- Very similar in scope to PROMIS SF v2.0 - Companionship 4a 6-23-2016.pdf, with expanded question set that doesn't fundamentally change topic focus.
- xvi) PROMIS SF v2.0 - Emotional Support 4a 6-23-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate positive statements describing the respondent's emotional support resources (focused on person or people- "someone"). PROMIS SF v2.0 - Emotional Support 6a 6-23-2016.pdf and PROMIS SF v2.0 - Emotional Support 8a 6-23-2016.pdf use the same format with progressively expanded question set.



- xvii) PROMIS SF v2.0 - Emotional Support 6a 6-23-2016.pdf
  - (1) Six (6) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate positive statements describing the respondent's emotional support resources (focused on person or people- "someone"). PROMIS SF v2.0 - Emotional Support 6a 6-23-2016.pdf and PROMIS SF v2.0 - Emotional Support 8a 6-23-2016.pdf use the same format with progressively expanded question set.
- xviii) PROMIS SF v2.0 - Emotional Support 8a 6-23-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate positive statements describing the respondent's emotional support resources (focused on person or people- "someone"). PROMIS SF v2.0 - Emotional Support 6a 6-23-2016.pdf and PROMIS SF v2.0 - Emotional Support 8a 6-23-2016.pdf use the same format with progressively expanded question set.
- xix) PROMIS SF v2.0 - Informational Support 4a 6-23-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate statements describing available sources of information and advice.
- xx) PROMIS SF v2.0 - Informational Support 8a 6-23-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate statements describing available sources of information and advice.
- xxi) PROMIS SF v2.0 - Instrumental Support 4a 6-23-2016.pdf
  - (1) Four (4) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate statements describing available support resources (e.g. help if you're confined to bed, someone to take you to the doctor, someone to help with daily chores if you are sick, someone to run errands as needed). PROMIS SF v2.0 - Instrumental Support 6a 6-23-2016.pdf and PROMIS SF v2.0 - Instrumental Support 8a 6-23-2016.pdf use identical format and add questions about meal preparation, and responsibilities at home but do not fundamentally change the scope of topics covered.
- xxii) PROMIS SF v2.0 - Instrumental Support 6a 6-23-2016.pdf
  - (1) Six (6) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate statements describing available support resources (e.g. help if you're confined to bed, someone to take you to the doctor, someone to help with daily chores if you are sick, someone to run errands as needed). PROMIS SF v2.0 - Instrumental Support 6a 6-23-2016.pdf and PROMIS SF v2.0 - Instrumental Support 8a 6-23-2016.pdf use identical format and add questions about meal preparation, and responsibilities at home but do not fundamentally change the scope of topics covered.
- xxiii) PROMIS SF v2.0 - Instrumental Support 8a 6-23-2016.pdf
  - (1) Eight (8) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate statements describing available support resources (e.g. help if you're confined to bed, someone to take you to the doctor, someone to help with daily chores if you are sick, someone to run errands as needed). PROMIS SF v2.0 - Instrumental Support 6a 6-23-2016.pdf and PROMIS SF v2.0 - Instrumental Support 8a 6-23-2016.pdf use identical format and add questions about meal preparation, and responsibilities at home but do not fundamentally change the scope of topics covered.

- xxiv) PROMIS SF v2.0 - Satisfaction with Social Roles 4a 6-26-2016.pdf
- (1) Four (4) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate statements describing the respondent's satisfaction with various aspects of social roles and activities (e.g. do things for family, do fun things with others, do things for friends, perform daily routines). PROMIS SF v2.0 - Satisfaction with Social Roles 6a 6-23-2016.pdf and PROMIS SF v2.0 - Satisfaction with Social Roles 8a 6-23-2016.pdf utilize identical format and expanded question set that includes "fun outside of my home" and "satisfaction with one's ability to do the work that is really important to" the respondent.
- xxv) PROMIS SF v2.0 - Satisfaction with Social Roles 6a 6-23-2016.pdf
- (1) Six (6) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate statements describing the respondent's satisfaction with various aspects of social roles and activities (e.g. do things for family, do fun things with others, do things for friends, perform daily routines). PROMIS SF v2.0 - Satisfaction with Social Roles 6a 6-23-2016.pdf and PROMIS SF v2.0 - Satisfaction with Social Roles 8a 6-23-2016.pdf utilize identical format and expanded question set that includes "fun outside of my home" and "satisfaction with one's ability to do the work that is really important to" the respondent.
- xxvi) PROMIS SF v2.0 - Satisfaction with Social Roles 8a 6-23-2016.pdf
- (1) Eight (8) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate statements describing the respondent's satisfaction with various aspects of social roles and activities (e.g. do things for family, do fun things with others, do things for friends, perform daily routines). PROMIS SF v2.0 - Satisfaction with Social Roles 6a 6-23-2016.pdf and PROMIS SF v2.0 - Satisfaction with Social Roles 8a 6-23-2016.pdf utilize identical format and expanded question set that includes "fun outside of my home" and "satisfaction with one's ability to do the work that is really important to" the respondent.
- xxvii) PROMIS SF v2.0 - Social Isolation 4a 6-23-2016.pdf
- (1) Four (4) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate statements describing the respondent's perception of social isolation. PROMIS SF v2.0 - Social Isolation 6a 6-23-2016.pdf and PROMIS SF v2.0 - Social Isolation 8a 6-23-2016.pdf include additional questions that do not fundamentally change the scope of the instruments.
- xxviii) PROMIS SF v2.0 - Social Isolation 6a 6-23-2016.pdf
- (1) Six (6) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate statements describing the respondent's perception of social isolation. PROMIS SF v2.0 - Social Isolation 6a 6-23-2016.pdf and PROMIS SF v2.0 - Social Isolation 8a 6-23-2016.pdf include additional questions that do not fundamentally change the scope of the instruments.
- xxix) PROMIS SF v2.0 - Social Isolation 8a 6-23-2016.pdf
- (1) Eight (8) questions utilizing a five-point response scale and a first-person perspective, asking the respondent to rate statements describing the respondent's perception of social isolation. PROMIS SF v2.0 - Social Isolation 6a 6-23-2016.pdf and PROMIS SF v2.0 -

Social Isolation 8a 6-23-2016.pdf include additional questions that do not fundamentally change the scope of the instruments.

**4) Parent Proxy Item Banks**

- a) Global Health
  - i) PROMIS Parent Proxy Bank v2.0 - Asthma Impact 7-29-2016.pdf
  - ii) PROMIS Scale v1.0 - Parent Proxy Global Health 7 3-31-2016.pdf
  - iii) PROMIS Scale v1.0 - Parent Proxy Global Health 7+2 5-5-2016.pdf
- b) Mental Health
  - i) PROMIS Bank v1.0 - Parent Proxy Life Satisfaction 5-6-2016.pdf
  - ii) PROMIS Bank v1.0 - Parent Proxy Meaning and Purpose 5-6-2016.pdf
  - iii) PROMIS Bank v1.0 - Parent Proxy Phys Stress Exp 5-6-2016.pdf
  - iv) PROMIS Bank v1.0 - Parent Proxy Positive Affect 5-5-2016.pdf
  - v) PROMIS Bank v1.0 - Parent Proxy Psych Stress Experiences 5-5-2016.pdf
  - vi) PROMIS Parent Proxy Bank v2.0 - Anxiety 7-29-2016.pdf
  - vii) PROMIS Parent Proxy Bank v2.0 - Depressive Symptoms 7-29-2016.pdf
- c) Physical Health
  - i) PROMIS Bank v1.0 - Parent Proxy Physical Activity 5-5-2016.pdf
  - ii) PROMIS Bank v1.0 - Parent Proxy Strength Impact 5-5-2016.pdf
  - iii) PROMIS Parent Proxy Bank v2.0 - Fatigue 7-29-2016.pdf
  - iv) PROMIS Parent Proxy Bank v2.0 - Mobility\_7-29-2016.pdf
  - v) PROMIS Parent Proxy Bank v2.0 - Pain Interference 7-29-2016.pdf
  - vi) PROMIS Parent Proxy Bank v2.0 - Upper Extremity 7-29-2016.pdf
- d) Social Health
  - i) PROMIS Parent Proxy Bank v2.0 - Peer Relationships 7-29-2016.pdf

**5) Parent Proxy Profiles**

- a) PROMIS Parent Proxy-25 Profile v2.0 7-26-2016.pdf
- b) PROMIS Parent Proxy-37 Profile v2.0 7-26-2016.pdf
- c) PROMIS Parent Proxy-49 Profile v2.0 7-29-2016.pdf

**6) Parent Proxy Short Forms**

- a) Global and Other
  - i) PROMIS Parent Proxy SF v2.0 - Asthma Impact 8a\_7-20-2016.pdf
- b) Mental Health
  - i) PROMIS Parent Proxy Scale v2.0 - Anger 5a 7-29-2016.pdf
  - ii) PROMIS Parent Proxy SF v2.0 - Anxiety 8a 7-29-2016.pdf
  - iii) PROMIS Parent Proxy SF v2.0 - Depressive Symptoms 6a 7-29-2016.pdf
  - iv) PROMIS SF v1.0 - Parent Proxy Life Satisfaction 4a 5-6-2016.pdf
  - v) PROMIS SF v1.0 - Parent Proxy Life Satisfaction 8a 5-6-2016.pdf
  - vi) PROMIS SF v1.0 - Parent Proxy Meaning and Purpose 4a 5-6-2016.pdf
  - vii) PROMIS SF v1.0 - Parent Proxy Meaning and Purpose 8a 5-6-2016.pdf
  - viii) PROMIS SF v1.0 - Parent Proxy Phys Stress Exp 4a 5-6-2016.pdf
  - ix) PROMIS SF v1.0 - Parent Proxy Phys Stress Exp 8a 5-6-2016.pdf
  - x) PROMIS SF v1.0 - Parent Proxy Positive Affect 4a 5-5-2016.pdf
  - xi) PROMIS SF v1.0 - Parent Proxy Positive Affect 8a 5-5-2016.pdf
  - xii) PROMIS SF v1.0 - Parent Proxy Psych Stress Experiences 4a 5-5-2016.pdf

- xiii) PROMIS SF v1.0 - Parent Proxy Psych Stress Experiences 8a 5-5-2016.pdf
  - c) Physical Health
    - i) PROMIS Parent Proxy SF v2.0 - Fatigue 10a 7-29-2016.pdf
    - ii) PROMIS Parent Proxy SF v2.0 - Mobility 8a 7-29-2016.pdf
    - iii) PROMIS Parent Proxy SF v2.0 - Pain Interference 8a 7-29-2016.pdf
    - iv) PROMIS Parent Proxy SF v2.0 - Upper Extremity 8a 7-29-2016.pdf
    - v) PROMIS SF v1.0 - Parent Proxy Physical Activity 4a 5-5-2016.pdf
    - vi) PROMIS SF v1.0 - Parent Proxy Physical Activity 8a 5-5-2016.pdf
    - vii) PROMIS SF v1.0 - Parent Proxy Strength Impact 4a 5-5-2016.pdf
    - viii) PROMIS SF v1.0 - Parent Proxy Strength Impact 8a 5-5-2016.pdf
  - d) Social Health
    - i) PROMIS Parent Proxy SF v2.0 - Peer Relationship 7a 7-29-2016.pdf
- 7) Pediatric Item Banks**
  - a) Global and Other
    - i) PROMIS Pediatric Bank v2.0 - Asthma Impact 7-28-2016.pdf
  - b) Mental Health
    - i) PROMIS Pediatric Item Bank v1.0 - Life Satisfaction 7-7-2016.pdf
    - ii) PROMIS Pediatric Item Bank v1.0 - Meaning and Purpose 7-14-2016.pdf
    - iii) PROMIS Pediatric Item Bank v1.0 - Phys Stress Experiences 7-14-2016.pdf
    - iv) PROMIS Pediatric Item Bank v1.0 - Positive Affect 7-14-2016.pdf
    - v) PROMIS Pediatric Item Bank v1.0 - Psych Stress Experiences 7-14-2016.pdf
    - vi) PROMIS Pediatric Item Bank v2.0 - Anxiety 7-28-2016.pdf
    - vii) PROMIS Pediatric Item Bank v2.0 - Depressive Symptoms 7-28-2016.pdf
  - c) Physical Health
    - i) PROMIS Pediatric Item Bank v1.0 - Physical Activity 7-14-2016.pdf
    - ii) PROMIS Pediatric Item Bank v1.0 - Strength Impact 7-14-2016.pdf
    - iii) PROMIS Pediatric Item Bank v2.0 - Fatigue 7-28-2016.pdf
    - iv) PROMIS Pediatric Item Bank v2.0 - Mobility 7-28-2016.pdf
    - v) PROMIS Pediatric Item Bank v2.0 - Pain Interference 7-28-2016.pdf
    - vi) PROMIS Pediatric Item Bank v2.0 - Upper Extremity 7-28-2016.pdf
  - d) Social Health
    - i) PROMIS Pediatric Item Bank v2.0 - Peer Relationships 7-28-2016.pdf
- 8) Pediatric Profiles**
  - a) PROMIS Pediatric v2.0 Profile-25\_7-28-2016.pdf
  - b) PROMIS Pediatric v2.0 Profile-37\_8-01-2016.pdf
  - c) PROMIS Pediatric v2.0 Profile-49\_9-23-2016.pdf
- 9) Pediatric Short Forms**
  - a) Global and Other
    - i) PROMIS Pediatric Scale v1.0 - Global Health 7 7-14-2016.pdf
    - ii) PROMIS Pediatric Scale v1.0 - Global Health 7+2 7-14-2016.pdf
    - iii) PROMIS Pediatric SF v2 0 - Asth Imp 8a 7-20-2016.pdf
  - b) Mental Health
    - i) PROMIS Pediatric Scale v2.0 - Anger 9a\_7-27-2016.pdf
    - ii) PROMIS Pediatric SF v1.0 - Life Satisfaction 4a 7-14-2016.pdf

- iii) PROMIS Pediatric SF v1.0 - Life Satisfaction 8a 7-14-2016.pdf
  - iv) PROMIS Pediatric SF v1.0 - Meaning and Purpose 4a 7-14-2016.pdf
  - v) PROMIS Pediatric SF v1.0 - Meaning and Purpose 8a 7-14-2016.pdf
  - vi) PROMIS Pediatric SF v1.0 - Phys Stress Experiences 4a 7-14-2016.pdf
  - vii) PROMIS Pediatric SF v1.0 - Phys Stress Experiences 8a 7-14-2016.pdf
  - viii) PROMIS Pediatric SF v1.0 - Positive Affect 4a 7-14-2016.pdf
  - ix) PROMIS Pediatric SF v1.0 - Positive Affect 8a 7-14-2016.pdf
  - x) PROMIS Pediatric SF v1.0 - Psych Stress Experiences 4a 7-14-2016.pdf
  - xi) PROMIS Pediatric SF v1.0 - Psych Stress Experiences 8a 7-14-2016.pdf
  - xii) PROMIS Pediatric SF v2.0 - Anger5a\_7-27-2016.pdf
  - xiii) PROMIS Pediatric SF v2.0 - Anxiety 8a 7-27-2016.pdf
  - xiv) PROMIS Pediatric SF v2.0 - Depressive Symptoms 8a 7-28-2016.pdf
- c) Physical Health
- i) PROMIS Pediatric SF v1.0 - Physical Activity 4a 7-14-2016.pdf
  - ii) PROMIS Pediatric SF v1.0 - Physical Activity 8a 7-14-2016.pdf
  - iii) PROMIS Pediatric SF v1.0 - Strength Impact 4a 7-14-2016.pdf
  - iv) PROMIS Pediatric SF v1.0 - Strength Impact 8a 7-14-2016.pdf
  - v) PROMIS Pediatric SF v2.0 - Fatigue 10a 7-28-2016.pdf
  - vi) PROMIS Pediatric SF v2.0 - Mobility 8a 7-28-2016.pdf
  - vii) PROMIS Pediatric SF v2.0 - Pain Interference 8a 7-28-2016.pdf
  - viii) PROMIS Pediatric SF v2.0 - Upper Extremity 8a 7-28-2016.pdf
- d) Social Health
- i) PROMIS Pediatric SF v2.0 - Peer Relationships 8a 7-28-2016.pdf

## ***Appendix H: PRO TEP Post TEP Teleconference Call #1 Minutes***

**End Stage Renal Disease (ESRD) Quality Measure Development, Maintenance, and Support Project  
ESRD Patient Reported Outcomes (PRO) Technical Expert Panel (TEP)  
Post-TEP Teleconference Call #1 Minutes  
July 19, 2017 11:00am – 1:00pm (ET)**

TEP Members Present	UM-KECC	CMS
Jennifer Flythe	Claudia Dahlerus	Joel Andress
Michelle Richardson	Joseph Messana	Elena Balovlenkov
Kerri Cavanaugh	Richard Hirth	
Paul Conway	Lan Tong	
Lorien Dalrymple	Jordan Affholter	<b>CMS/CM</b>
Derek Forfang		Julia Zucco
Patrick Gee		Debra Dean-Whittaker
Jennifer Geiger		Elizabeth Goldstein
Amanda Grandinetti		
Daniel Iniguez		<b>RTI</b>
Jacqueline Javier-Burns		Judith Lynch
Sherry Rivera		Scott Scheffler
Brigitte Schiller		Celia Eicheldinger
Nancy Scott		
Francesca Tentori		
John Ware		

### **Introductions**

Claudia Dahlerus, PhD from the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC), welcomed everyone to the first Patient Reported Outcomes (PRO) Post-TEP teleconference call, which was a follow-up call from the in-person meeting on May 23-24, 2017. Dr. Dahlerus stated the call was open to the public, being recorded, and that the last five minutes of each hour was set aside for public comments.

Dr. Dahlerus provided a basic overview of the pre-TEP call agenda. Dr. Dahlerus stated that the first hour of the call would be an opportunity for TEP members to have an open discussion with the ICH CAHPS (In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems) team from the Centers for Medicare & Medicaid Services (CMS). Dr. Dahlerus stated that TEP members would have the opportunity to ask questions and provide feedback on the ICH CAHPS survey to the ICH CAHPS team. Dr. Dahlerus explained that during the in-person meeting PRO TEP meeting there was agreement to defer discussion topics related to ICH CAHPS to a follow-up teleconference call where that discussion could occur with the ICH CAHPS team. Dr. Dahlerus stated that the second part of the call would focus on the Results of the Environmental Scan and Discussion on Patient Safety and Life Goals.

Dr. Dahlerus conducted an ordered roll call of the TEP members in attendance.

The following ICH CAHPS (In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems) representatives were in attendance: Julia Zucco, PhD (CMS/CM), Debra Dean-Whittaker, PhD

(CMS/CM), Elizabeth Goldstein, PhD (CMS/CM), Judith Lynch (RTI), Scott Scheffler, MS (RTI), and Celia Eicheldinger, MS (RTI).

Joel Andress, PhD and Elena Balovlenkov, RN (CMS) from the Centers for Medicare & Medicaid Services (CMS) were in attendance. Joel Andress, PhD (CMS) is the Project Contracting Officer's Representative (COR). Elena Balovlenkov, RN, (CMS) is the Dialysis Facility Compare (DFC) lead for Public Reporting.

### **TEP Feedback and Discussion on the ICH CAHPS Survey**

Dr. Dahlerus explained that during the in-person PRO TEP meeting in May, there was TEP agreement to defer discussion topics related to experience of care and ICH CAHPS to a follow-up teleconference call where that discussion could occur with the ICH CAHPS team. Dr. Dahlerus explained that the main reason why this topic was deferred is because it was outside of the scope of the TEP charter. Dr. Dahlerus stated that UM-KECC recognized that there was TEP interest in speaking with ICH CAHPS team about questions on the survey. Dr. Dahlerus explained that the open TEP discussion with the ICH CAHPS team would not be recorded in the PRO TEP Teleconference Call minutes. Dr. Dahlerus opened up the discussion for TEP members to speak with the ICH CAHPS team.

### **Results of the Environmental Scan and Discussion on Patient Safety**

Dr. Dahlerus stated the goal of the second part of the call was to begin to define some basic content for patient safety and life goals measures. During the in-person meeting, TEP members recommended these two topics as highest priority. Dr. Dahlerus explained that the results of the literature search would inform the TEP discussion. Dr. Dahlerus stated that the intent of this discussion is not to define specific survey questions or quality metrics. Dr. Dahlerus stated that the decisions and recommendations from this teleconference call would be appended to the final ESRD PRO TEP Summary Report. Dr. Dahlerus presented a brief recap of the recommendations from the PRO TEP in-person meeting and then handed the discussion over to the TEP co-chairs (see slide 103 in Appendix J).

One of the TEP co-chairs provided a summary on the environmental scan and literature search results for the patient safety topic. The TEP co-chair explained that UM-KECC completed the environmental scan and did not identify any existing kidney disease-specific or dialysis patient safety measures. The TEP co-chair stated that based on the previous discussion (from the in-person meeting) that the intent was a measure based on patient reporting of their level of safety at a dialysis clinic.

The TEP co-chair stated that two related measures were found: (1) the Patient Measure of Safety (inpatient PMOS) and (2) a primary care PMOS. The TEP co-chair stated that the PMOS survey (Giles et al, 2013) has approximately 40 questions. The TEP co-chair asked if the PMOS questions address the specific patient safety topics of interest to the TEP. The TEP co-chair further explained that the TEP could consider if patient safety questions should be incorporated into the ICH CAHPS as it is an existing patient experience of care instrument that is already administered to patients.

One TEP member asked the TEP co-chair if there were any safety questions in the ICH CAHPS. The TEP co-chair stated that there were not safety questions in the ICH CAHPS that address if patients “feel safe”.

Another TEP member asked if there were any questions on ICH CAHPS that could be considered a safety question. Dr. Dahlerus explained there is one ICH CAHPS question asking patients about whether they

experience problems in their treatment that would be the closest question to address patient safety on the ICH CAHPS survey. There may be other questions that could be considered safety-related depending on interpretation.

UM-KECC displayed the Patient Measure of Safety (PMOS) for the TEP members to review during the call. The TEP members reviewed the PMOS measure. The TEP co-chair stated that one question on the PMOS addresses technician competence, which relates to a topic brought up the TEP at the in-person meeting. The TEP co-chair explained that none of the PMOS questions directly apply to the dialysis setting.

One TEP member asked the TEP if there were any PMOS questions that could be useful for a potential safety question. The TEP co-chair stated that many of the PMOS questions are similar to many of the ICH CAHPS questions.

Dr. Dahlerus asked the TEP if there is interest in global items or specific items for patient safety.

One TEP member stated that the TEP previously discussed patient perception of safety. The TEP co-chair concurred and asked for TEP member perspectives on if a question such as “do you feel safe when you are receiving your dialysis treatment?” would capture a patient safety question.

One TEP member stated that a broad question asking “whether you feel safe or not safe” could be a good start. The TEP member stated that if a patient responds they feel unsafe, then there could be further specific questions asking patients why they do not feel safe (e.g., lack of technician experience, infection concerns).

The TEP co-chair asked for additional items that could be covered under a global patient safety question. One TEP member mentioned vascular access management as another potential item to be considered as a further question.

Another TEP member agreed that asking a high-level global question would be helpful. A third TEP member agreed that a patient safety measure should start with a high level question and then drill down into more specific questions.

One TEP member stated they would favor one overall (global) patient safety question in order to limit burden. The TEP member asked if linking the patient safety question to ICH CAHPS would be the best approach.

The TEP co-chair responded the TEP needs to consider whether the topic of patient safety should (or could) be adopted into ICH CAHPS. They explained adding such a questions (or questions) to the ICH CAHPS was potentially identified as a more expedient option for implementation of a patient safety measure. The TEP co-chair stated that as discussed at the in-person meeting it is important for facilities to be able to respond to results (from the survey questions) and for patients to receive feedback that their concerns were addressed. The TEP co-chair stated the current method for collecting and reporting the ICH CAHPS does not allow for this feedback. The TEP co-chair recommended that if the TEP agrees to recommend including patient safety in the ICH CAHPS that the survey administration and reporting method be modified so patients can receive feedback. The TEP co-chair asked for any comments on the issue.



Both TEP co-chairs supported the importance for facilities to be able to respond to patient concerns. They stated that it was currently unclear if ICH CAHPS is the best source for a patient safety measure or question.

One TEP member asked that the following be reflected in the minutes: TEP members support a measure of patient safety irrespective of whether it is part of ICH CAHPS. The TEP member also asked if the TEP supports the most expedient way to include the patient safety.

The TEP co-chair asked members if there are downsides to incorporating a patient safety measure (or question) into ICH CAHPS.

One TEP member stated it appears that the current version of ICH CAHPS will be continued for the near future, and that any changes to the current version of ICH CAHPS may take a longer to implement.

Another TEP member posed a broader question about the overall purpose of the patient safety measure. The TEP member stated that if the goal is to create measures that address patient experience from a patient perspective, then the number of questions may not be as important as asking the important (right) questions. The TEP member stated they are less concerned about survey fatigue, and more concerned about increasing the quality of care for patients. The TEP member expressed the importance of communicating the goal of the survey (or any patient survey) to patients. The TEP member stated that if a patient does a survey and knows that the survey increases the quality of care for other patients, then the patient is more likely to understand and appreciate the importance of the survey and complete the survey.

The TEP co-chair summarized that the group was supportive for the consideration of patient safety measure, and patient safety questions to be included in the ICH CAHPS if the ICH CAHPS survey was modified to reduce the length of the survey. The TEP co-chair further stated that it would be important for there to be a feedback mechanism where facilities can respond to patient concerns. The TEP co-chair stated that they did not hear any strong objections to putting a patient safety question(s) in the ICH CAHPS as long as a feedback mechanism is included. The TEP co-chair asked for any comments on patient safety.

One TEP member asked for clarification. The TEP member stated that if a patient safety question(s) measure was added to ICH CAHPS, then there is not currently a mechanism to provide feedback to patients. Currently, the ICH CAHPS survey is anonymous to protect patient anonymity and protect patients from a fear of retribution. The TEP member stated that it is important to consider how the feedback loop works, and if the feedback loop would require patients to identify themselves. The TEP member recommended being thoughtful on considerations around anonymity and patient retribution concerns.

Another TEP member agreed with the previous concern. The TEP member stated that it is important to believe that the unit level summary is important and representative. The TEP member stated it may be necessary to encourage other areas of reporting such as through patient complaints or patient advocacy. The TEP member stated that anonymity and retribution concerns are very high on the radar for CMS and ICH CAHPS. On the topic of addressing patient concerns, the TEP member stated that it may be difficult to balance the goal of having individual measurement and actionability for individual concerns versus evaluation of concerns at the facility/practice level that would be addressed.

The TEP co-chair asked patient TEP members if patients need individual level feedback or if unit level would be appropriate.

One patient TEP member stated that the concern about anonymity is important and it is important to protect patients. The TEP member stated that it is important that patients understand that the process (for reporting about patient safety) improves care. The TEP member stated that information given at unit level that would be good. The TEP member stated that they don't want to risk any threat to patient anonymity.

The TEP co-chair stated that the group is committed to anonymity. The TEP co-chair stated that it is important for the survey results to get back to facilities at a unit level so that the facility can take broad actions.

Another TEP member agreed with this statement. The TEP member stated that there may be some concerns around smaller facilities if they have a smaller number of patients.

The TEP co-chair asked for any final comments on patient safety. There were no further comments.

### **Results of the Environmental Scan and Discussion on Life Goals**

The other TEP co-chair transitioned to the life goals discussion and provided a summary of the life goals environmental scan. The TEP co-chair explained that the literature on life goals is focused primarily in the following condition or subpopulations: patients with cancer, rehabilitative treatment, end of life and palliative care, hospice, and setting treatment specific goals.

The TEP co-chair explained that there were no patient reported outcome measures that capture life goals in the dialysis setting. The TEP co-chair stated that there were several life goals measures but often the instruments were long, open-ended questions, or did not have much psychometric testing.

The TEP co-chair discussed a review article on goal directed healthcare by Waters and Sierpina (2006). The TEP co-chair explained that this may help frame the discussion of life goals. Goal directed healthcare focuses on how to improve patient care by focusing on life goals.

The TEP co-chair presented an excerpt and table from the article (Waters and Sierpina, 2006) and read through several sample life goals questions included as examples in the article. The TEP co-chair asked for TEP member feedback.

One TEP member stated that their organization has tried to implement a goal-directed healthcare approach. The TEP member stated that using a goal-directed health-care approach, emphasizing what is important to the patient, often changed the perspective of patients and resulted in many selecting home dialysis. They stated patient's decisions were more often based on what was important from their perspective (as patients), not necessarily based on the clinical benefits of home dialysis.

Another TEP member stated that several of the questions presented from the Waters article may be applicable to what the TEP identified as the basic intent of a life goals measure.

One TEP member asked if the TEP should focus on life goals or end of life planning. The TEP co-chair responded by asking if a life goals measure could potentially encompass end of life care that is

important to the patient. Several TEP members agreed that life goals could encompass end of life care planning.

One TEP member explained that starting dialysis is a very stressful experience, and asking end of life questions at that time may not be the best approach. The TEP member stated that end of life questions could be proposed at a later time. The TEP member stated that the sequence of questions is also very important. Another TEP member agreed and stated that the focus should be on life goals as distinct from end of life care planning.

The TEP co-chair summarized that there is general TEP agreement that global life goals should be the starting point for a life goals measure. The TEP co-chair asked the TEP for any comments on how frequent patients should be asked about life goals, which providers should be involved, and what questions should be asked to determine if patients were asked about life goals (i.e., that the provider asked the questions).

One TEP member stated that it will be important that a life goals measure is not a checkbox measure. The TEP member stated that life goals should be an ongoing discussion. TEP member stated that the whole care team should be involved in this ongoing discussed. Another TEP member agreed that the whole team needs to be involved, and that is the purpose of this measure.

A third TEP member agreed that the whole team needs to be involved and it is important that the responsibility for the life goals conversation is not put entirely on the social worker. The TEP member also mentioned the importance of the care team discussing modality options with the patient. They said that often the modality discussion is treated as a check box item.

The TEP co-chair stated that one potential question that could be asked is if the life goals conversation happened. This could also include follow-up questions drilling into more specific detail. The TEP co-chair asked the TEP member to provide potential questions. The TEP member offered the following potential life goal questions: (1) "Did this conversation take place?", (2) "How many people in your care team had this conversation with you?", (3) "How often did you hear it?", and then (4) "after I had this conversation I understood that by choosing a modality I might be (better) able to \_\_\_\_\_ (i.e., keep working, travel, and spend more time with family)." The TEP member stated it was important to have a question that links the question to something practical (and important) in a patient's life.

The TEP co-chair stated that the TEP member linked life goals to modality. The TEP co-chair asked if life goals could be broader than modality. The TEP member responded yes that life goals could be broader than modality.

The TEP co-chair asked for final comments on life goals.

A TEP member stated that not all facilities offer all modalities. They stated that is important for the nephrologist to be involved in the discussion. The TEP member further stated that it is important to ask questions such as "Do you feel like you have a strong voice in your care?", and "Does your care plan match what you want to do with your life?" The TEP member stated that the life goals discussion should be held at least annually in the care planning process.

Another TEP member agreed that the care team should be involved and that the doctor should be the chairperson for the life goals conversation.

The TEP co-chair asked for any final comments. There were no more final comments. The TEP co-chair passed the meeting back to Dr. Dahlerus (UM-KECC).

### **Administrative Follow-up to the In-Person Meeting**

Dr. Dahlerus reminded the TEP that the TEP recommendations and this call's discussion will help inform future PRO work. The final recommendations for life goals and patient safety measures will be documented in the final PRO TEP summary report. Dr. Dahlerus stated there was also an administrative follow-up to the in-person PRO TEP meeting. Dr. Dahlerus stated that after the in-person meeting a couple of TEP members contacted CMS and UM-KECC to express concern that treatment tolerance and recovery time were two important topics that were not fully discussed during the in-person meeting. Dr. Dahlerus stated that in order to be responsive to the TEP members they wanted to ask TEP members if an additional call should be scheduled to discuss treatment tolerance and recovery time.

The TEP provided their feedback and there was TEP consensus on having a separate post-TEP teleconference call in order to discuss the topics of recovery time and treatment tolerance. Dr. Dahlerus explained that a second call would be scheduled and that it will be an open discussion on these two topics.

### **Public Comments**

There were no public comments received during this TEP call.

### **Closing Questions and Remarks**

Dr. Dahlerus closed the call and thanked the TEP members for attending the teleconference. Dr. Dahlerus stated that UM-KECC would follow-up with the TEP members in order to schedule the next teleconference call.

### **References**

Giles SJ, Lawton RJ, Din I, et al. Developing a patient measure of safety (PMOS). *BMJ Qual Saf* 2013;22:554-562.

Waters, D and VS Sierpina. Goal-directed health care and the chronic pain patient: A new vision of the healing encounter. *Pain Physician*. 2006 9(4): 353-360.

### **Appendix:**

Dr. Schiller provided the following comments for potential life goals questions that were sent through the WebEx Chat function during the call and approved that the following to be appended to the TEP minutes.

1. "How well did you feel supported at the start of dialysis (first 90-120 days) to adapt to dialysis?" Likert scale, 1-10
2. "How well were you supported to pursue your life goals?" Likert scale, 1-10
3. "Did you have a team of people supporting you?" – yes or no – not sure

## ***Appendix I: PRO TEP Post TEP Teleconference Call #2 Minutes***

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The PRO TEP Post TEP Teleconference Call #2 Minutes from the PRO TEP call on August 30, 2017 are provided on the next several pages.

**End Stage Renal Disease (ESRD) Quality Measure Development, Maintenance, and Support Project**  
**ESRD Patient Reported Outcomes (PRO) Technical Expert Panel (TEP)**  
**Post-TEP Teleconference Call #2 Minutes**  
August 30, 2017 12:00pm – 1:00pm (ET)

<b>TEP Members Present</b>	<b>UM-KECC</b>	<b>CMS</b>
Jennifer Flythe	Claudia Dahlerus	Joel Andress
Kerri Cavanaugh	Joseph Messana	Elena Balovlenkov
Lorien Dalrymple	Richard Hirth	Jesse Roach
Derek Forfang	Jennifer Sardone	
Patrick Gee	Jordan Affholter	
Amanda Grandinetti	Yuqing Lin	
Lori Hartwell		
Daniel Iniguez		
Jacqueline Javier-Burns		
Michael "Jack" Lennon		
Sherry Rivera		
Brigitte Schiller		
Nancy Scott		
Francesca Tentori		
John Ware		

**Introductions**

Claudia Dahlerus, PhD from the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC), welcomed everyone to the second Patient Reported Outcomes (PRO) Post-TEP teleconference call. Dr. Dahlerus stated the call was open to the public and being recorded.

Dr. Dahlerus provided a basic overview of the pre-TEP call agenda. Dr. Dahlerus stated that the focus of the call would be to discuss the topics of treatment tolerance and recovery time. At the end of the teleconference call on July 19, 2017, the TEP was asked if there was interest in a separate teleconference call to further discuss the topics of treatment tolerance and recovery time. The consensus of the TEP was to have this additional call to discuss these two topics. Dr. Dahlerus explained that the last five minutes of call would be set aside for public comments.

Dr. Dahlerus conducted an ordered roll call of the TEP members in attendance.

Joel Andress, PhD, Elena Balovlenkov, RN, and Jesse Roach, MD (CMS) from the Centers for Medicare & Medicaid Services (CMS) were in attendance. Joel Andress, PhD (CMS) is the Project Contracting Officer's Representative (COR). Elena Balovlenkov, RN, (CMS) is the Dialysis Facility Compare (DFC) lead for Public Reporting. Jesse Roach, MD is a Medical Officer (Nephrology) and nephrologist working for the Centers for Medicare & Medicaid Services (CMS).

**Introduction to the Discussion on Treatment Tolerance and Recovery Time**

Dr. Dahlerus handed the call off to the TEP co-chair. The TEP co-chair welcomed everyone to the TEP call and thanked the TEP members for their time. The TEP co-chair presented a recap of the in-person TEP recommendations. The TEP co-chair stated that the minutes and recommendations from today's meeting will be

appended to the PRO TEP Summary Report. The TEP co-chair clarified that recommendations from the in-person meeting will still apply, but any additional recommendations from this call will be documented as additional recommendations. The TEP co-chair provided a recap of the in-person meeting recommendations (see section 4.8c TEP Recommendations and Discussion in the PRO TEP Summary Report).

The TEP co-chair explained that during the in-person TEP meeting, the two topics of recovery time and treatment tolerance were mainly discussed in the context of symptoms and symptom management associated with the dialysis treatment. Those two topics were added to the list of un-prioritized topics identified during the in-person TEP meeting (see section 4.5h Summary Discussion in the PRO TEP Summary Report).

The co-chair provided a brief re-cap of the in-person meeting discussion on these two topics. With respect to recovery time, the following points were made at the in-person meeting: TEP members felt it is important for providers to evaluate recovery time at regular intervals; some TEP members identified the importance of providers asking patients how long it took them to recover from their last treatment versus asking about recovery from the last several treatments (the latter being more subject to problems of recall). On the topic of treatment tolerance, the following were points of discussion at the in-person meeting: how the treatment makes the patient feel and if the patient experienced a bad treatment; a patient may have received a bad treatment if they experienced a negative symptom such as crashing or cramping during treatment; TEP members felt that reporting treatment tolerance places responsibility on the facility to address those symptoms and that this may have an important impact on how patients experience dialysis treatment.

The TEP co-chair then provided examples of potential PRO questions that were proposed by TEP members at the in-person meeting, such as “How was your treatment, was it tolerable?” or “How long does it take you to feel back to normal?”

The TEP co-chair stated that the goal of the current teleconference was to provide an opportunity for TEP members to have a general discussion on these two topics of treatment tolerance (i.e., symptoms) and recovery time. The TEP co-chair asked for feedback on the summary that they had provided.

One TEP member stated that the term treatment tolerance accurately reflects the (patient experience of treatment) construct that had been discussed at the in-person meeting.

#### **Discussion on Treatment Tolerance and Recovery Time**

The TEP co-chair asked the TEP how these two topics may be structured as a potential PRO measure and if there is evidence supporting these topics. The TEP co-chair also asked the TEP if there were any recommendations for these measures topics. (Note: in this discussion TEP members often referred to symptoms as part of treatment tolerance, e.g., the symptom of cramping was a marker of treatment tolerance. This usage will be reflected in these minutes).

One TEP member asked if it would be possible to ask patients how long it takes them to recover after receiving their dialysis treatment. The TEP co-chair stated that in one study researchers looked at different ranges of recovery time. Specifically, the TEP co-chair stated there is a validated single question recovery time measure (developed by Lindsay et al, 2006).

One TEP member asked if there is any measure that asks the patient a question about whether they experience cramping (or other symptoms). The TEP co-chair stated that the only measure that currently asks about symptoms is the symptoms question in the KDQoL-36. The TEP co-chair responded that there is not an existing (separate) instrument that asks the patient to report if they have a given symptom. They further noted

symptoms have not been studied in a very systematic way due to lack of available and uniform data on this topic (symptoms).

The TEP co-chair then asked this TEP member if they prioritized one topic over the other (i.e., symptoms/treatment tolerance versus recovery time). The TEP member responded they support either a treatment tolerance or recovery time measure. The TEP member further stated the key to improving patient quality of life is to give the patient the best treatment possible, because if a patient is crashing or cramping repeatedly they may not feel well and then miss future treatments (because of their bad experience with the treatment). The TEP member made the point that if a patient tells their care team they are not tolerating treatment well, it would encourage the care team to assess why and consider additional treatments/modalities or other adjustments to the patient's treatment. In turn, focusing on treatment tolerance may be a way to encourage the delivery of more individualized patient care tailored to the patient's needs.

Another TEP member asked how often the question of treatment tolerance would be asked. One TEP member stated that a single item question (on recovery time or symptoms) could be asked at every treatment, but if there are multiple questions for such a measure (for example: twenty questions), it would not be feasible to ask all of the questions at every treatment.

The TEP co-chair asked if the concept of treatment tolerance could be captured by one question, or if it would be a multi-symptom questionnaire. One TEP member responded that there are standard symptoms (i.e., nausea, cramping, crashing) that most dialysis patients experience. The TEP member further stated that the question(s) would have to be asked at each treatment to understand what symptoms are bothering the patient.

Another TEP member asked how patients would feel about being asked the same (symptom) question at each treatment. A patient TEP member responded that asking (symptom) questions often is important in order to identify if there is a pattern with certain symptoms being experienced regularly. The patient TEP member stated that asking the question weekly could potentially be frequent enough.

As part of the TEP's discussion about potential questions asking about treatment tolerance, one TEP member proposed the patient would be asked to report on a questionnaire the symptoms they experienced during treatment. For example, the patient could be asked "if you have any of the following symptoms during your treatment?" The TEP member stated the importance of asking about symptoms at each treatment as opposed to weekly, because a patient's symptoms may differ throughout the week and therefore make it difficult to attribute a symptom(s) to a specific treatment during the week.

The TEP co-chair stated that as a provider they ask their patients about a range of symptoms several times a month when they round (at their facility). The TEP co-chair stated that by asking their patients about specific symptoms it opens up a dialogue between patients and providers about how they are doing with their treatment as well as identify other potential issues that need to be addressed (by the physician).

Another TEP member stated that in their experience as a patient, a patient experiencing negative symptoms is likely having a more difficult (and longer) time recovering from the treatment.

The TEP discussion returned to the issue of whether it would be beneficial to ask patients about symptoms after every treatment. One TEP member responded that if providers are receiving real time data on a patient's (reported) symptoms, it allows the care team to more immediately address concerns.



The TEP co-chair then asked the TEP, between these two topics, if they prioritized the topic symptoms (treatment tolerance) or recovery time.

One TEP member responded that they ask about both symptoms and recovery time when they are working with patients, and that both are equally useful. The TEP member clarified that some patients may not fully understand the concept of recovery time as well. The TEP member stated they did not have a preference to prioritize either symptoms or recovery time over one another.

Another TEP member asked for a more specific definition of recovery time, i.e., what is considered a typical recovery time. For example, recovery time could have a functional definition such as at what time point after a treatment the patient is able to do the activities that they want to do (e.g., work). One TEP member gave an example, referring to their organization only, which uses less than two hours as a timeframe for defining a typical recovery time. But they recognize that sometimes there is a need to consider alternative methods for defining recovery time.

One TEP member stated that they were in favor of keeping the definition of recovery time broad, and not determining a specific time period and definition for recovery time. They said it should be left up to the patient to determine how long it takes them to feel back to normal after a treatment.

Another TEP member stated they were also in favor of keeping the recovery time question broad. They further explained that in the Dialysis Outcomes and Practice Patterns Study (DOPPS, of which they were an investigator) patients defined recovery time in terms of how it fit their individual needs.

In response to the earlier question posed by the TEP co-chair, one TEP member stated they prioritize recovery time (as a PRO measure topic) because it is possible to collect objective data. The TEP member stated that asking the question of recovery time also allows for an individualized approach to patient care (i.e., to better address each patient's needs). For example, the TEP member stated that the question of recovery time helps providers consider what interventions may be possible for patients. The TEP member also felt that symptoms and recovery time are related. They further stated that opening the discussion with a validated question (for recovery time) is a good topic for this PRO TEP to consider.

Returning to the earlier topic of defining a typical recovery time, one TEP member asked the provider TEP members what is considered an acceptable recovery time. For example, the TEP member stated that a patient experiencing negative symptoms during treatment may be related to a prolonged recovery time. Another TEP member responded that as a provider they have heard that patients believe that it is normal to require a full day to recover. The TEP member stated there is work to do in this area (in terms of improving the dialysis treatment) if patients require a full day to recover.

Regarding variation in how long it may take patients to recover, one TEP member made the point that a large number of patients drive themselves home after treatment, and this can be a safety concern if patients have not fully recovered from their treatment (for example, if they are still experiencing adverse symptoms).

The TEP co-chair asked TEP members whether they felt the facility (through their clinical practices) can influence the dialysis treatment in order to limit the time to recovery. By way of example on this point, the TEP co-chair referenced the article by Hussein and co-authors (Hussein et al., 2017) that one of the TEP members circulated to the TEP. The TEP co-chair summarized that this study (by Hussein et al 2017) found patients that had faster ultrafiltration rates experienced a longer time to recovery. The TEP co-chair stated that another study that also examined higher rates of fluid removal (higher ultrafiltration rates) however did not find that patients had

longer recovery times. The TEP co-chair stated that from their experience (as a provider) a patient's recovery time can vary. The TEP co-chair noted that therefore the evidence for recovery time is mixed and asked the TEP to comment on the evidence for recovery time.

One TEP member stated the importance of patients having continuity in their care (from the same provider) as this makes it more likely the provider will be able to observe (and act on if needed) a trend in a patients' recovery time.

Another TEP member referenced again some of the findings of the DOPPS study (of which they were an investigator) noting they did not find evidence indicating attribution of recovery time to facility practices. The TEP member stated there is mixed evidence suggesting whether facility practice affects recovery time, but they also noted that asking the question of recovery time is still important.

One TEP member stated that while they do not believe there is strong evidence to support that providers can influence recovery time, they do believe the recovery time question could be very important from a patient's perspective in order to address patient concerns. The TEP member stated they were in favor of regular recovery time evaluation as part of routine clinical practice and that it is a meaningful patient outcome measure for individual patient care. The TEP member however stated a concern that they were unsure how it can be used as a performance measure to assess facility performance given the limited evidence.

The TEP co-chair asked the TEP member (who is a provider) to provide further feedback on the following based on their dialysis organization's implementation of a recovery time question: (1) the frequency of asking the recovery time question, (2) who asked the patient about recovery time, and (3) how the question was documented. The TEP member responded saying first the recovery time question needs to be standardized in order to be implemented across providers. They explained that dieticians asked the recovery time question, and that the majority of patients understood the recovery time question very well. They noted that the patients answered using different time frames such as minutes, hours, or full days, and that the recovery time question was documented in the patient's record. The TEP member stated that they found patients often answer the question of recovery time based on a set of treatments over a period of time, and not specific to the last treatment. The TEP member stated that some patients also require an explanation of recovery time, because they (the patient) were not exactly sure what they were being asked. The TEP member stated that in these cases they asked the recovery time question a little differently: "How long again does it take you to feel normal again?"

Another TEP member agreed with the earlier point made about whether or to what extent recovery time can be directly attributed to facility care. They also agreed it is important (for individual patient care) that patients be asked about recovery time. The TEP member, speaking from their experience as a dialysis patient, stated that they needed an evening treatment session to better manage their recovery time. The TEP member stated that as a patient having the option to have an evening session (where they can then rest and go to sleep soon afterward) may be beneficial for a patient if they are experiencing long recovery times.

One TEP member re-stated their earlier point about importance of focusing on how patients are experiencing treatment as this will give members of the patient's care team the chance to improve their patient's care.

### **Summary of the TEP call discussion**

The TEP co-chair asked for any additional final TEP member comments before the final call summary. No additional comments were provided. The TEP co-chair then summarized the key points based on the TEP's discussion during this call. The TEP co-chair stated that treatment tolerance (or symptom experience) and

recovery time are both very important (PRO topics) for the TEP. The TEP co-chair stated that the TEP discussion focused more on recovery time due to the following: (1) there is a validated question, (2) it is a single question that is flexible and allows for patient interpretation (about how to report recovery times), and (3) the TEP felt that recovery time is related to symptoms. For example, it was noted (during the discussion) that patients with a longer recovery time may have had a more difficult treatment or experienced worse symptoms. Overall the TEP was interested in both treatment tolerance (i.e., symptom experience) and recovery time as PRO topics. The TEP co-chair further stated that the consensus among the TEP was that the question of recovery time is important to ask to engage with patients, but there is limited evidence on whether the facility can improve the time to recovery and therefore it would not necessarily be appropriate to use as a performance metric. The TEP co-chair then asked TEP members if they agreed with this summary of the call discussion and to provide any comments about this summary.

One TEP member responded that the validated question for recovery time (by Lindsay et al 2006) was published and has been used, but the question did not go through a formal and rigorous validation process. The TEP member stated that their statement was a clarifying statement and they were not presenting this as a reason to not use a recovery time measure.

Another TEP member agreed with the discussion summary presented by the TEP co-chair, specifically that symptoms and recovery time are related but also that recovery time cannot be attributable to facility care. They gave the example that even if a patient has a good treatment, they may still have a long recovery time and vice versa.

There were no further comments or questions from the TEP members and the TEP co-chair closed the discussion section of this call.

### **Wrap-Up**

Dr. Dahlerus (UM-KECC) stated that the discussions from this call and the discussions from the previous post-TEP teleconference call (on July 19, 2017) and the final in-person TEP meeting recommendations will also be incorporated into the final PRO TEP summary report that will be delivered to CMS for final review. Dr. Dahlerus stated that the TEP recommendations will inform future work on PROs.

### **Public Comments**

There were no public comments received during this TEP call.

### **Closing Questions and Remarks**

The TEP co-chair thanked the TEP members for their outstanding service on this TEP.

Dr. Dahlerus (UM-KECC) thanked the TEP co-chairs for leading the TEP and thanked the TEP members for providing their feedback on the topic of PROs. Dr. Dahlerus stated that UM-KECC would document the discussions from this call and incorporate the recommendations into the final PRO TEP summary report. Dr. Dahlerus closed the call.

### **References**

1. Wael F. Hussein, Rohini Arramreddy, Sumi J. Sun, Marc Reiterman, and Brigitte Schiller. "Higher Ultrafiltration Rate Is Associated With Longer Dialysis Recovery Time in Patients Undergoing Conventional Hemodialysis." *Am J Nephrol* 46 (1), 3-10. 2017 May 30.

2. Robert M. Lindsay, Paul A. Heidenheim, Gihad Nesrallah, Amit X. Garg, and Rita Suri; on behalf of the Daily Hemodialysis Study Group London Health Sciences Centre. "Minutes to Recovery after a Hemodialysis Session: A Simple Health-Related Quality of Life Question That Is Reliable, Valid, and Sensitive to Change." *Clin J Am Soc Nephrol* 1: 952–959, 2006. doi: 10.2215/CJN.00040106

## Appendix

### List of PRO TEP Members

Jennifer Flythe, MD, MPH, (*TEP co-chair*)  
University of North Carolina Hospitals Dialysis Services,  
University of North Carolina at Chapel Hill

Michelle M. Richardson, Pharm D., (*TEP co-chair*)  
Tufts Medical Center,  
Dialysis Clinic, Incorporated

Kerri Cavanaugh, MD, MS,  
Vanderbilt Dialysis Clinic-Campus,  
Vanderbilt University Medical Center

Paul T. Conway, BA,  
American Association of Kidney Patients (AAKP),  
Mid-Atlantic Renal Coalition (MARC),  
Polycystic Kidney Disease Foundation (PKDF)

Lorien S. Dalrymple, MD, MPH,  
Fresenius Medical Care North America (FMCNA),  
University of California, Davis

Derek Forfang,  
National Forum of ESRD Networks,  
National Kidney Foundation

Patrick O. Gee,  
Quality Insights Mid-Atlantic Renal Coalition Network 5,  
National Kidney Foundation

Jennifer Geiger, MSW, LSW, NSW-C,  
Fresenius Medical Care North America (FMCNA),  
Quality Insights Renal Network 3

Amanda Grandinetti, MPH,  
American Academy of Dermatology,  
National Kidney Foundation

Lori Hartwell,  
Renal Support Network,

Kidney Care Partners,  
ESRD National Quality Forum

Daniel Iniguez,  
Dialysis Patient Citizens

Jacqueline Javier-Burns, RN,  
Dialyze Direct

Michael "Jack" Lennon, MBA,  
Cincinnati Children's Hospital Medical Center,  
National Kidney Foundation of Greater Cincinnati, OH

Klemens Meyer, MD,  
Tufts Medical Center,  
Tufts University School of Medicine,  
Dialysis Clinic, Incorporated

Sherry Rivera, DNP, APRN, ANP-C,  
New Orleans Nephrology Associates

Brigitte Schiller, MD,  
Satellite Healthcare, Inc.,  
Stanford University

Nancy L. Scott,  
Dialysis Patient Citizens Education Center,  
Henrietta Johnson Medical Center

Francesca Tentori, MD, MS,  
DaVita Clinical Research,  
Vanderbilt University Medical Center,  
American Association of Kidney Patients

John E. Ware, Jr., PhD,  
John Ware Research Group,  
University of Massachusetts Medical School,  
Tufts University School of Medicine

## ***Appendix J: TEP In-person Meeting Presentation Slides***

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The PRO TEP In-person Meeting Presentation Slides are provided on the following pages in this section.

# ESRD Patient Reported Outcomes (PRO)

Technical Expert Panel  
May 23-24, 2017

# Agenda: May 23, 2017

- 9:00 – 9:30 Introductions and Conflict of Interest Disclosures
- 9:30 – 9:45 Overview of Measure Development Process
- 9:45 – 10:45 Summary of HRQoL (in dialysis) and HRQoL Instruments
- *10:45 – 11:00 BREAK*
- 11:00 – 12:00 Patient and Provider Perspectives on Existing PRO HRQoL Instruments
- *12:00 – 1:00 LUNCH*



# Agenda: May 23, 2017 Continued

- 1:00 – 3:00                      Prioritization of Patient Reported Outcome Topic Areas
- 3:00 – 3:15                      *BREAK*
- 3:15 – 4:45                      Continue discussion
- 4:45 – 5:00                      Public Comment Period

# Agenda: May 24, 2017

- 9:00 – 10:45 Identify Candidate PRO Measure Concepts
- 10:45 – 11:00 *BREAK*
- 11:00 – 12:00 Continue Discussion
- 12:00 – 1:00 *LUNCH*
- 1:00 – 2:30 TEP Recommendations and Meeting Wrap-up
- 2:30 – 3:00 Public Comment Period
- 3:00 Meeting Adjourns

# TEP Members

Name	Title & Organization	Potential Conflicts of Interest
<b>Jennifer Flythe, MD, MPH</b> <i>TEP-co-chair</i>  <b>Medical Director</b>  <b>Assistant Professor and Research Fellow</b>	University of North Carolina Hospitals Dialysis Services, Chapel Hill, NC  University of North Carolina at Chapel Hill, Chapel Hill, NC	Research grant from Renal Research Institute (RRI) to develop a PRO related to fluid symptoms management.
<b>Michelle M. Richardson, Pharm D.</b> <i>TEP-co-chair</i>  <b>Director of Dialysis Outcomes Programs, Director of Communications, and Assistant Professor of Medicine</b>  <b>Director, Outcomes Monitoring Program</b>	Tufts Medical Center, Boston, MA  Dialysis Clinic Incorporated, Nashville, TN	Dialysis Clinic, Inc. has a contract with Tufts Medical Center to pay Dr. Richardson's salary for directing the Outcomes Monitoring Program." Dr. Richardson is an employee of Tufts Medical Center and was a co-investigator on Chronic Kidney Disease-Computerized Adaptive Testing (CKD-CAT), a potential survey to be considered by this TEP.
<b>Kerri Cavanaugh, MD, MS</b> <b>Medical Director</b>  <b>Associate Professor of Medicine</b>	Vanderbilt Dialysis Clinic-Campus  Division of Nephrology & Hypertension, Department of Medicine, Vanderbilt University Medical Center Nashville, TN	None

# TEP Members

Name	Title & Organization	Potential Conflicts of Interest
<p><b>Paul T. Conway, BA</b> <i>President</i></p> <p><i>Board Member</i></p> <p><i>Board Member</i></p>	<p>American Association of Kidney Patients (AAKP)</p> <p>Mid-Atlantic Renal Coalition (MARC)</p> <p>Polycystic Kidney Disease Foundation (PKDF)</p>	<p>None</p>
<p><b>Lorien S. Dalrymple, MD, MPH</b> <i>Vice President of Epidemiology and Research</i></p> <p><i>Volunteer Clinical Faculty, Associate Professor</i></p>	<p>Fresenius Medical Care North America (FMCNA)</p> <p>Department of Medicine, Division of Nephrology, University of California, Davis</p>	<p>Employed by Fresenius Medical Care NA, member of the Kidney Care Quality Alliance (KCQA) Steering Committee, and participates in a patient-reported outcomes initiative.</p>

# TEP Members

Name	Title & Organization	Potential Conflicts of Interest
<b>Derek Forfang</b> <i>Board of Directors Member and Kidney Patient Advisory Council Chair</i>	National Forum of ESRD Networks  National Kidney Foundation	None
<b>Kidney Advocacy Committee Member and Public Policy Committee Member</b>		
<b>Patrick O. Gee</b> <i>Patient Advisory Committee Chair and Subject Matter Expert</i>	Quality Insights Mid-Atlantic Renal Coalition Network 5  National Kidney Foundation	None
<b>Kidney Advocacy Committee Member</b>		
<b>Jennifer Geiger, MSW, LSW, NSW-C</b> <i>Regional Lead Social Worker</i>	Fresenius Medical Care North America (FMCNA)  Quality Insights Renal Network 3	None
<b>Medical Review Board Member</b>		

# TEP Members

Name	Title & Organization	Potential Conflicts of Interest
<b>Amanda Grandinetti, MPH</b> <i>Senior Specialist, Performance Measures and Analysis</i>	American Academy of Dermatology	None
<i>Kidney Action Committee Member</i>	National Kidney Foundation	
<b>Lori Hartwell</b> <i>Founder and President</i>	Renal Support Network	None
<i>Board of Directors Member</i>	Kidney Care Partners	
<i>NQF Renal Standing Committee Member</i>	ESRD National Quality Forum	
<b>Daniel Iniguez</b> <i>Secretary of the Board of Directors</i>	Dialysis Patient Citizens	None

# TEP Members

Name	Title & Organization	Potential Conflicts of Interest
<b>Jacqueline Javier-Burns, RN</b> <i>Director of Patient Care Services</i>	Queens Long Island Renal Institute, New Hyde Park, NY	None
<b>Michael "Jack" Lennon, MBA</b> <i>Program Manager</i>	Division of Nephrology and Hypertension, Cincinnati Children's Hospital Medical Center, Cincinnati, OH	None
<b>Medical Advisory Committee Member</b>	National Kidney Foundation of Greater Cincinnati, OH	
<b>Klemens Meyer, MD</b> <i>Director of Dialysis Services</i>  <i>Professor of Medicine</i>  <i>Medical Director</i>	Tufts Medical Center, Boston, MA  Tufts University School of Medicine, Boston, MA  Boston, Walden Pond, and Somerville clinics, Dialysis Clinic, Incorporated	Dr. Meyer's employer, the Tufts Medical Center Physician Organization receives payments from Dialysis Clinic Inc. (DCI) a dialysis provider, for his services) as the medical director of DCI facilities; and for his services as DCI's national Medical Director for Information Technology. DCI also pays for meeting fees, travel, accommodations, and meals and meetings at which Dr. Meyer represents the organization; for travel undertaken on their behalf; Dr. Meyer receives no consulting fees from DCI; he has worked with Investigators including John Ware, PhD and Michelle Richardson, PharmD to develop a computer adaptive tool to evaluate quality of life across the stages of chronic kidney disease. The first has not been published.

# TEP Members

Name	Title & Organization	Potential Conflicts of Interest
<b>Sherry Rivera, DNP, APRN, ANP-C</b> <i>Nurse Practitioner</i>	New Orleans Nephrology Associates, Marrero, LA	None
<b>Brigitte Schiller, MD</b> <i>Chief Medical Officer and Vice President of Scientific Affairs</i>  <i>Consulting Associate Professor</i>	Satellite Healthcare, Inc., San Jose, CA  Department of Medicine, Division of Nephrology, Stanford University, Palo Alto, CA	None
<b>Nancy L. Scott</b> <i>President</i>  <i>Chairperson of the Board of Directors</i>	Dialysis Patient Citizens Education Center  Henrietta Johnson Medical Center, Wilmington, DE	None



# TEP Members

Name	Title & Organization	Potential Conflicts of Interest
<b>Francesca Tentori, MD, MS</b> <i>Medical Director</i>	Outcomes Research, DaVita Clinical Research, Minneapolis, MN	Dr. Tentori is a current employee of DaVita Clinical Research. She has received research grants from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Patient-Centered Outcomes Research Institute (PCORI) and a consortium of industry sponsors that support the Dialysis Outcomes and Practice Patterns Study (DOPPS) (see <a href="http://www.dopps.org">www.dopps.org</a> for more details).
<i>Adjunct Instructor in Medicine</i>	Department of Internal Medicine, Division of Nephrology, Vanderbilt University Medical Center, Nashville, TN	
<i>Medical Advisory Board Member</i>	American Association of Kidney Patients	
<b>John E. Ware, Jr., PhD</b> <i>President, Founder, and Chief Science Officer</i>	John Ware Research Group, Watertown, MA	Dr. Ware is a major shareholder in John Ware Research Group, Inc., an NIH SBIR grant and medical products industry supported corporation, affiliated with University of Massachusetts Medical School, that develops computerized adaptive outcome measures for use in health care research and practice. Dr. Ware was the principal developer and first author of the SF-36, SF-12, and SF-8 Health Surveys and articles documenting their development and evaluation during the Medical Outcomes Study; and, he is a co-author of articles documenting the development and evaluation of PROMIS physical functioning and other domain item banks.
<i>Professor and Division Chief</i>	Quantitative Health Sciences, University of Massachusetts Medical School, Worcester, MA	
<i>Research Professor</i>	Department of Medicine, Tufts University School of Medicine, Boston, MA	

# UM-KECC Team

University of Michigan Kidney Epidemiology and Cost Center (UM KECC)

## Measure Developer Contractor Staff

Claudia Dahlerus, PhD, MA, *Principal Scientist*

Joseph Messana, MD, *Swartz Collegiate Professor of Nephrology, University of Michigan Health System and Interim Director, UM-KECC*

Richard Hirth, PhD, *Professor and Chair of Health Management and Policy*

Lan Tong, MPH, *Lead Research Analyst*

Casey Parrotte, PMP, *Project Manager/ Research Analyst*

Jennifer Sardone, PMP, *Project Manager/ Research Analyst*

Jordan Affholter, BA, *Research Analyst*

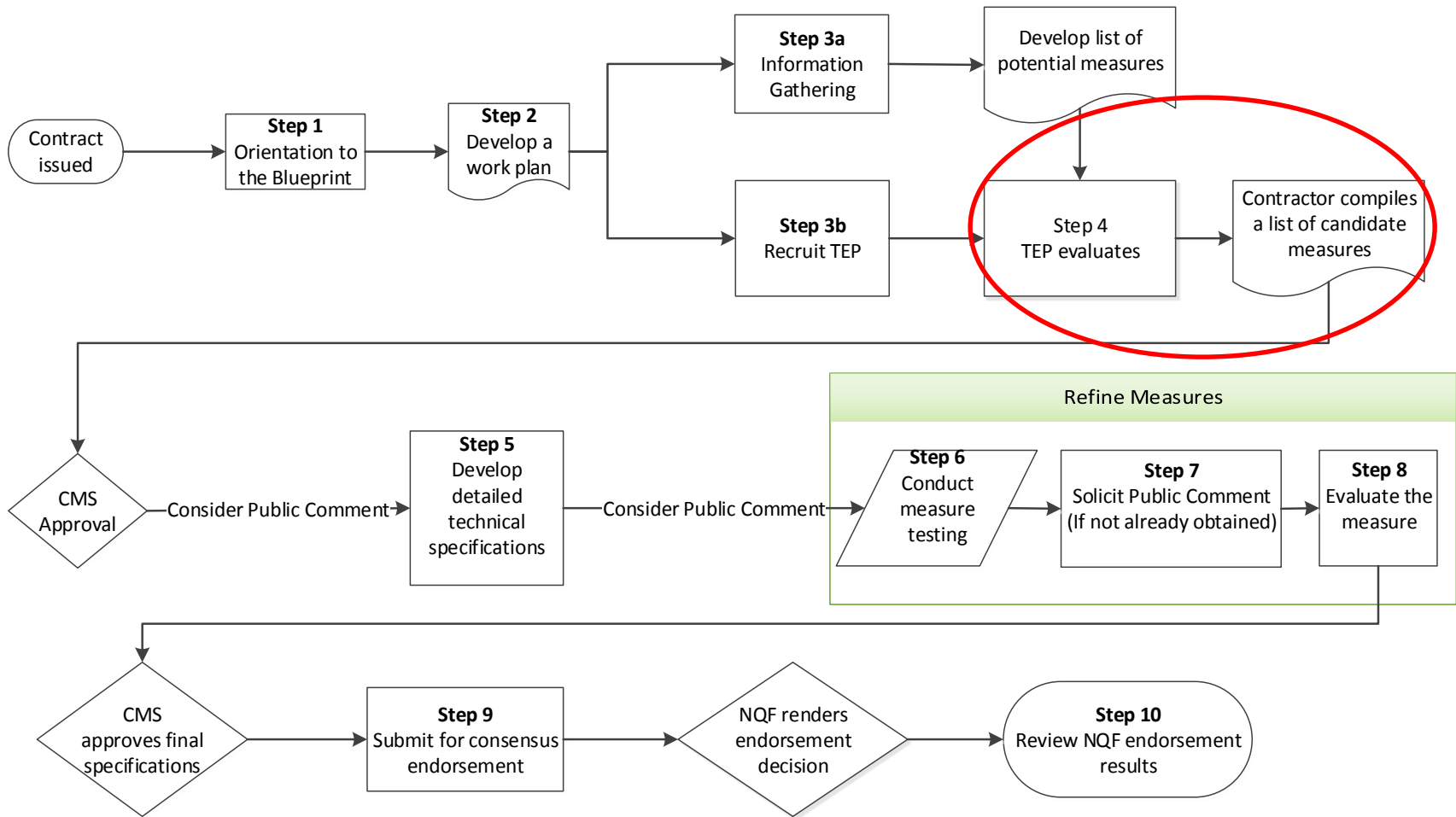
# Overview of Measure Development Process

# Quality Measure Development and Implementation

- CMS uses the Measures Manager Blueprint to guide measure development and implementation\*
- Quality Measures developed based on expert and stakeholder input (TEPs)
- Stakeholder review occurs through public comment
  - Public comment is part of the submission to and review by the National Quality Forum (NQF) before endorsement
- NQF review of measures by expert Standing Committee
- Developed Measures are proposed for Public Reporting:
  - DFC: CMS announces measures on a National Provider Call
  - ESRD QIP: CMS submits measures to the NQF Measures Application Partnership for stakeholder input; next CMS proposes measures through Federal Rulemaking

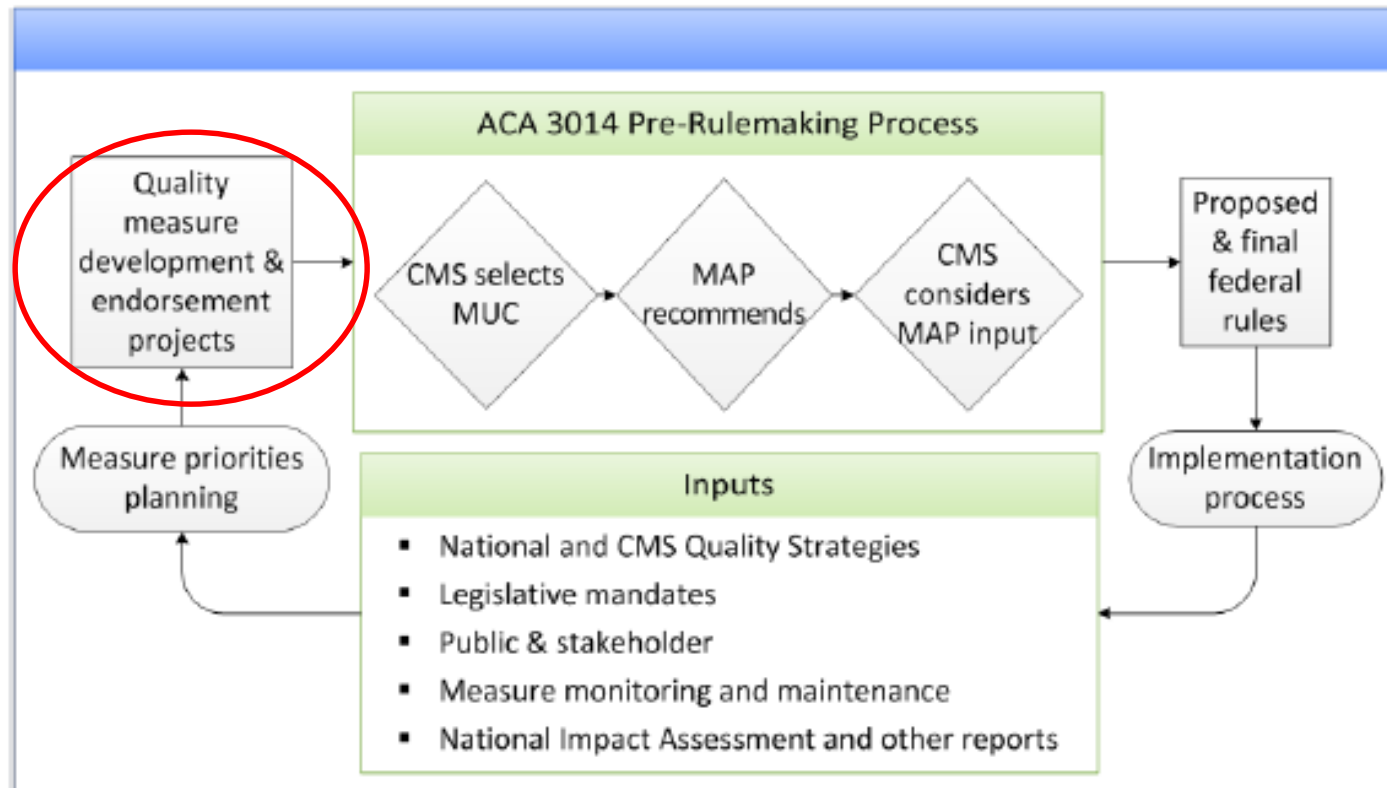
\*Centers for Medicare & Medicaid Services (CMS). "Blueprint for the CMS Measure Management System". Blueprint version 12.0 MAY 2016. Accessed May 11, 2017. [https://www.cms.gov/Medicare/Quality Initiatives Patient Assessment Instruments/MMS/Downloads/Blueprint\\_120.pdf](https://www.cms.gov/Medicare/Quality%20Initiatives/Patient%20Assessment%20Instruments/MMS/Downloads/Blueprint_120.pdf)

# Flow of Measure Development Processes



\*Centers for Medicare & Medicaid Services (CMS). "Blueprint for the CMS Measure Management System". Blueprint version 12.0 MAY 2016. Accessed May 11, 2017. [https://www.cms.gov/Medicare/Quality Initiatives Patient Assessment Instruments/MMS/Downloads/Blueprint 120.pdf](https://www.cms.gov/Medicare/Quality%20Initiatives/Patient%20Assessment%20Instruments/MMS/Downloads/Blueprint%20120.pdf)

# Quality Measure Implementation



\*Centers for Medicare & Medicaid Services (CMS). "Blueprint for the CMS Measure Management System". Blueprint version 12.0 MAY 2016. Accessed May 11, 2017. [https://www.cms.gov/Medicare/Quality Initiatives Patient Assessment Instruments/MMS/Downloads/Blueprint 120.pdf](https://www.cms.gov/Medicare/Quality%20Initiatives/Patient%20Assessment%20Instruments/MMS/Downloads/Blueprint%20120.pdf)

# Measure Evaluation Criteria

# Measure Evaluation Criteria

- The National Quality Forum (NQF) evaluates quality measures based on the following criteria\*:
  - Importance to Measure and Report: Evidence, Performance Gap, and Priority (Impact)
  - Scientific Acceptability: Reliability and Validity
  - Feasibility
  - Usability
  - Comparison to Related or Competing Measures (Harmonization)

\*National Quality Forum (NQF). "Measure Evaluation Criteria". 2017. Accessed May 17, 2017.  
[http://www.qualityforum.org/Measuring\\_Performance/Submitting\\_Standards/Measure\\_Evaluation\\_Criteria.aspx](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards/Measure_Evaluation_Criteria.aspx)



# Measure Evaluation Criteria

- Evidence:
  - Extent to which the specific measure focus is evidence-based
- Scientific Acceptability:
  - Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care

\*National Quality Forum (NQF). "Measure Evaluation Criteria". 2017. Accessed May 17, 2017.  
[http://www.qualityforum.org/Measuring\\_Performance/Submitting\\_Standards/Measure\\_Evaluation\\_Criteria.aspx](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards/Measure_Evaluation_Criteria.aspx)

# Measure Evaluation Criteria

- Feasibility: Data that are readily available or could be captured without undue burden
- Usability: Stakeholders (e.g., consumers, purchasers, providers, policy makers) can use measure performance results for both accountability and performance improvement
- Comparison to Related or Competing Measures (Harmonization)
  - If there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure

\*National Quality Forum (NQF). "Measure Evaluation Criteria". 2017. Accessed May 17, 2017.  
[http://www.qualityforum.org/Measuring\\_Performance/Submitting\\_Standards/Measure\\_Evaluation\\_Criteria.aspx](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards/Measure_Evaluation_Criteria.aspx)

# PROs and National Quality Forum (NQF)

- NQF Report on “Patient Reported Outcomes (PROs) in Performance Measurement” (January 2013)\*
- PRO Definition: *“Any report of the status of a patient’s (or person’s) health condition, health behavior, or experience with healthcare that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else.”\*\**
- NQF Report outlines recommendations on PRO development
  - Figure 2. Pathway from PRO to NQF-endorsed PRO-PM

\*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](http://www.qualityforum.org/Projects/n_r/Patient_Reported_Outcomes/Patient_Reported_Outcomes.aspx)

\*\*U.S. Food and Drug Administration. “Guidance for Industry, Patient Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims.” Fed Regist. 2009; 74(35):65132-65133. Accessed August 12, 2016: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf>

# TEP Objectives: PRO TEP Charter

- Review existing health related quality of life (HRQoL) measures, recovery time measures and the PROMIS set; evaluate evidence and usability for patients and providers; address existing testing or need for psychometric testing within the ESRD population; and data collection feasibility.
- Make recommendations on the potential development of PRO measures including health related quality of life, recovery time, and measures derived from PROMIS item banks/domains, or potentially other measures identified by the TEP.

# Measures of HRQoL and What we Know

# Brief summary of what we know about health-related QOL and how to measure it

John E. Ware, Jr., PhD

Professor & Division Chief, Dept. of Quantitative Health Sciences, UMass Medical School  
Chief Science Officer and Founder, JWRG, Incorporated, Worcester, MA

PRO TEP Meeting, Bethesda, MD, May 23-24, 2017



# Quantifying two important and distinct patient-reported outcomes (PRO)

- Health care services  
(patient experience & satisfaction)
- Health status  
("health-related quality of life")

# World Health Organization definition of health

“**Health** is a state of complete **physical**, **mental**, and **social** well-being and not merely the absence of disease or infirmity”

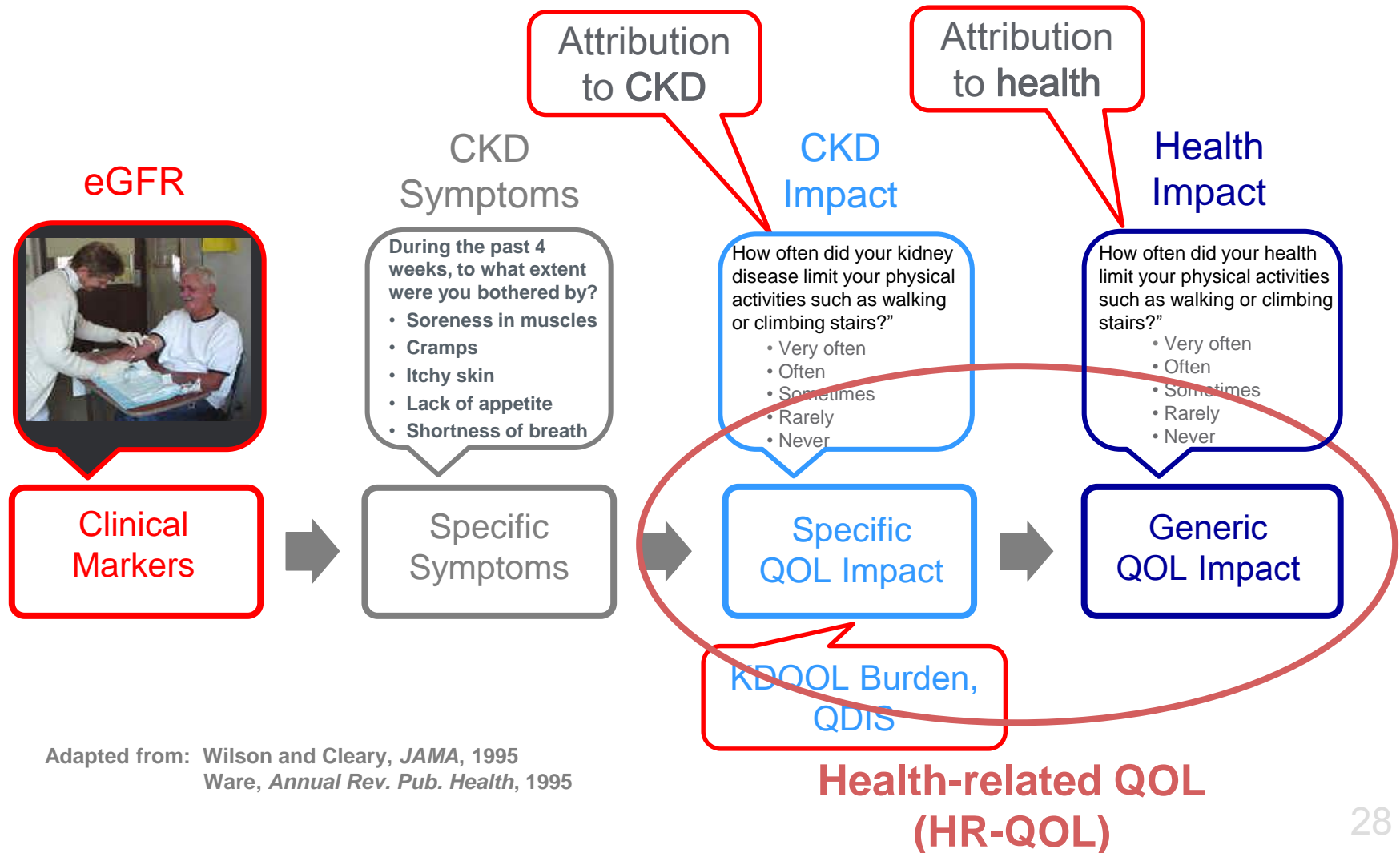
*WHO, 1948*



# Noteworthy QOL developments

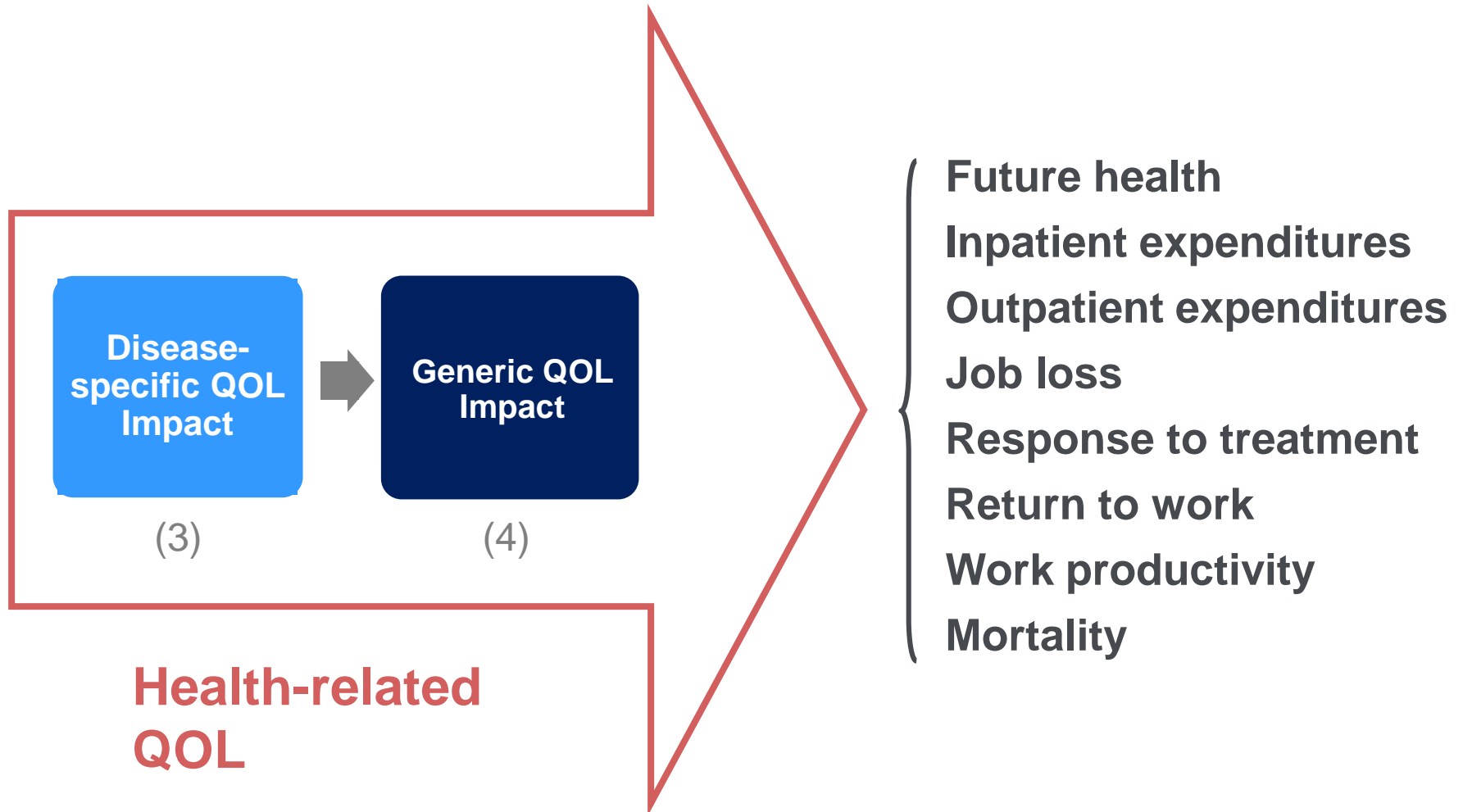
- Conceptual and psychometric advances
- Standardization of content and metrics
- Norms for generic *and* disease-specific PROs
- Improved interpretation guidelines
- Electronic data capture and Internet-based connectivity
- Adaptive and other methods matched to purpose
- More practical and integrated surveys

# Conceptually, how do CKD-specific and generic QOL measures differ?

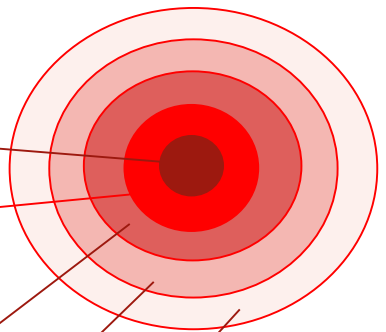


Adapted from: Wilson and Cleary, *JAMA*, 1995  
Ware, *Annual Rev. Pub. Health*, 1995

# QOL is one of the best predictors of most important outcomes in health care



# Health can be measured using different operational definitions

- 
- Bodily structure & function
  - Specific symptoms
  - What you did/are able to do – functioning
  - How you feel – subjective ill- and well-being (- and +)
  - How good you say it is – personal evaluation

**QOL**

# 40-year summary of health represented in widely-used measures

Is "perfect health" the absence of:

- Emotional distress
- Fatigue
- Limitations in functioning
- Pain

Concepts/Domains	hometric									Utility			
	SIP	HIE	QLI	COOP	DUKE	MOS FWBP	MOS SF-36®	PROMIS® 29-57	QWB	EQ-5D	HUI	SF-6D	
Physical functioning (-)	•		•	•	•	•	•	•	•	•	•	•	
Social functioning (-)	•	•	•	•	•	•	•	•	•	•		•	
Role functioning (-)	•	•	•	•	•	•	•	•	•	•		•	
Psychological distress (-)	•	•	•	•	•	•	•	•		•	•	•	
Health perception (general)		•	•	•	•	•	•						
Pain (-)		•	•		•	•	•	•		•	•	•	
Fatigue (-) } Vitality		•	•		•	•	•	•	•				
Energy		•				•	•					•	
Psychological well-being		•				•	•	•					
Sleep	•		•			•	•		•				
Cognitive functioning (-)	•					•	•				•		
Quality of life		•			•		•						
Evaluated health outcome					•		•	•					

**Psychometric**  
 SIP =Sickness Impact Profile (1976) HIE=Health Insurance Experiment (1979) NHP=Nottingham Health Profile (1980) QLI=Quality of Life Index (1981)  
 COOP=Dartmouth Function Charts (1987) DUKE=Duke Health Profile (1990) MOS FWBP=MOS Functioning & Well-Being Profile (1992)  
 MOS SF-36=36-Item Short-Form Health Survey (1992) PROMIS®=Patient Reported Outcomes Measurement Information System (2004-on)

**Utility**  
 QWB=Quality of Well-Being Scale (1973) EQ-5D= European Quality of Life Index (1990) HUI=Health Utility Index (1996) SF-6D=SF-36 Utility Index (2002)

Source: Adapted from Ware 1987; Ware, 1995

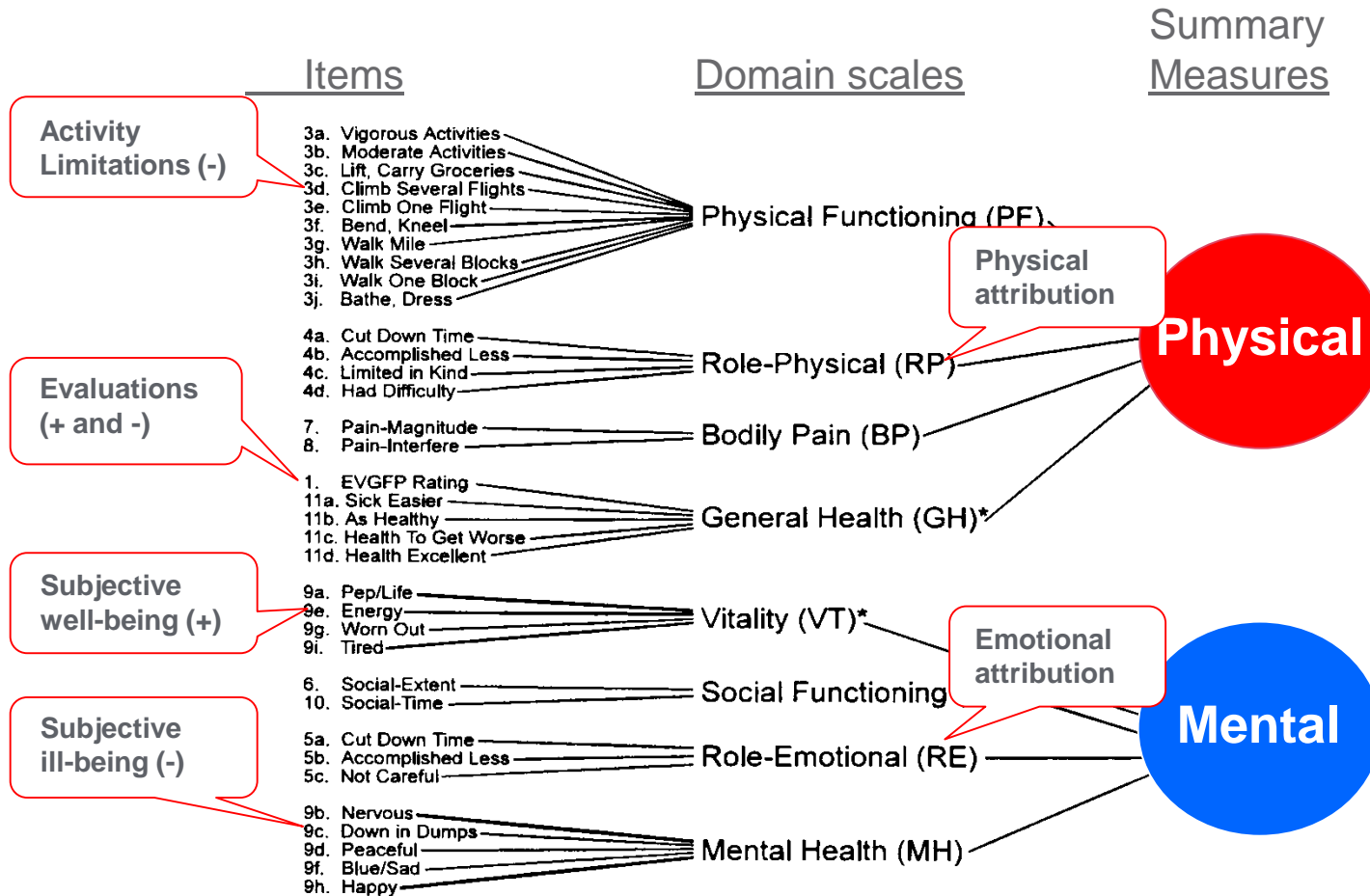


# Comparison of domain content for generic and disease-specific measures

Health Domains*	Comprehensive Generic			Disease-Specific						
	SIP	MOS FWBP	PROMIS 29-57	DQOL	KD QOL	ML-HFQ	SAQ	St Georg	WO-MAC	QDIS
Physical functioning	●	●	●	●		●	●	●	●	●
Social functioning	●	●		●	●	●		●		●
Role functioning	●	●	●	●	●	●		●		●
Psychological distress	●	●	●	●	●	●	●			●
Health perceptions		●				●		●		●
Pain (bodily)		●	●	●			●		●	
Energy/fatigue		●	●		●	●		●		●
Psychological well-being		●								●
Sleep	●	●	●	●		●		●		●
Cognitive functioning	●	●								●
Quality of life		●			●		●			●
Health transition (B/S/W)		●								
Sexual functioning				●	●	●		●		
Specific symptoms				●	●	●	●	●	●	
Specific treatments				●	●	●	●			

**SIP**=Sickness Impact Profile (1976); **MOS FWBP**=MOS Functioning and Well-Being Profile, 149 items (1992); **PROMIS®**=Patient Reported Outcomes Measurement Information System (2004-on); **DQOL**=Diabetes Quality of Life Measure; **KDQOL**=Kidney Disease Quality of Life Instrument; **MLHFQ**=Minnesota Living with Heart Failure® Questionnaire; **SAQ**=Seattle Angina Questionnaire; **St George**=St George's Respiratory Questionnaire; **WOMAC®**=Western Ontario and McMaster Universities Osteoarthritis Index; **QDIS®**=QOL Disease Impact Scale. **Source:** Adapted from Ware 1987; Ware, 1995.

# SF-36 Health Survey measurement model

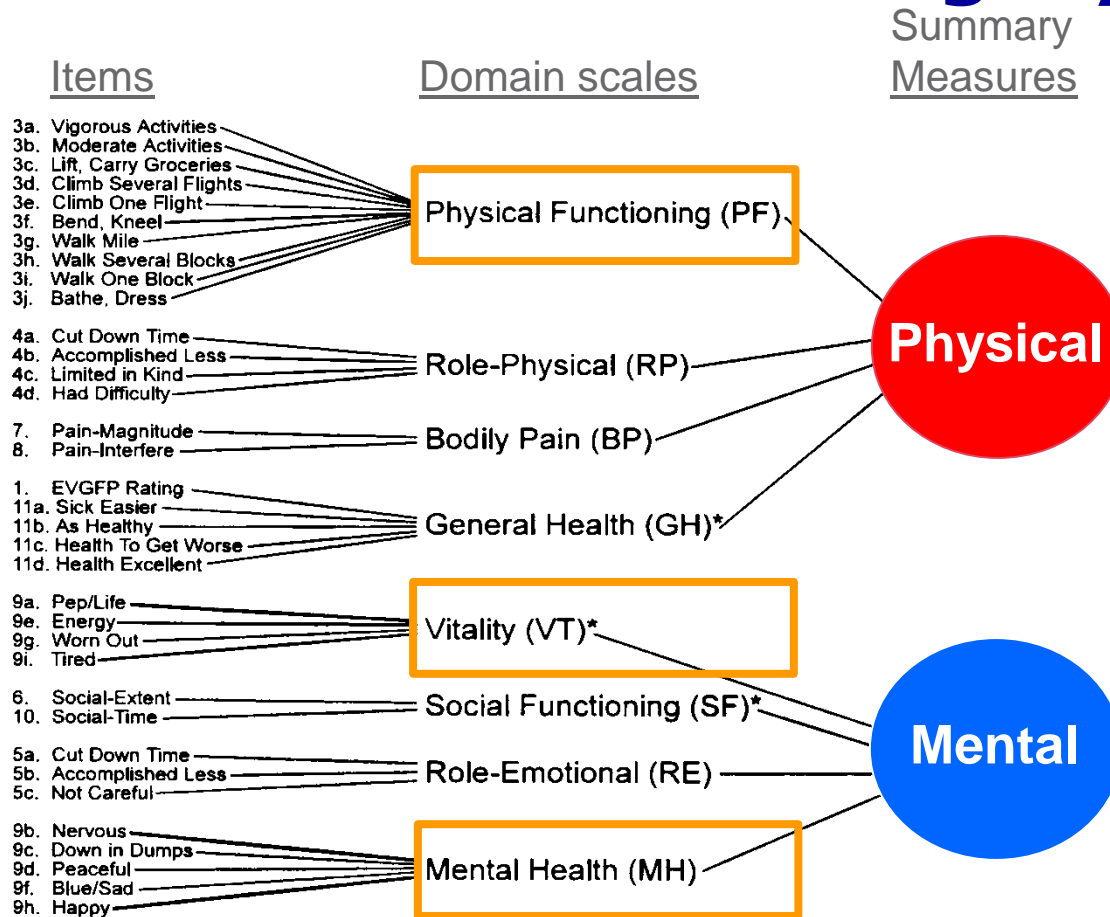


\* Significant correlation with other summary measure.

Reference: Ware JE, Jr., Kosinski M, Keller SD: *SF-36 Physical and Mental Summary Scales: A User's Manual*. Boston, MA: The Health Institute; 1994.



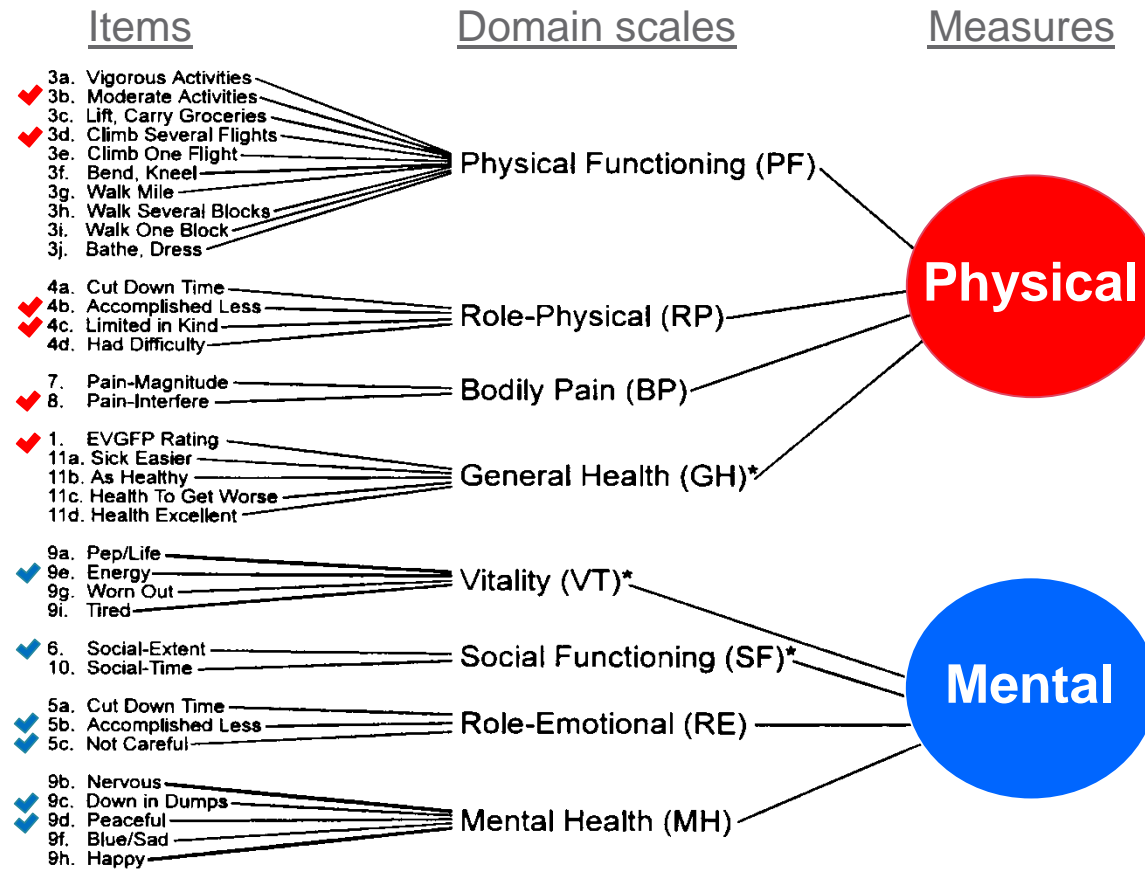
# Item banks for three domains link SF-36, PROMIS and other legacy tools



\* Significant correlation with other summary measure.



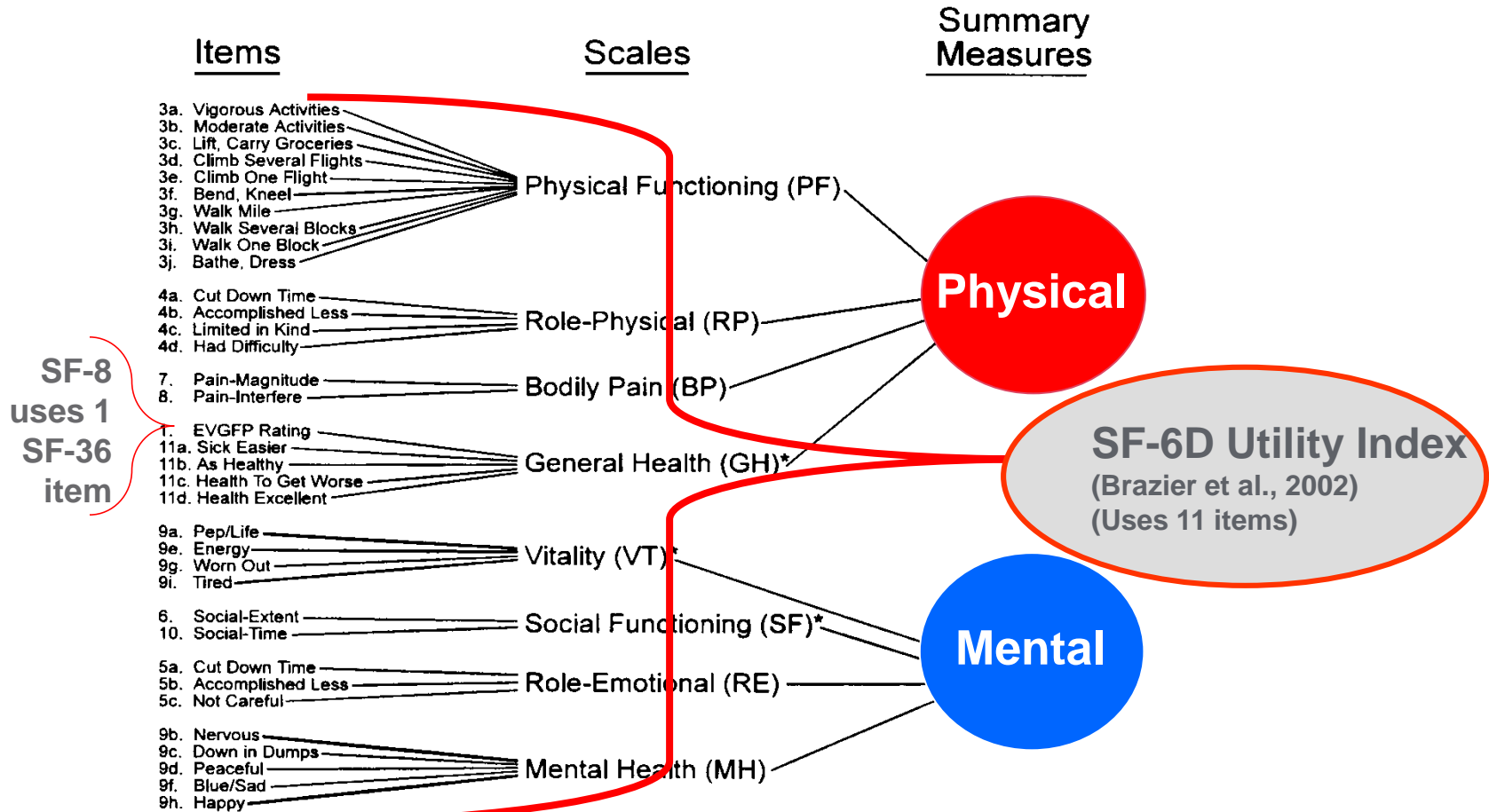
# For physical and mental summary scores respondent burden could be reduced to only 12 items (SF-12)



\* Significant correlation with other summary measure.



# First health utility index (SF-6D) estimate from a psychometric tool



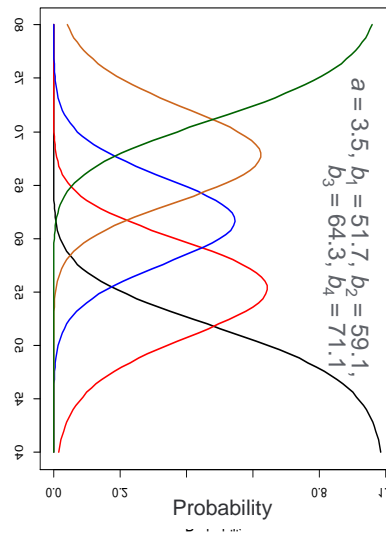
\* Significant correlation with other summary measure.



# Anatomy of a survey item

During the past 4 weeks, how often did your **kidney disease** limit your ability to do your everyday activities such as work, school or chores?

Very often  
Often  
Sometimes  
Rarely  
Never



**Disease-specific attribution**

## References:

Patrick DL, Deyo RA. Generic and disease-specific measures in assessing health status and quality of life. *Medical Care*. 1989;27(3 Suppl.):S217-S232.

Ware JE, Gandek B, Guyer R, Deng N. Standardizing disease-specific quality of life measures across multiple chronic conditions: Development and initial evaluation of the QOL Disease Impact Scale (QDIS®). *Health and Quality of Life Outcomes* 2016; 14:84.

# Anatomy of a survey item

**Domain:**  
Physical functioning

To what extent did health problems limit you in your everyday physical activities (such as walking and climbing stairs)?

- Not at all
- Slightly
- Moderately
- Quite a bit
- Extremely

**Operational definition:** Extent of physical limitations with examples of physical activities

# Anatomy of a survey item

**Domain:**  
Physical functioning

How difficult is it for you to do your everyday physical activities (such as walking and climbing stairs)?

- Very easy
- Easy
- Slightly difficult
- Difficult
- Very difficult

**Operational definition:**  
Easy vs. difficult physical activities

## References:

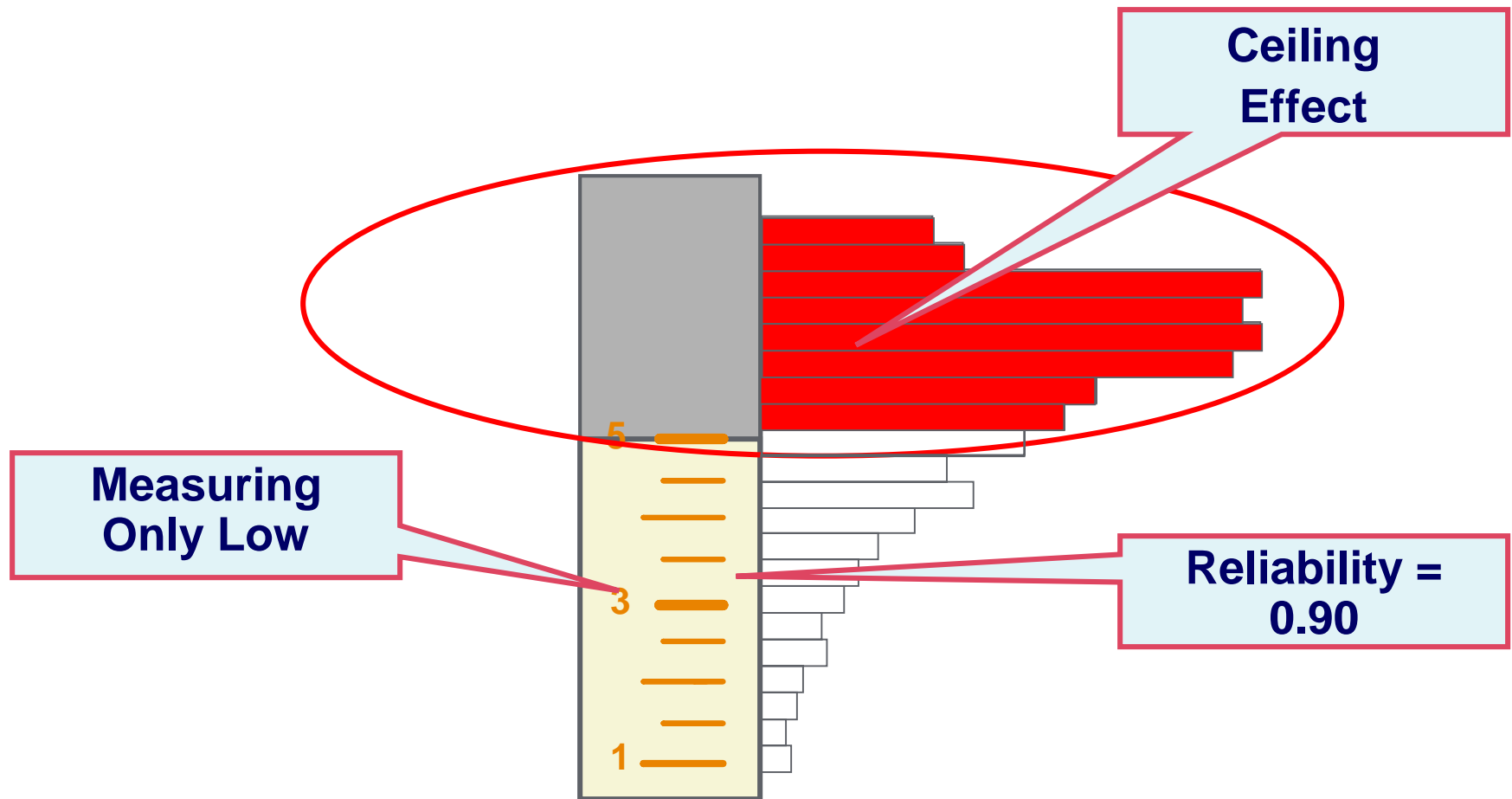
- Fisher Jr WP, Eubanks RL, Marier RL. Equating the MOS SF36 and the LSU HSI physical functioning scales. *J Outcome Meas.* 1997;1:329–62.
- Liegl G, Gandek B, Fischer FH, Bjorner JB, Ware JE, Rose N, Fries JF, and Nolte S. Varying the item format improved the range of measurement in patient-reported outcome measures assessing physical function, *Arthritis Research & Therapy* 2017;19: 66.

# QOL content and operational definitions are best developed using multiple methods

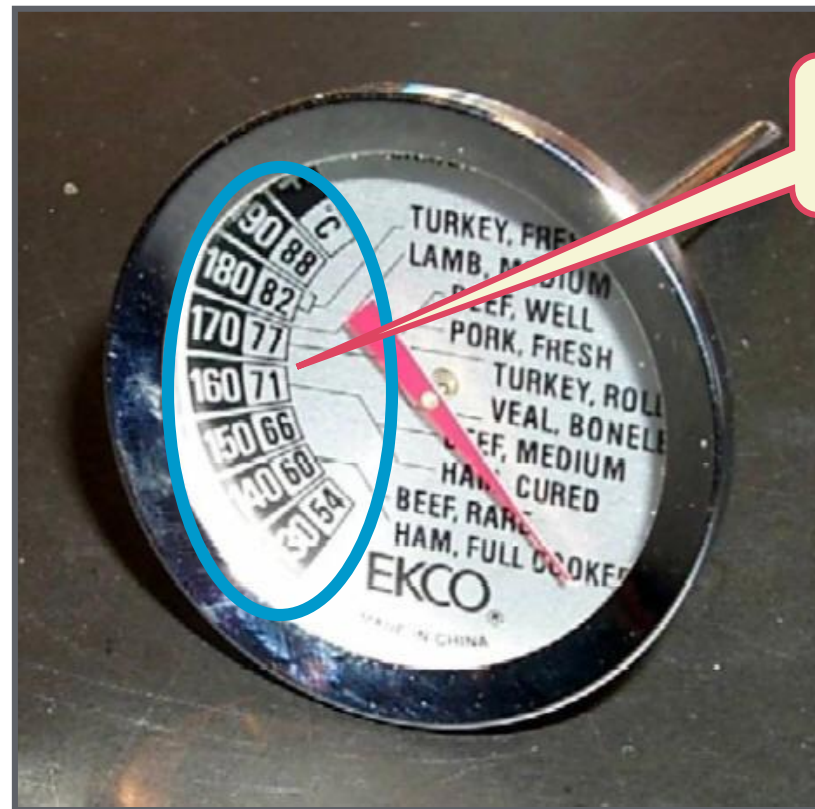
- Qualitative
- Quantitative

**Reference:** Martin ML, Patrick DL, Gandra SR, Bennett AV, Leidy NK, Nissenson AR, Finkelstein FO, Lewis EF, Wu AW, Ware, JE, Jr.: Content Validation Two SF-36 Subscales For Use In Type 2 Diabetes and Non-dialysis Chronic Kidney Disease Related Anemia. *Quality of Life Research*, 2011, Vol. 20: 889-901. doi: 10.1007/s11136-010-9812-4

# Use of PROs in general populations identified substantial ceiling effects



# Like QOL scales, some thermometers measure only a narrow range

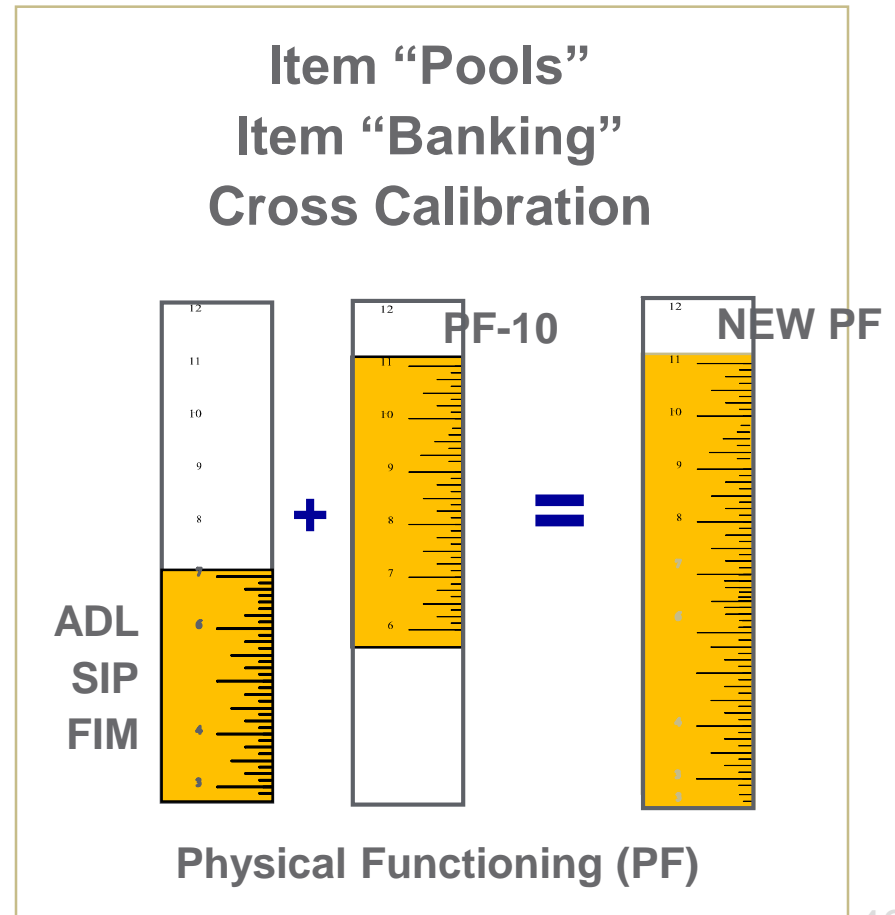
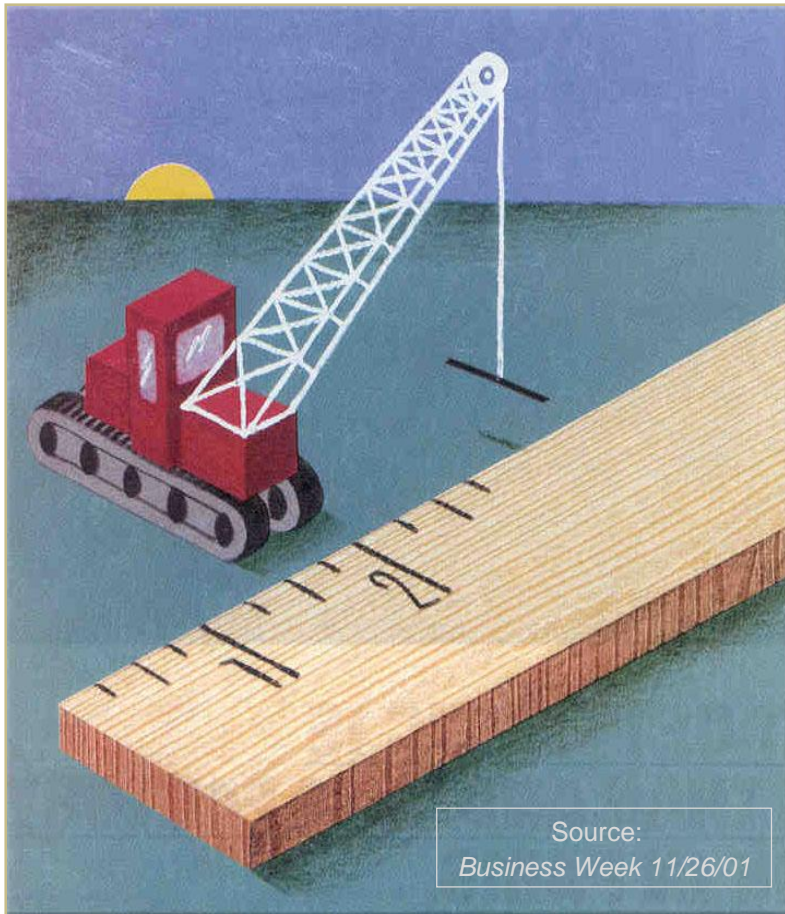


130-190 °F  
54-88 °C

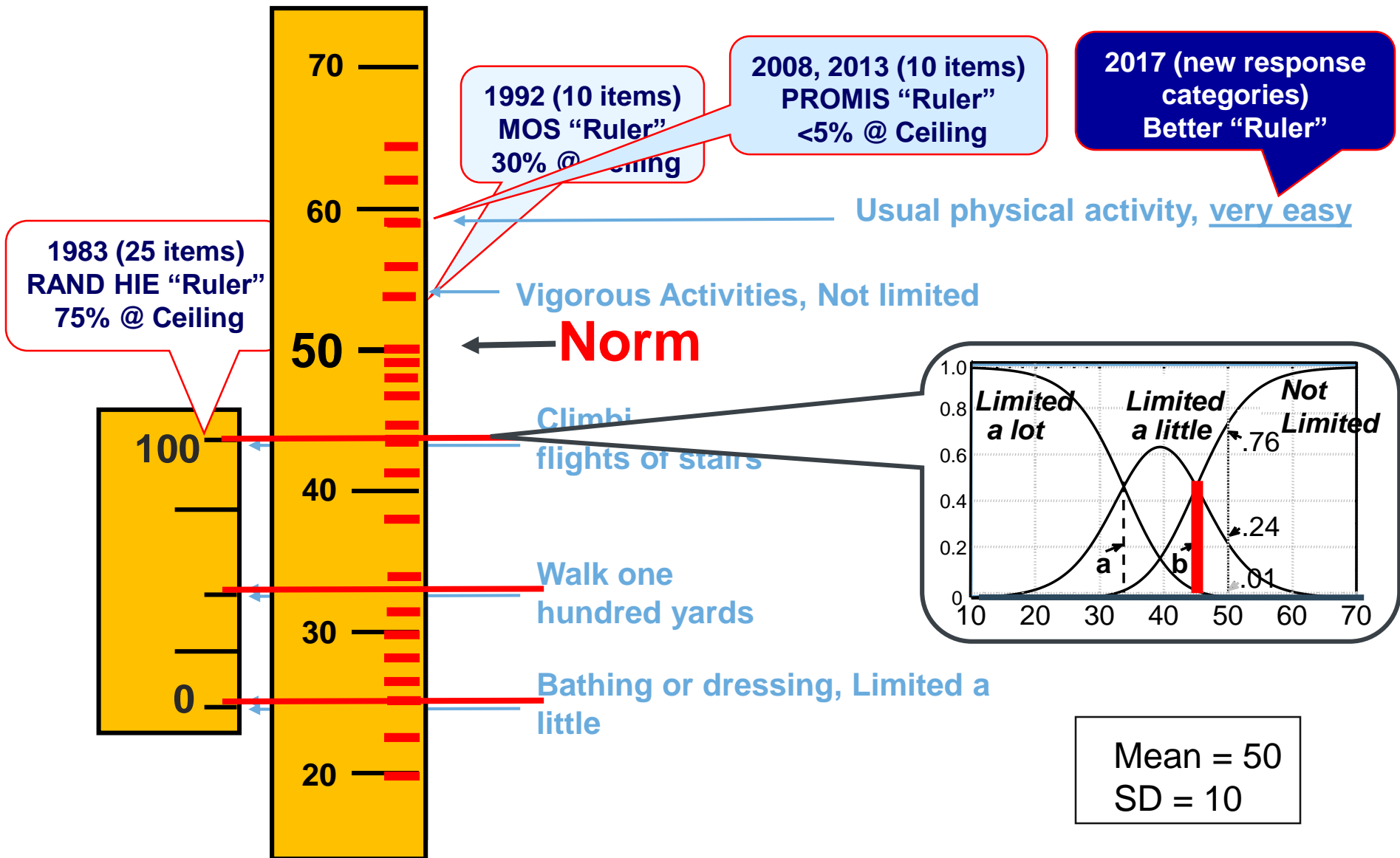
**Cooking Thermometer**



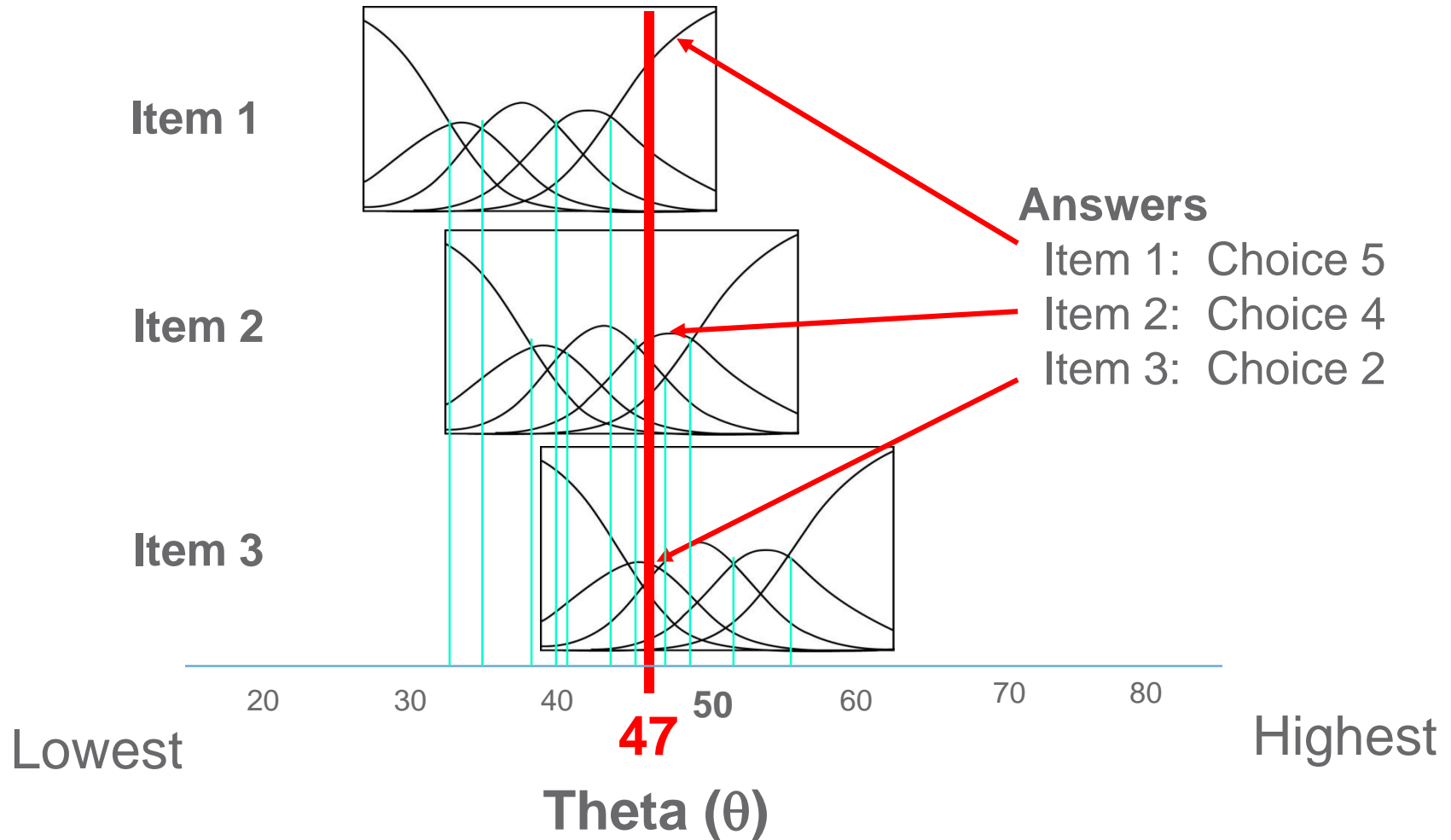
# Item response theory (IRT) enabled cross-calibration of items across tools



# Improving the physical function “ruler”



# Item response theory (IRT) models enable predictions of patient response



# What do the numbers mean? Cross-calibrating and interpreting temperature

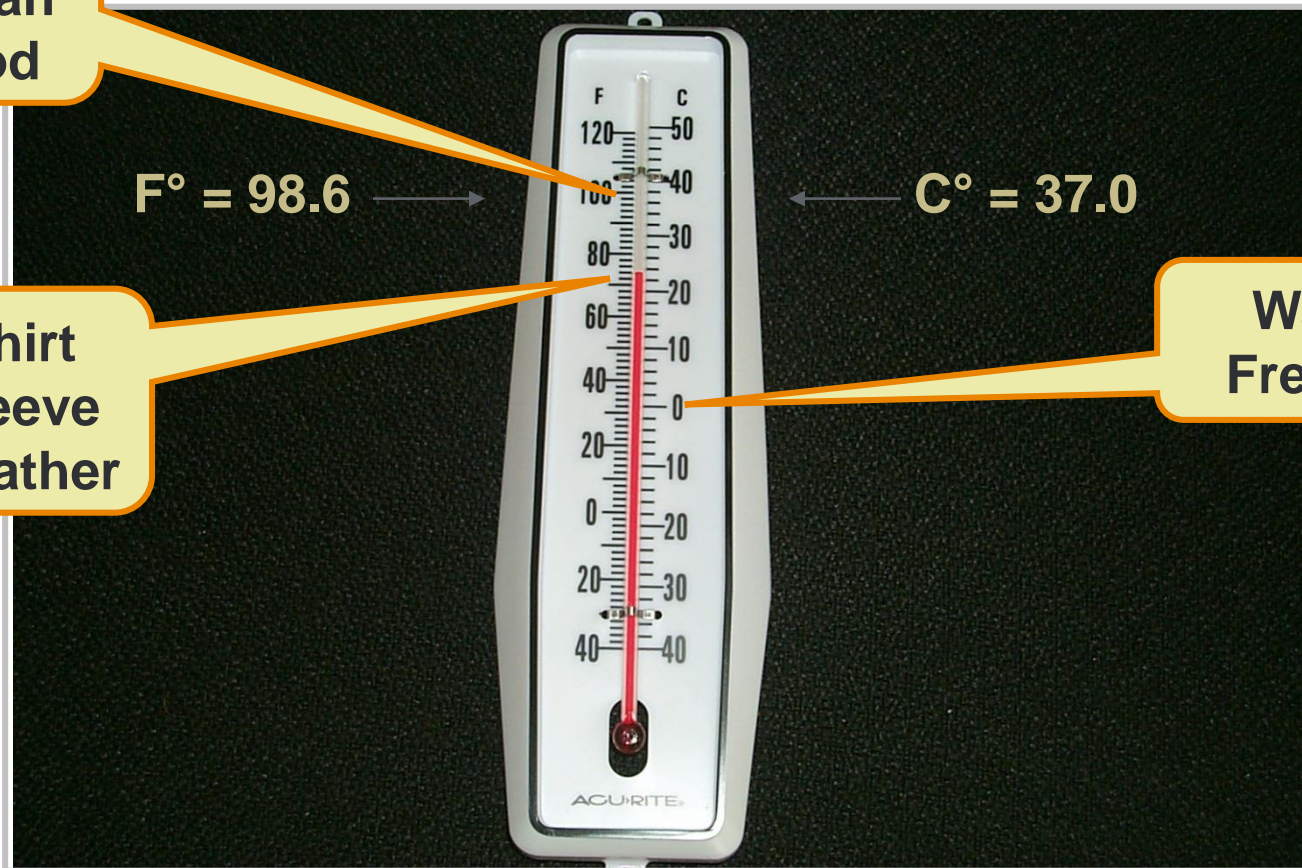
Normal  
Human  
Blood

$F^{\circ} = 98.6$

$C^{\circ} = 37.0$

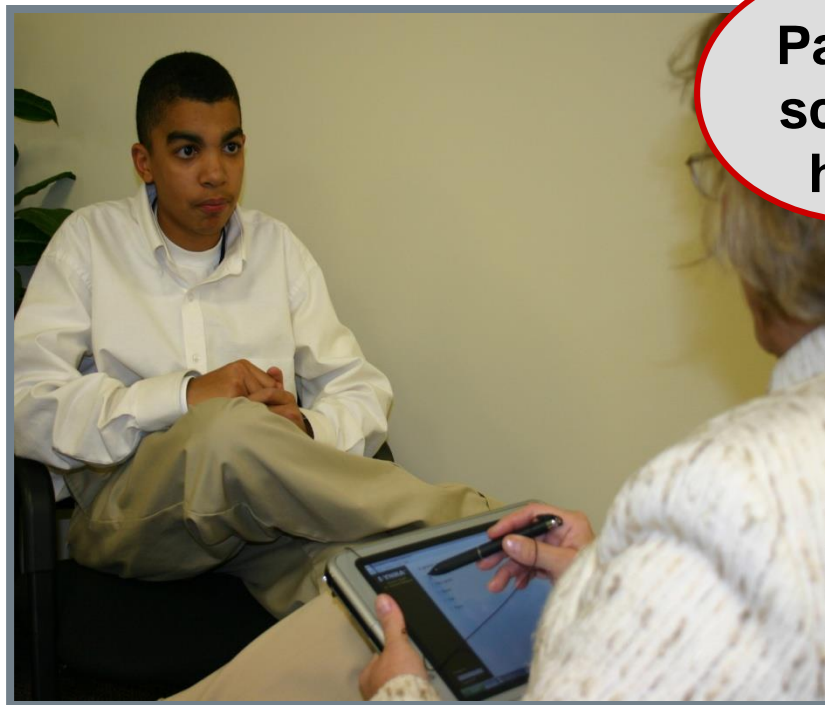
Shirt  
Sleeve  
Weather

Water  
Freezes

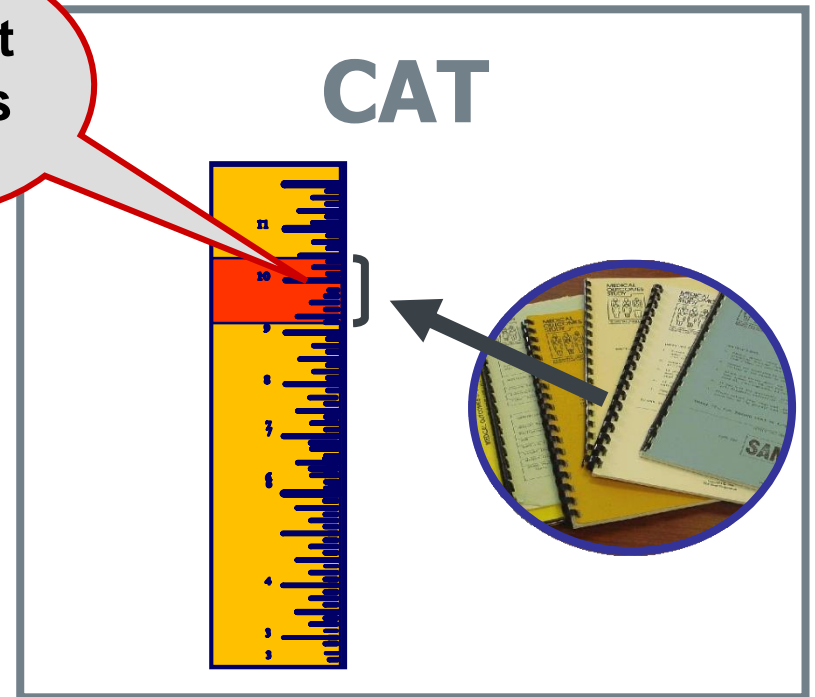


*Fahrenheit and Celsius*

# Computer adaptive test (CAT) uses IRT model to match items to patient level

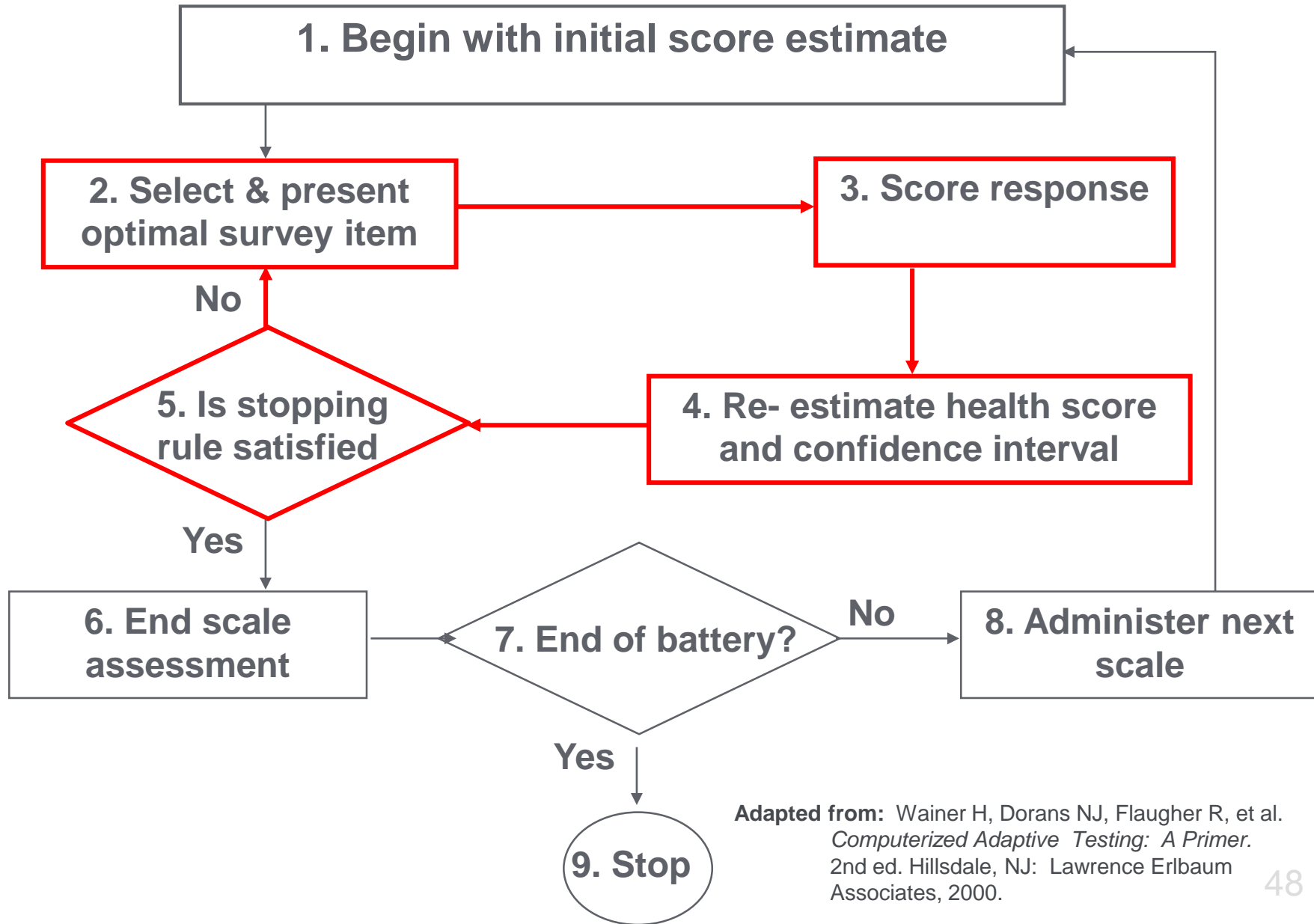


Patient scores here



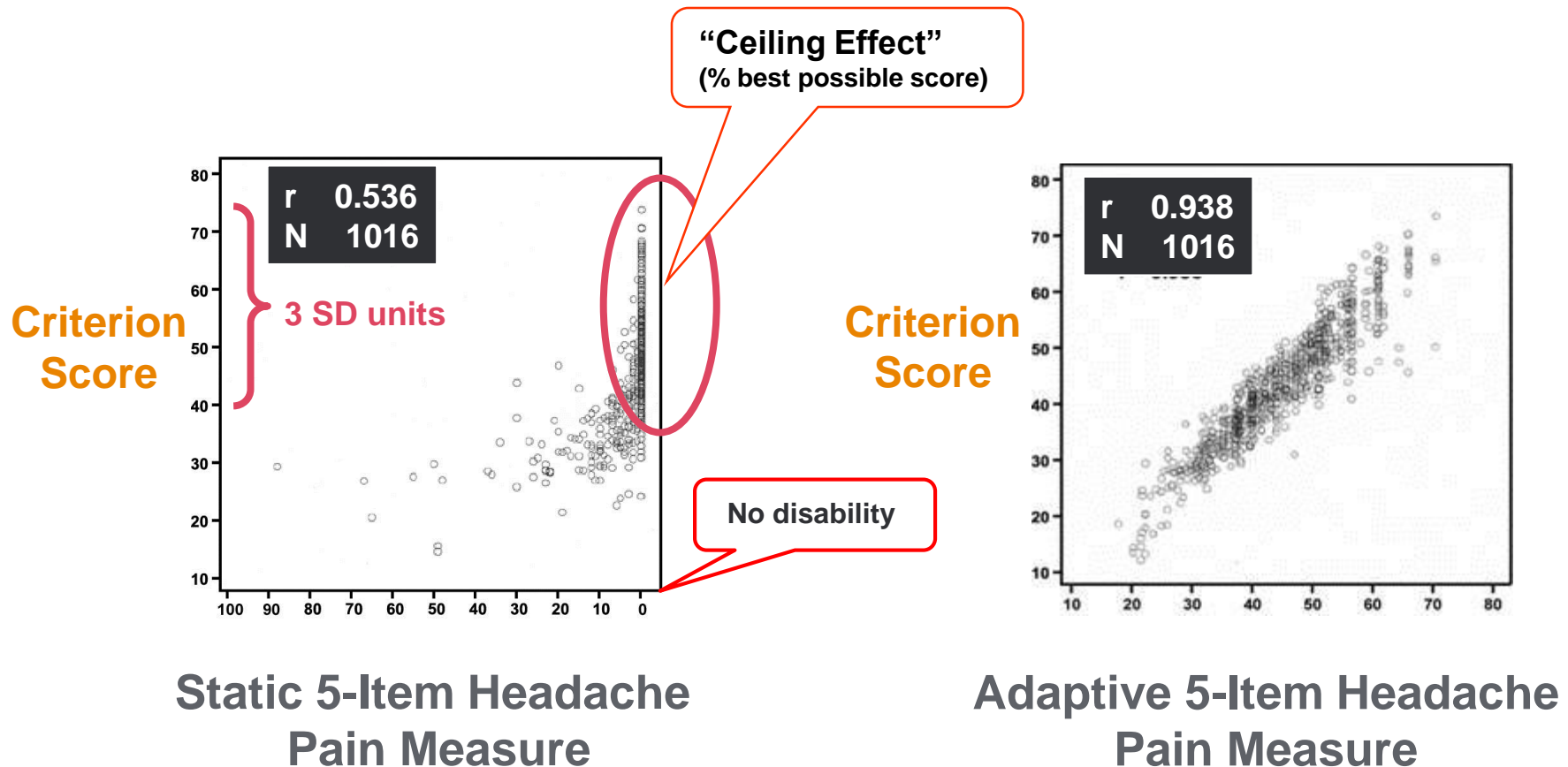
CAT = Computerized Adaptive Testing

# Logic of computerized adaptive testing (CAT)



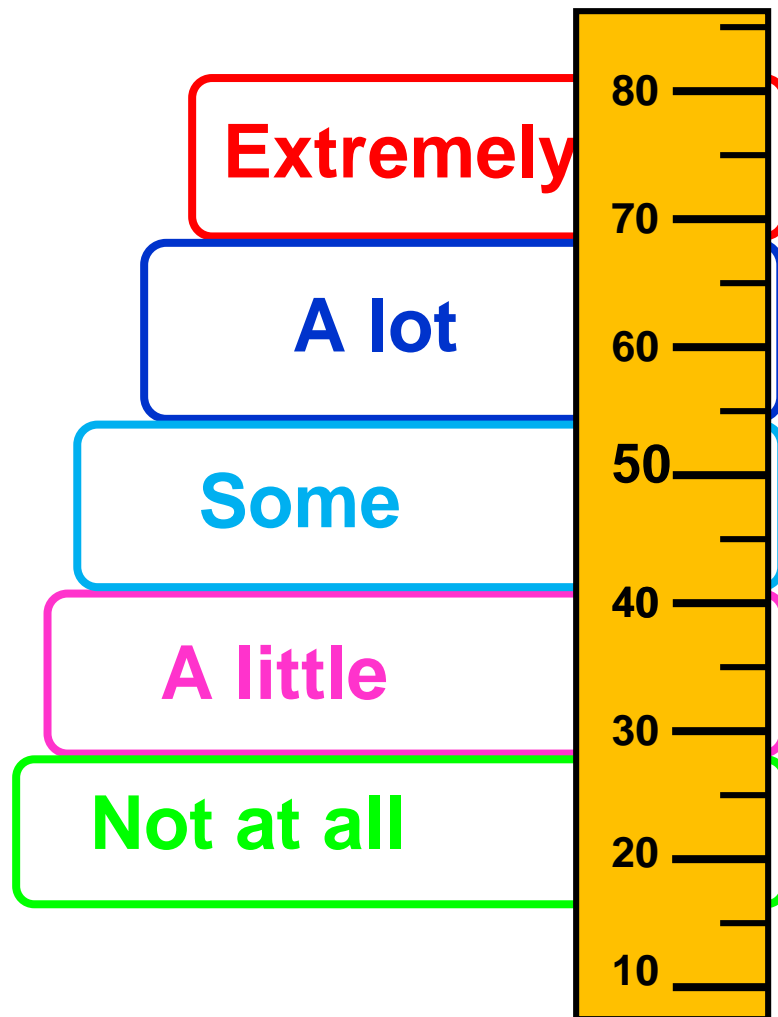
Adapted from: Wainer H, Dorans NJ, Flaugher R, et al. *Computerized Adaptive Testing: A Primer*. 2nd ed. Hillsdale, NJ: Lawrence Erlbaum Associates, 2000.

# An innovative approach in 1999: IRT model and CAT-based measurement



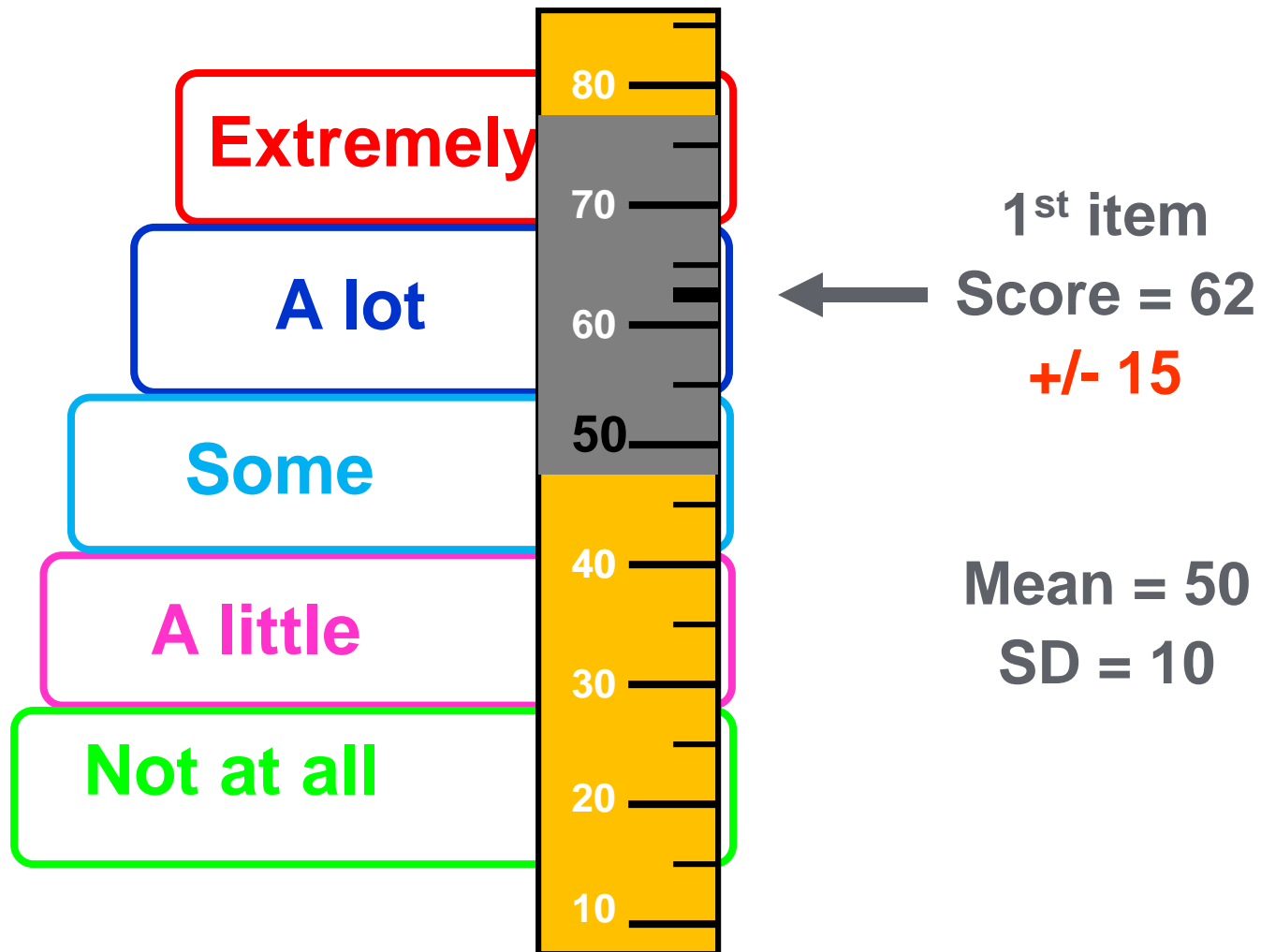
IRT: Item response theory  
CAT: Computerized adaptive testing

# Adaptive software can evaluate measurement in “real time”

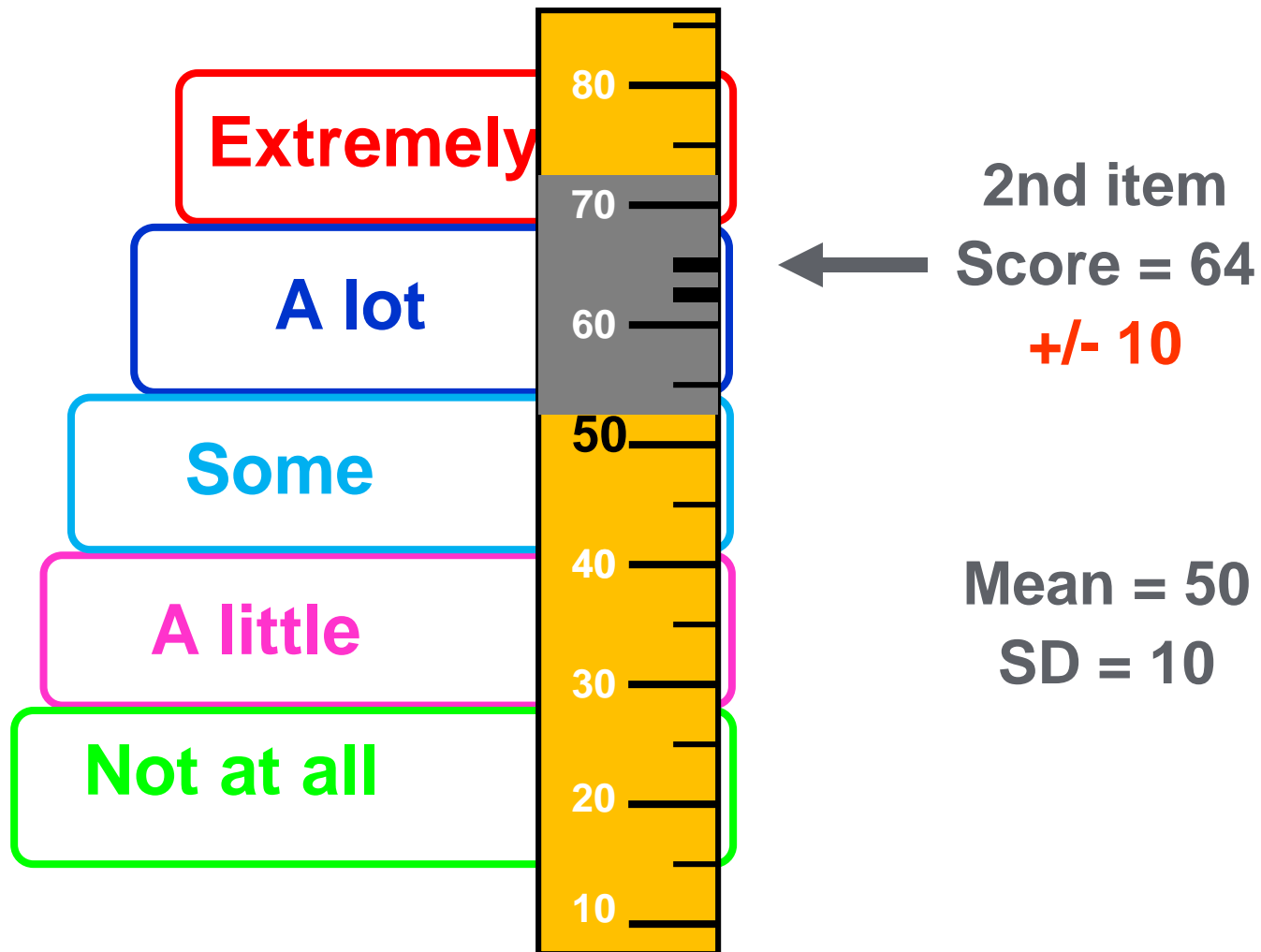




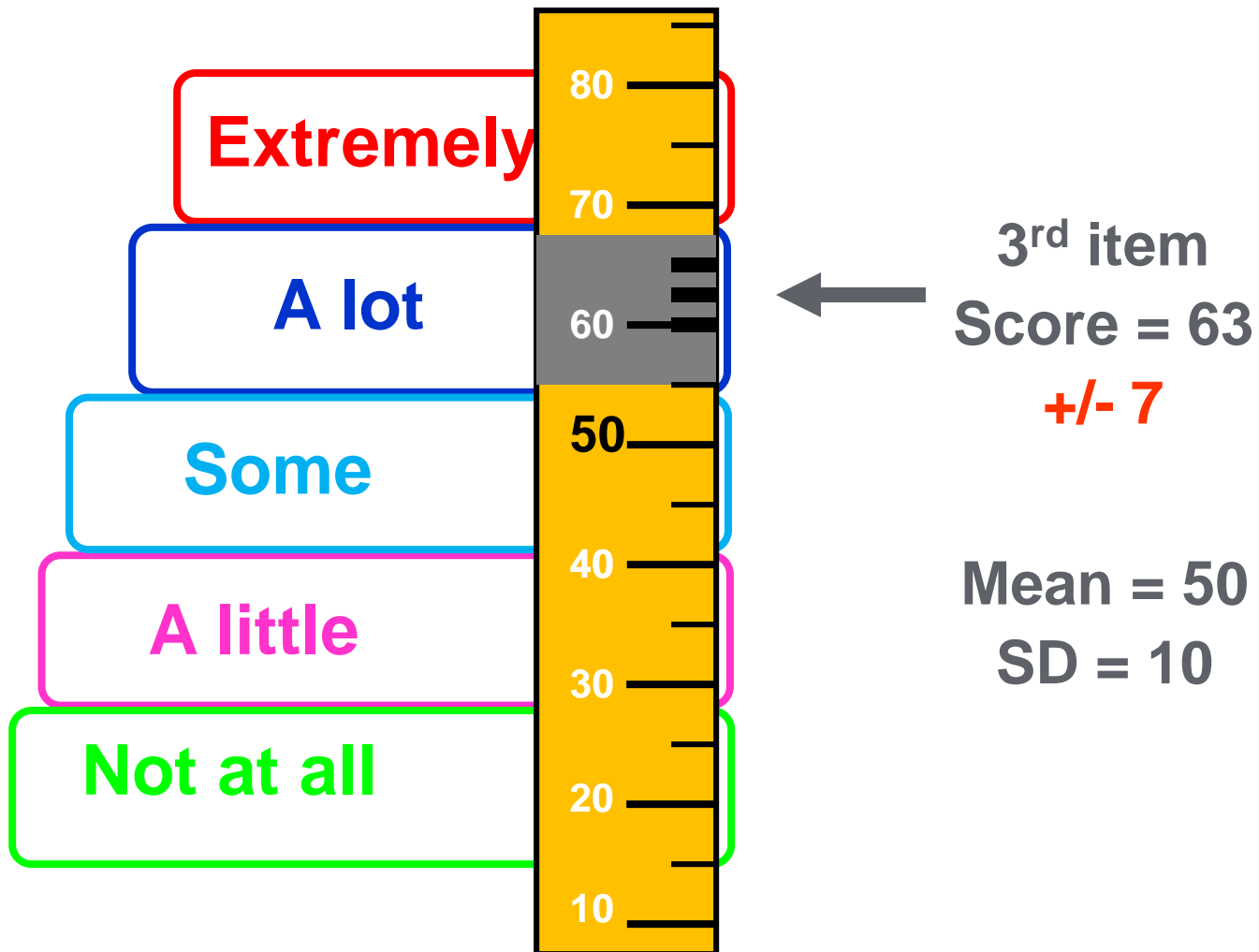
# 1<sup>st</sup> item yields noisy but unbiased score estimate



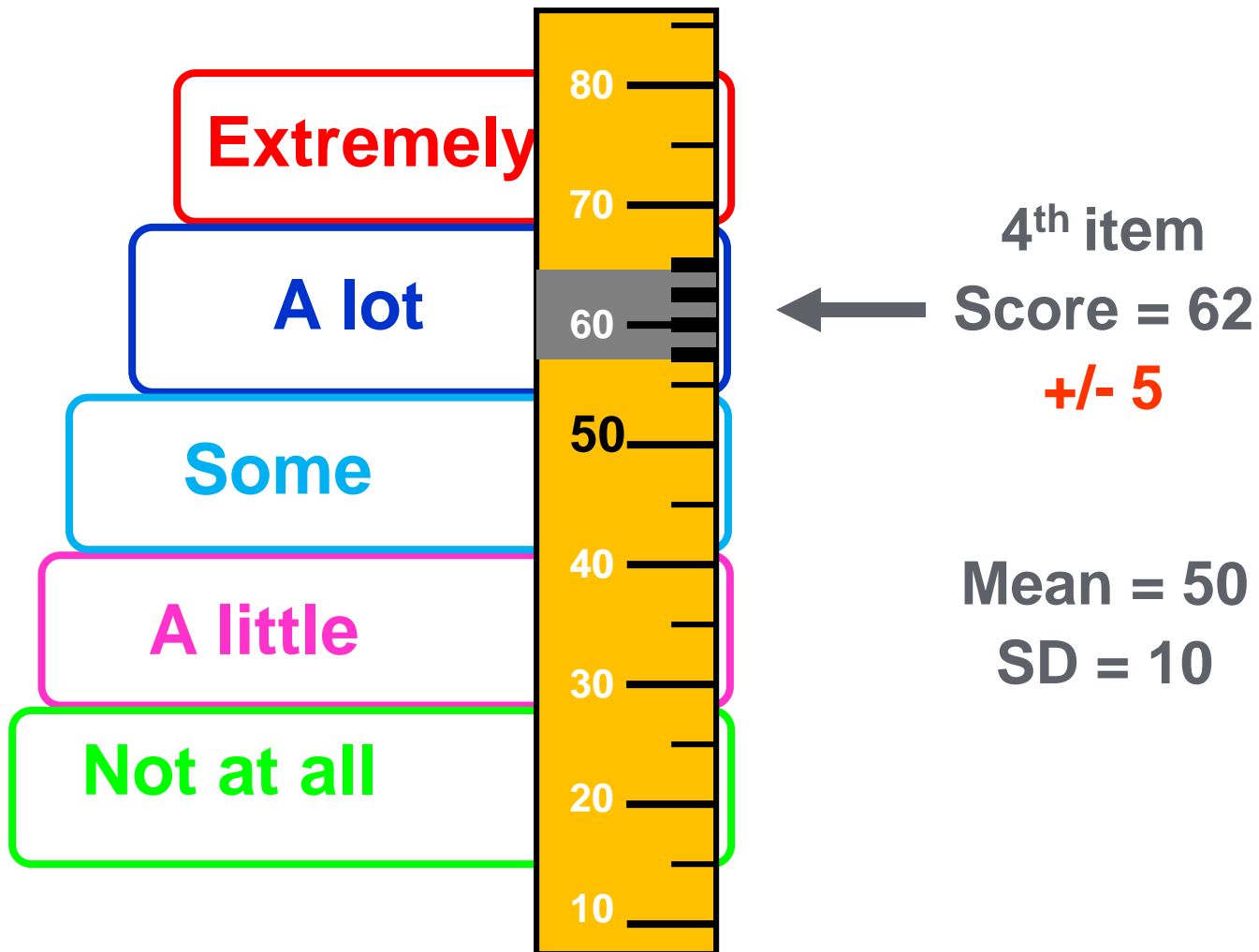
# 2<sup>nd</sup> item reduces error by 1/3



# 3<sup>rd</sup> item reduces error by 1/2



# 4<sup>th</sup> item reduces error by 2/3

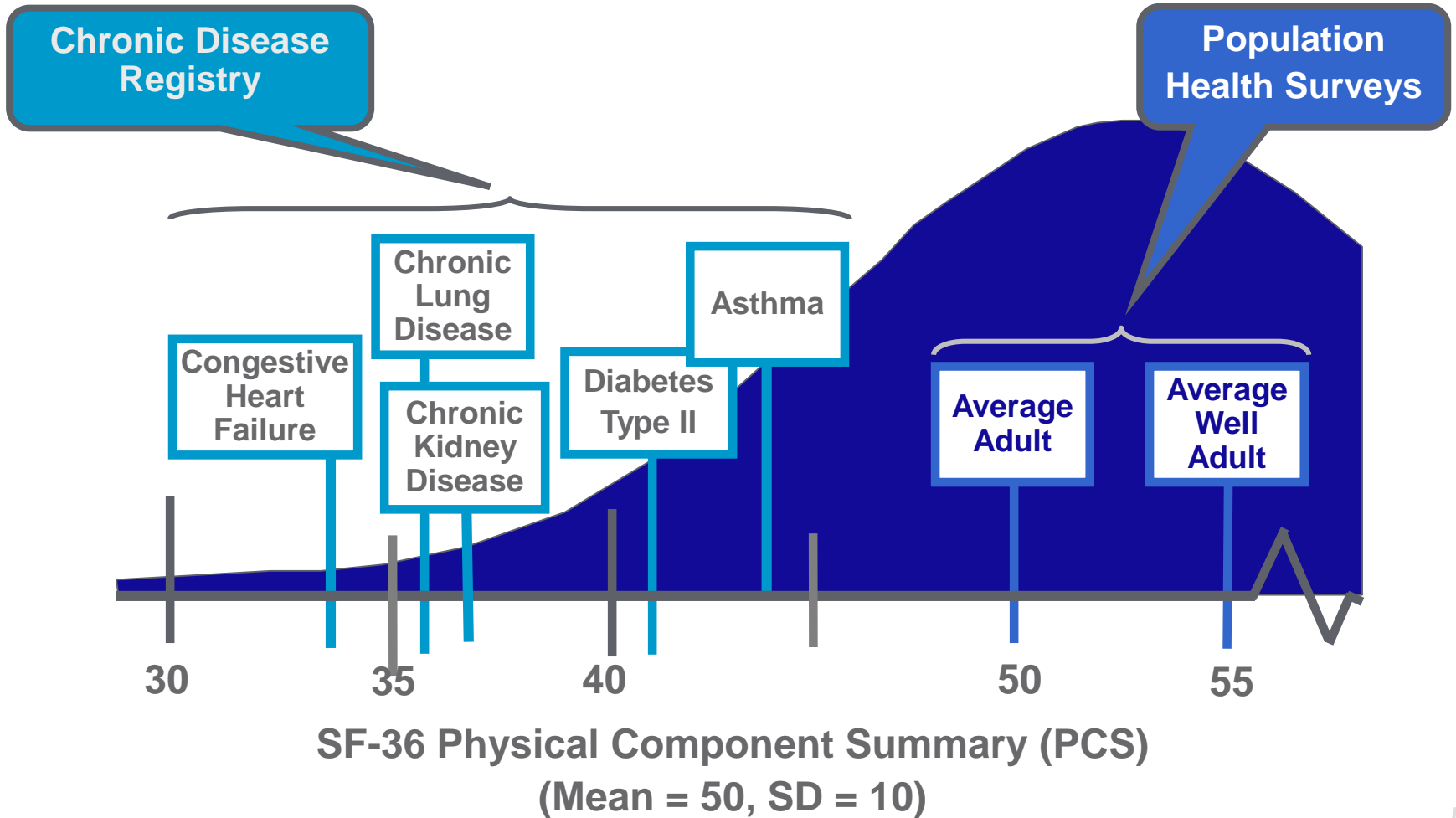


# CATs have noteworthy advantages but some limitations

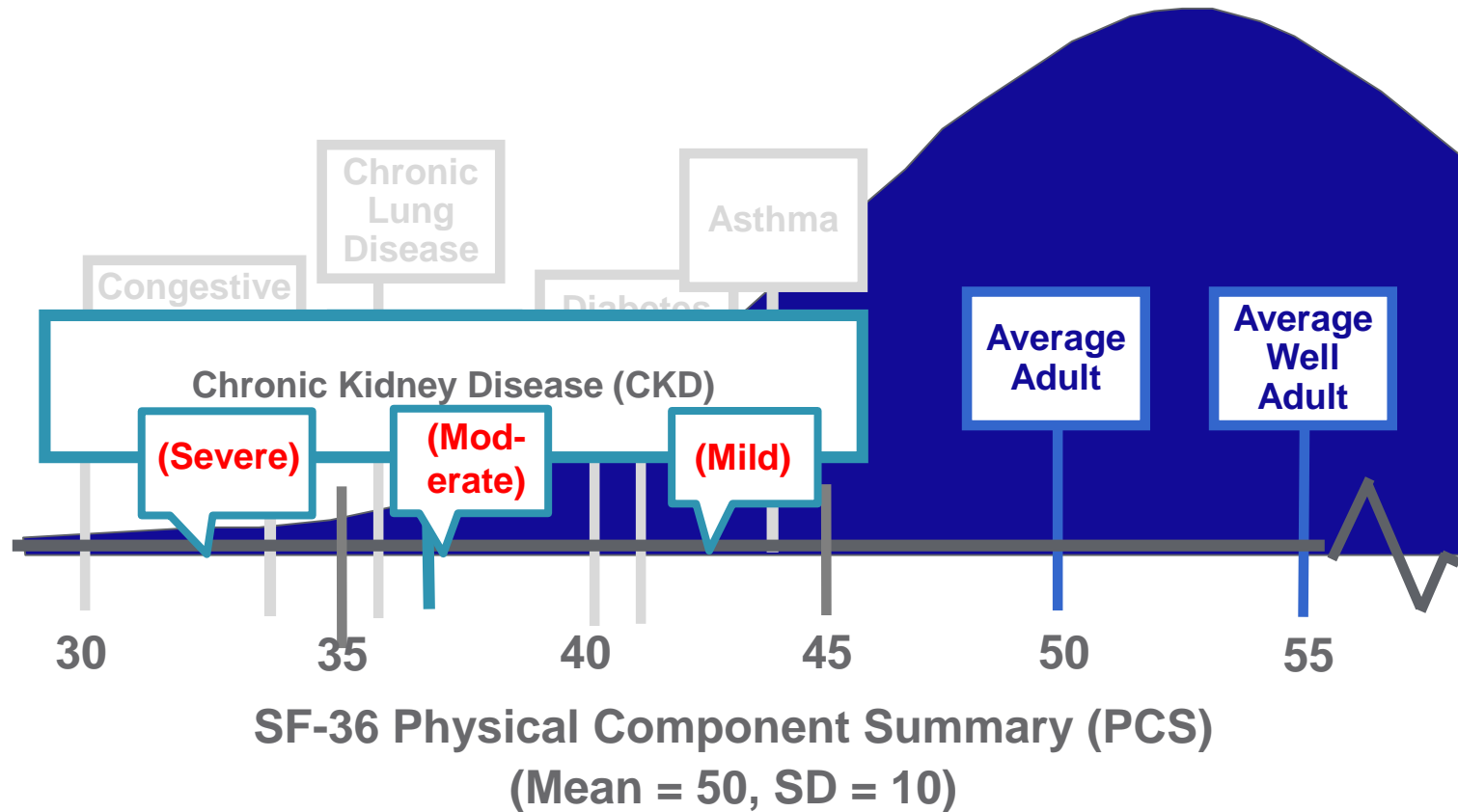
- More accurate risk screening
- Reliable enough to monitor individual outcomes
- Brevity of a short form – 70-90% reduction in *respondent burden*
- Better manage “ceiling” & “floor” effects
- Can be administered using various electronic data collection technologies
- Monitor data quality in real time

However, because of the number of core generic domains and comorbid conditions, routine CAT's won't solve the respondent burden problem

# Standardized norm-based generic scores enable comparisons of QOL impact



# Standardized norm-based generic scores differ across severity levels within CKD



# Reliability of disease-specific QOL impact scores (QDIS example)

Disease	% IRT Reliability $\geq$ 0.90 by Severity Level <sup>a</sup>				Alpha <sup>b</sup>	Test-retest <sup>c</sup>
	Mild	Moderate	Severe	Total		
Arthritis	N = 718 60.5	N = 587 93.5	N = 231 95.7	N = 1536 78.4	.94	.88
<b>CKD</b>	<b>N = 200 34.5</b>	<b>N = 61 82.0</b>	<b>N = 36 94.4</b>	<b>N = 297 51.5</b>	<b>.94</b>	<b>.91</b>
Cardiovascular	N = 483 55.5	N = 112 95.5	N = 36 91.7	N = 631 64.7	.94	.90
Diabetes	N = 921 38.6	N = 329 72.0	N = 63 100.0	N = 1313 49.9	.91	.83
Respiratory	N = 1152 36.4	N = 306 87.3	N = 112 93.8	N = 1570 50.4	.94	.88

<sup>a</sup> Percent with IRT estimated reliability  $\geq$ 0.90. Severity defined as Mild (None, Mild), Moderate, or Severe (Severe, Very Severe) in response to “How would you rate the severity of your <disease> in the past 4 weeks?”

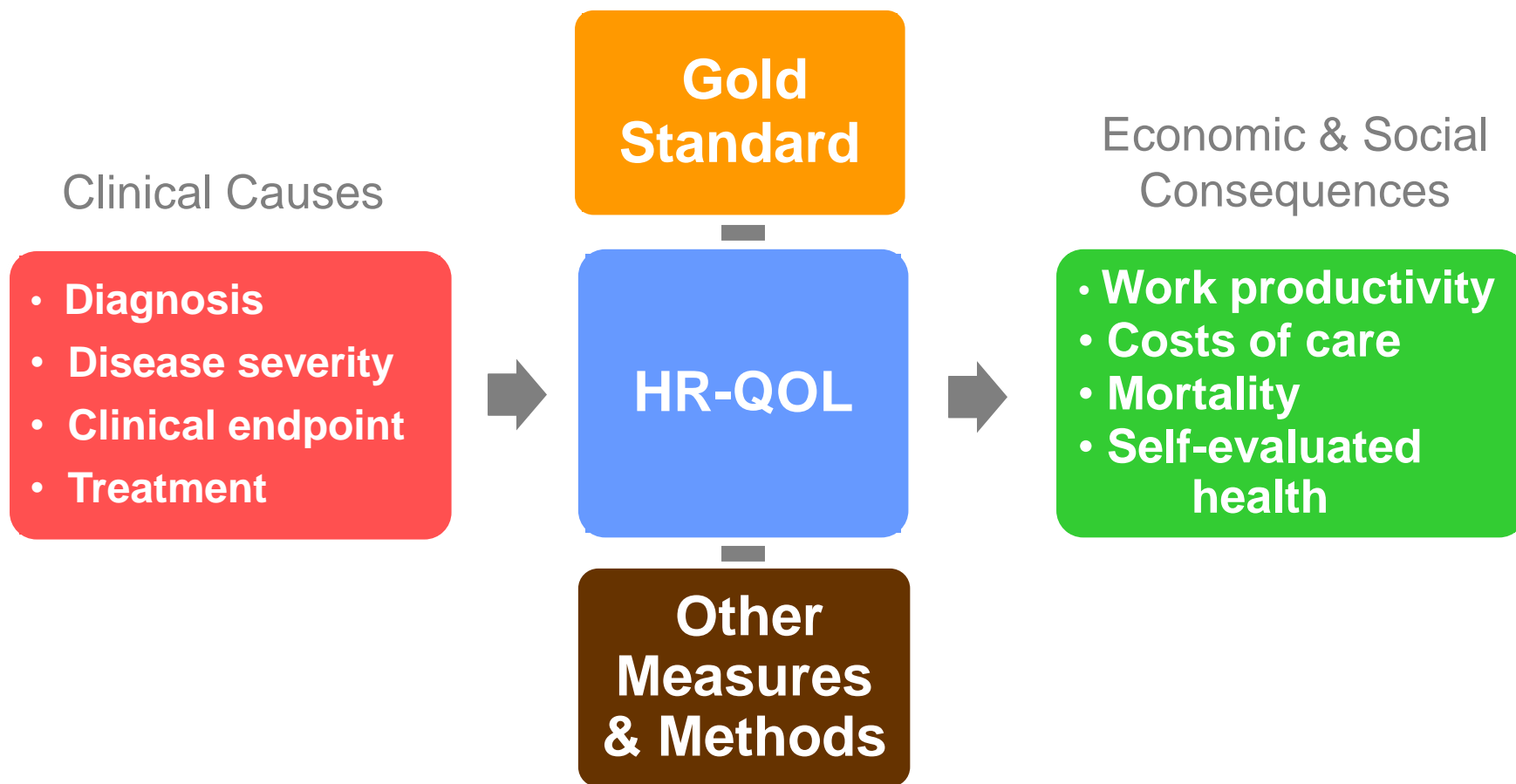
<sup>b</sup> Internal consistency reliability for arthritis (N=1,114), CKD (N=264), cardiovascular (N=580), diabetes (N=858) and respiratory conditions (N=1,115).

<sup>c</sup> Intraclass correlation coefficient for arthritis (N=109), CKD (N=37), cardiovascular (N=63), diabetes (N=75) and respiratory conditions (N=92); median of 8 days between test and retest.

**Reference:** Ware JE, Gandek B, Guyer R, Deng N. Standardizing disease-specific quality of life measures across multiple chronic conditions: Development and initial evaluation of the QOL Disease Impact Scale (QDIS®). *Health and Quality of Life Outcomes* 2016; 14:84.



# Validity tests of how well you measure what you want, require multiple criteria



Adapted from: Ware JE, Jr. and Keller SD: Interpreting general health measures, in: *Quality of Life and Pharmacoeconomics in Clinical Trials*. Philadelphia, PA: Lippincott-Raven Publishers; 1995: Chapter 47.

# Relative validity of CKD-specific (KDQOL, QDIS) & generic (SF-12) summary measures (N=207)

Measure <sup>a</sup>	Glomerular filtration rate (GFR) <sup>c</sup>			F-test	Relative Validity <sup>b</sup>
	<15	15-29	30-59		
<b>KDQOL-24 (+)</b>					
Symptoms	78.9	78.4	82.7	1.78	0.16*
Effects	73.3	82.2	85.2	4.04	0.37*
Burden	55.8	68.8	80.3	9.68	0.89
<b>QDIS-5 (-)</b>	<b>32.0</b>	<b>21.2</b>	<b>11.6</b>	<b>10.93</b>	<b>1.00</b>
<b>SF-12 (+)</b>					
Physical (PCS)	43.6	42.4	45.5	1.75	0.16*
Mental (MCS)	48.2	50.6	51.1	.79	0.05*

<sup>a</sup> Measures are CKD-specific 24-item KDQOL Symptom, Effects and Burden Scales, 5-item prototype of QDIS-CKD, and 12-item generic SF-12 PCS and MCS

<sup>b</sup> Relative validity (RV) is the ratio of how well legacy measures discriminate across 3 groups differing in GFR; relative to the best performing measure (RV = 1.00)

<sup>c</sup> Test of how well the kidneys are working

\*RV significantly lower than the best performing measure (RV = 1.00) using methods and data documented in Deng N, Allison JJ, Fang H, Ash AS, Ware JE. Using the Bootstrap to Establish Statistical Significance for Relative Validity Comparisons among Patient-Reported Outcome measures, *Health and Quality of Life Outcomes* 2013; 11:89.

# Responsiveness of disease-specific and generic measures

Measures	Mean Changes by Self-Evaluated Outcome Group					F-ratio	RV <sup>a</sup>
	Much Better (n=244)	Somewhat Better (n=245)	Same (n=1181)	Somewhat Worse (n=282)	Much Worse (n=378)		
<b>Disease-specific (-)</b>							
QDIS-7	-2.76	-0.04	1.29	3.20	5.87	29.8*	1.00**
<b>Generic (+)</b>							
SF-8 Physical (PCS)	1.36	-0.71	-0.28	-3.22	-4.98	14.2*	0.47
SF-8 Mental (MCS)	1.33	-0.47	0.14	-0.33	-0.91	2.1	0.07

Note: For each outcome, self-evaluated change groups were defined in response to the question: "Compared to nine months ago, how much better or worse is your <DISEASE> now?", where DISEASE was pre-defined and confirmed for nine chronic conditions analyzed here in the aggregate (total N=2330).

<sup>a</sup>Relative validity (RV) is the ratio of the comparator generic measure F-statistic over the best measure (QDIS) F-statistic

\*Significant F-ratio for comparison of average changes

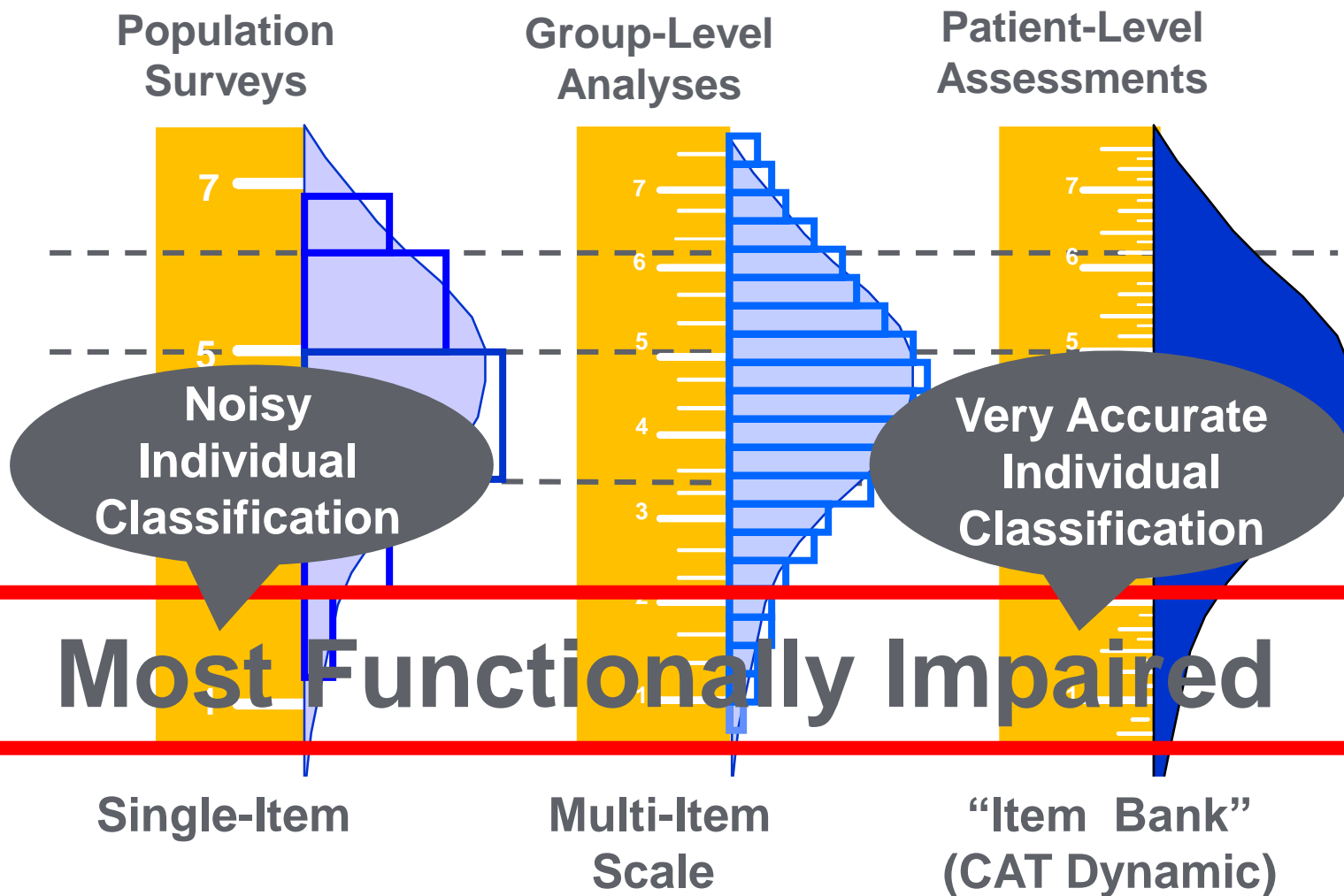
\*\*RV significantly greater RV for QDIS in comparison with generic measures using bootstrap method.

**Source:** Ware JE, Gandek B, Guyer R, Deng N. Standardizing disease-specific quality of life measures across multiple chronic conditions: Development and initial evaluation of the QOL Disease Impact Scale (QDIS®). *Health and Quality of Life Outcomes* 2016; 14:84.

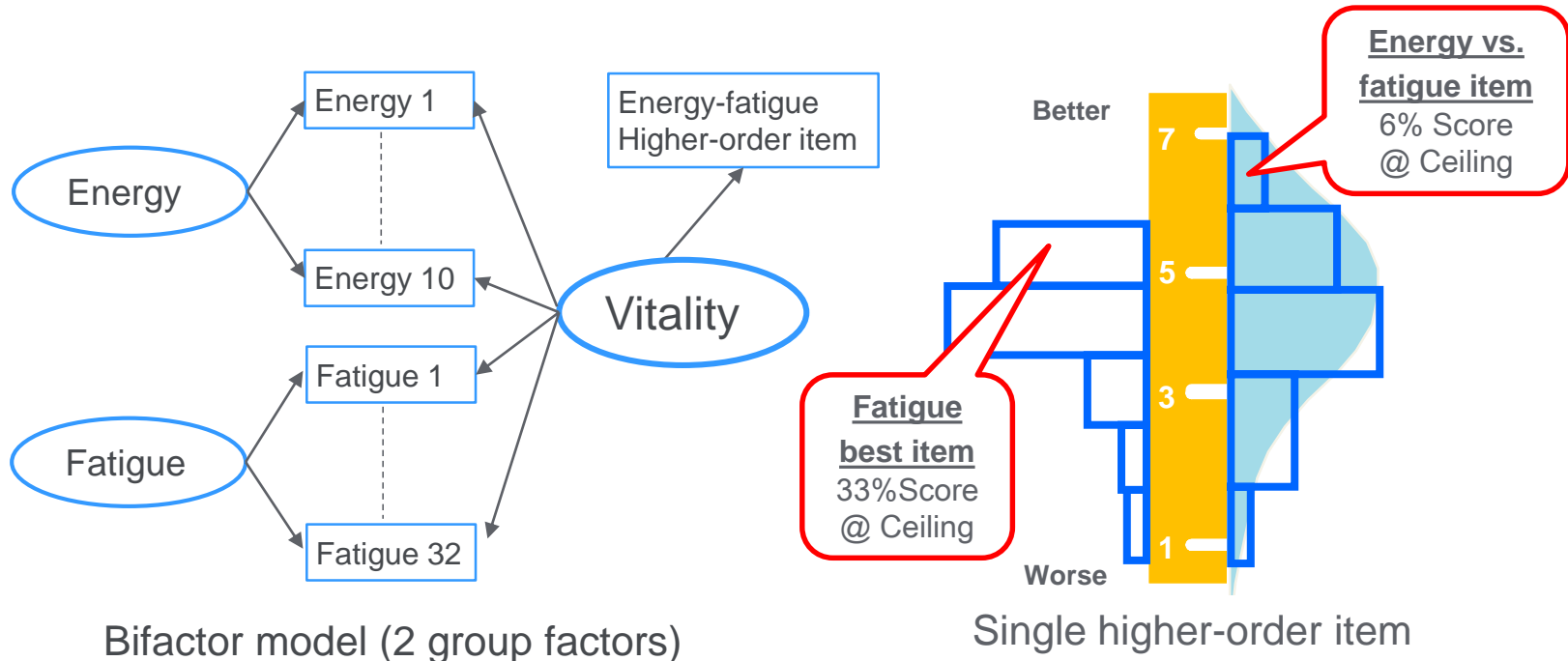
# **Matching methods to purposes: “Choosing the Right Horse for the Course”**

- Population monitoring
- Group-Level outcomes monitoring
- Patient-level monitoring and management

# How to match methods to purpose

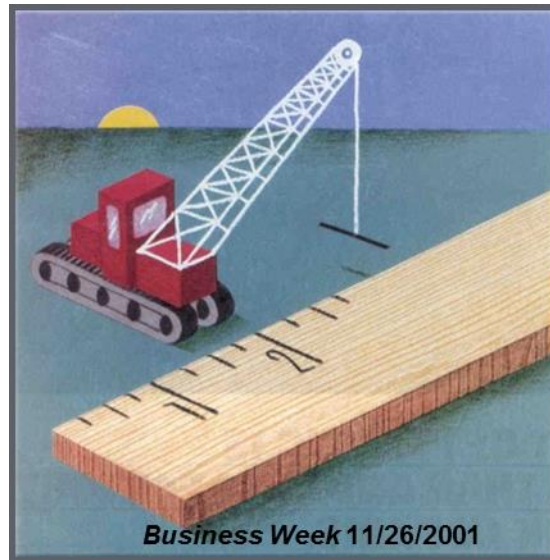


# Search for a better single-item measure of vitality (energy-fatigue)



**Reference:** Deng N, Guyer R, Ware JE. Energy, Fatigue or Both? A Bifactor Modeling Approach to the Conceptualization and Measurement of Vitality. *Quality of Life Research* 2015; 24:81-93.

# Final comments and discussion



*Business Week 11/26/2001*

# Patient and Provider Perspectives on current HRQoL measures

- Patient perspectives on current HRQoL measures
- Provider perspectives on current HRQoL measures



# HRQOL Assessment at DCI

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Michelle Richardson, PharmD  
Director



*"We are a service organization. The care of the patient is our reason for existence."*



Dialysis Clinic, Inc.  
The Outcomes Monitoring Program  
A Non-Profit Corporation

# Outcomes Monitoring Program

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- Began in 1994 with HRQOL assessment, 1 year later added patient satisfaction
- Goal - Improve patient care and ensure DCI meets CMS regulations by integrating HRQOL and patient experience of care into routine clinical practice and QAPI

# What does the OMP do?

---

## Objectives:

1. **Facilitate** proper administration of the surveys
2. **Educate** clinic staff on how to use results
3. **Resource** for clinic questions & problem resolution
4. **Process** survey data
5. **Produce** reports
6. **Consult** on implementing results into patient care and QAPI

# Health-Related Quality of Life

	HRQOL
<b>Who</b>	All DCI patients
<b>What</b>	Adult: KDQOL-36 or SF-36+24 Pediatric: PedsQL (surveys and scoring provided through the OMP)
<b>When</b>	- Within the first 4 months of starting dialysis and annually, prior to the patient's care plan - As Needed
<b>Where</b>	Within DCI facility, patients can take home
<b>By Whom</b>	DCI SW

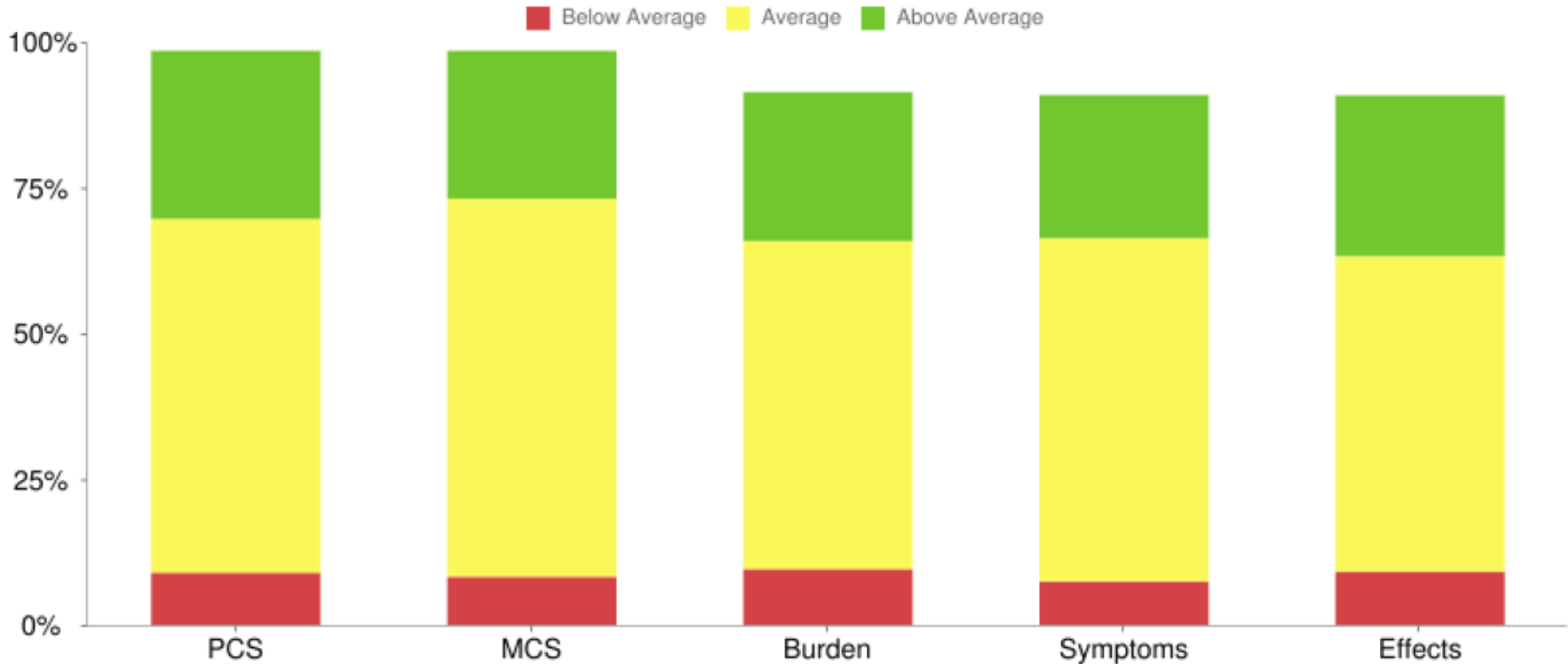
# PRO-surveys

## Dialysis Provider Experience

Brigitte Schiller, MD  
Chief Medical Officer

Tuesday, May 16, 2017  
1769 patients represented

### Ratings for Most Recent Survey

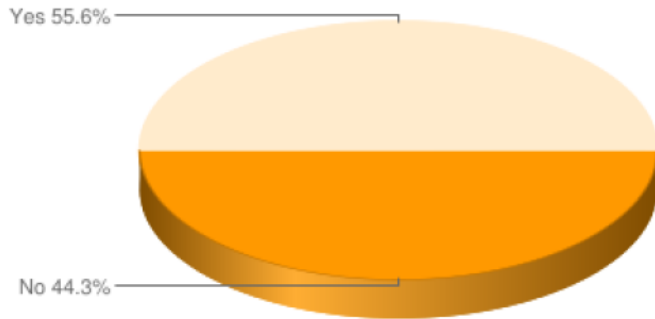


	PCS	MCS	Burden	Symptoms	Effects
Below Average	156 (8.9%)	144 (8.2%)	167 (9.6%)	130 (7.4%)	159 (9.1%)
Average	1055 (60.6%)	1127 (64.8%)	978 (56.2%)	1023 (58.8%)	941 (54.1%)
Above Average	501 (28.8%)	441 (25.3%)	444 (25.5%)	427 (24.5%)	479 (27.5%)

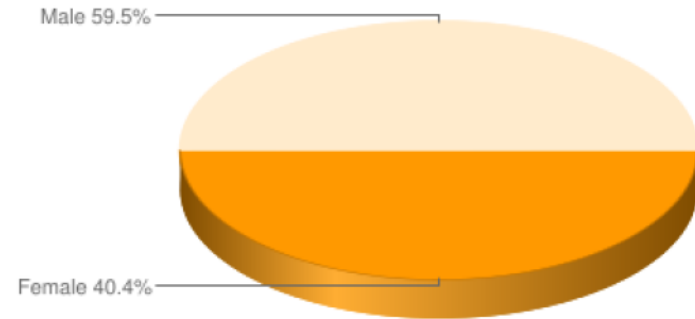
Q1, 2017

# Demographics of surveyed patients

### Diabetes



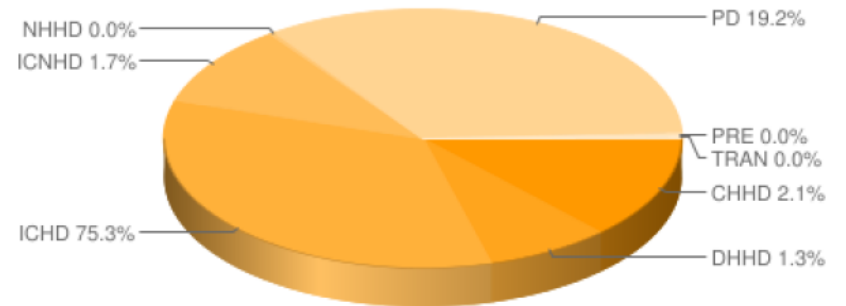
### Gender



### Age



### Dialysis



# 'Real World' Experience

	KDQOL administered	Refusal
2016	4107	629 (15%)
Q1 2017	1769	226 (13%)

- Refusal
  - minimum of three attempts to obtain completed survey and one attempt to do in person with the patient
  - outright refusal by patient
- Refusal – unable to do survey due to cognitive function
  - $77/226 = 3.5\%$
- Concerns:
  - Burn out of patients
  - Survey filled in as a 'favor' to their SW and less for the insight the survey provides the patient and the IDT.
  - After a number of years, refusal increasing for lack of pertinent information or new feedback from the survey.



# Reporting Measure – Depression Screening (Payment 2018)

## Reporting Measure Definitions

Clinical Depression Screening and Follow-Up reporting measure was finalized for PY 2018 (performance period begins Jan. 1, 2016)

Definition: Indicate the outcome of clinical depression **screening**<sup>1</sup> and **follow-up plan**<sup>2</sup> documented for the selected **patient**<sup>3</sup>

1. “Screening” – Completion of a clinical or diagnostic **standardized tool** used to identify people at risk of developing or having a certain disease or condition, even in the absence of symptoms
  - “Standardized tool” – an assessment tool that has been appropriately normalized and validated for the population in which it is used
2. “Follow-Up Plan” – A documented outline of care for a positive depression screening (see next slide)
3. “Patient” – Individual who has been admitted and received dialysis at a facility for the payment year in question



# Satellite Healthcare

## 2016 Depression Screening Data

	Count	%
<b>Administered (PHQ2)</b>	3987	95.1%
<b>Refused</b>	43	1.0%
<b>Not Administered</b> (Cognitive impairment, Language barrier, other...)	162	3.9%
<b>Total</b>	<b>4192</b>	<b>100.0%</b>

	Count	%
<b>Low Risk</b>	3710	93.1%
<b>High Risk</b>	277	6.9%
<b>Total</b>	<b>3987</b>	<b>100.0%</b>

# Satellite Healthcare

## 2016 Depression Screening Data – Menu B

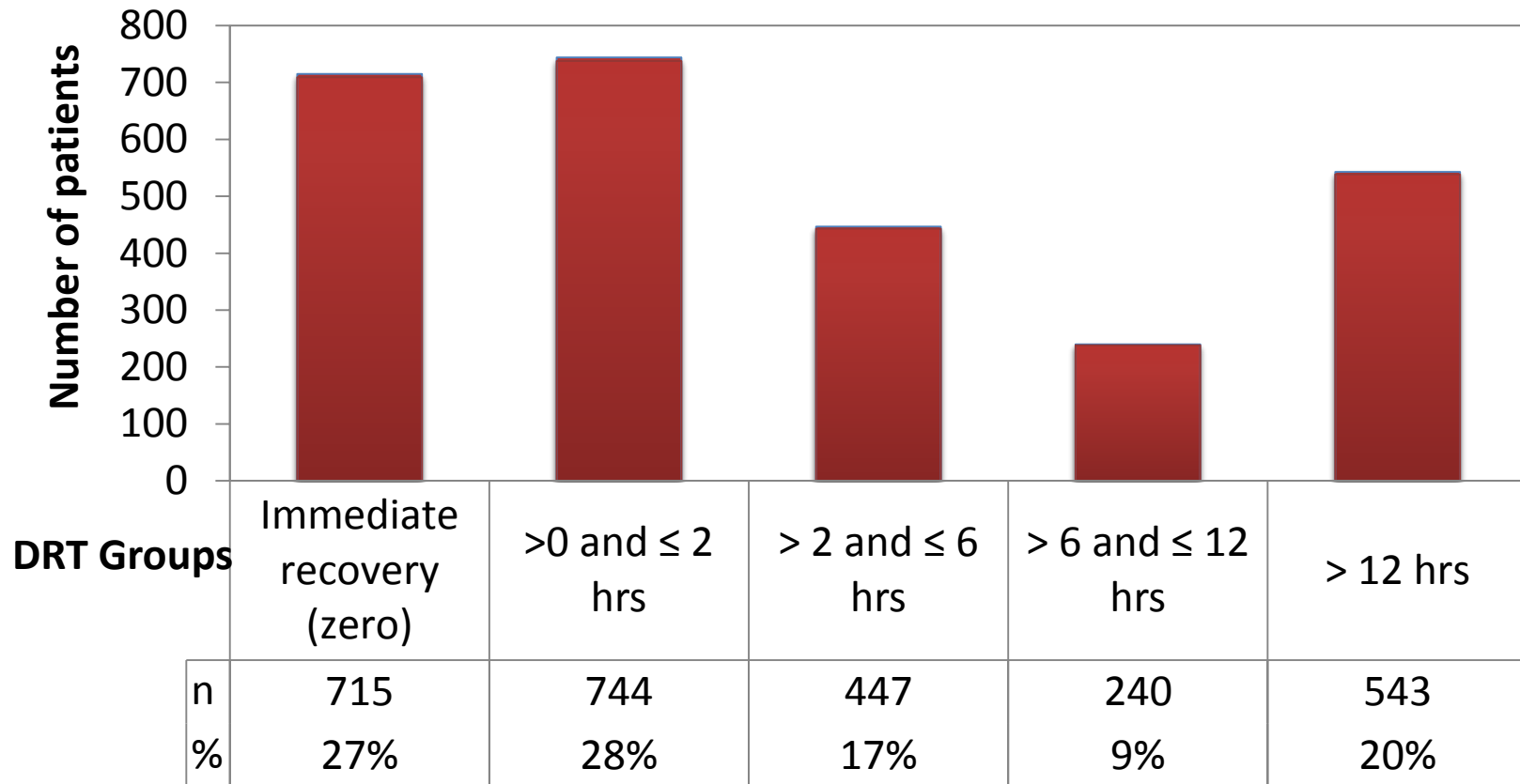
<b>Low Risk Population (3710)</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>
<b>Prior history of depression</b>	<b>13.7% (508)</b>	<b>86.3% (3202)</b>	<b>0.0% (0)</b>
<b>Active antidepressant medication</b>	<b>8.7% (324)</b>	<b>91.3% (3386)</b>	<b>0.0% (0)</b>
<b>IDT intervention</b>	<b>0.0% (0)</b>	<b>0.0% (0)</b>	<b>100% (3710)</b>
<b>External intervention</b>	<b>0.0% (0)</b>	<b>0.0% (0)</b>	<b>100% (3710)</b>

<b>High Risk Population (277)</b>	<b>Yes</b>	<b>No</b>	<b>N/A</b>
<b>Prior history of depression</b>	<b>37.9% (105)</b>	<b>55.2% (153)</b>	<b>6.9% (19)</b>
<b>Active antidepressant medication</b>	<b>23.8% (66)</b>	<b>69.3% (192)</b>	<b>6.9% (19)</b>
<b>IDT intervention</b>	<b>66.4% (184)</b>	<b>26.7% (74)</b>	<b>6.9% (19)</b>
<b>External intervention</b>	<b>20.2% (56)</b>	<b>72.9% (202)</b>	<b>6.9% (19)</b>

## 2015 Research Project: Center HD

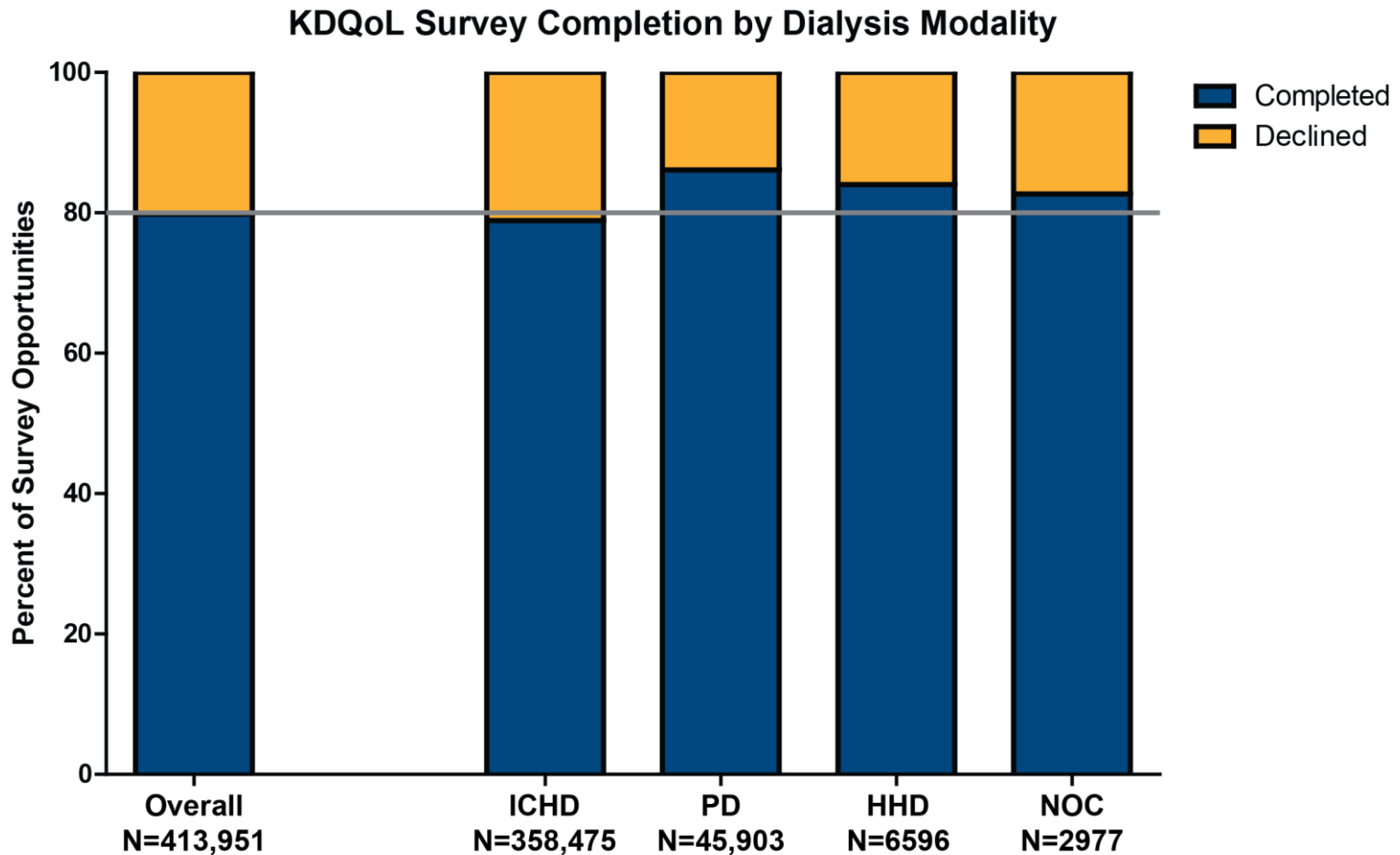
“How long does it take you to recover from dialysis?”

**Number of patients in dialysis recovery time groups (N = 2,689)**



# Placeholder for Dialysis Organization HRQoL Summary Data

# Survey Completion Rates



HHD, home hemodialysis; ICHD, in-center hemodialysis; NOC, nocturnal hemodialysis; PD, peritoneal dialysis

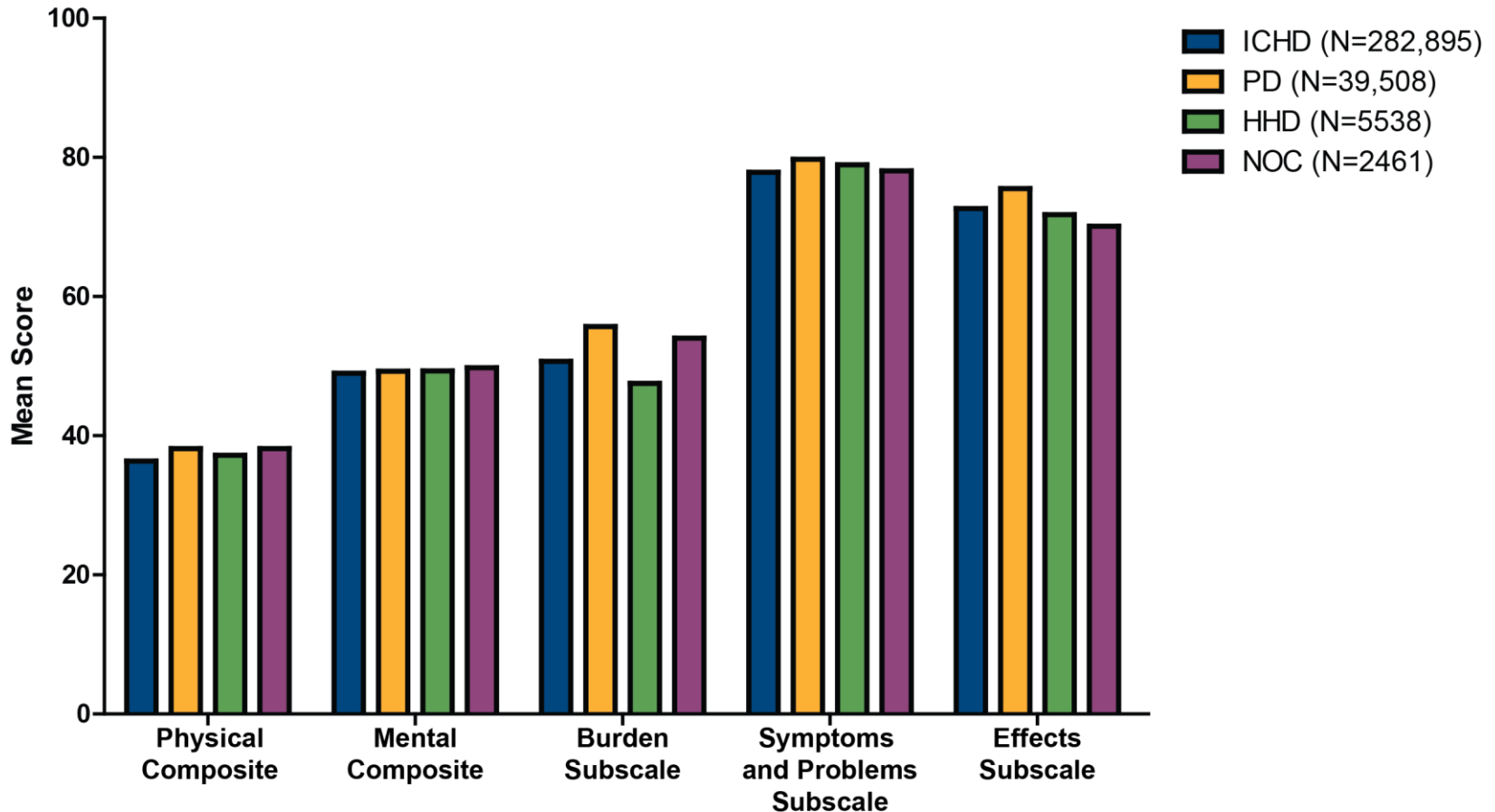
# Patient Characteristics by Survey Completion Status

	<b>Completed N=330,412</b>	<b>Declined N=83,552</b>
<b>Age</b> , years, mean $\pm$ SD	60.7 $\pm$ 14.7	64.0 $\pm$ 15.2
<b>Sex</b> , female, %	45%	43%
<b>BMI</b> , kg/m <sup>2</sup> , mean $\pm$ SD	28.9 $\pm$ 7.4	27.1 $\pm$ 7.0
<b>Vintage</b> , months, mean $\pm$ SD	40.3 $\pm$ 42.8	46.2 $\pm$ 45.3
<b>Charlson comorbidity index</b> , mean $\pm$ SD	5.3 $\pm$ 1.9	5.7 $\pm$ 2.0
<b>Diabetes</b> , %	68.2	70.0

Abbreviations: BMI, body mass index; SD, standard deviation

# KDQoL Scores by Dialysis Modality

Mean KDQoL Score by Dialysis Modality



HHD, home hemodialysis; ICHD, in-center hemodialysis; NOC, nocturnal hemodialysis; PD, peritoneal dialysis



# Lunch

12:00-1:00

# TEP Feedback on Patient Reported Outcome Topic Areas

# TEP Objectives: PRO TEP Charter

- Review existing health related quality of life (HRQoL) measures, recovery time measures and the PROMIS set; evaluate evidence and usability for patients and providers; address existing testing or need for psychometric testing within the ESRD population; and data collection feasibility.
- Make recommendations on the potential development of PRO measures including health related quality of life, recovery time, and measures derived from PROMIS item banks/domains, or potentially other measures identified by the TEP.

## Re-cap: Definition of PROs

- Definition of (PROs): *any report of the status of a patient's (or person's) health condition, health behavior, or experience with healthcare that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else\**
  - Referenced in the NQF PRO Report\*\*

\*U.S. Food and Drug Administration. "Guidance for Industry, Patient Reported Outcome Measures: Use in Medical Product Development to Support Labeling Claims." Fed Regist. 2009; 74(35):65132-65133. Accessed August 12, 2016: <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM193282.pdf>

\*\*National Quality Forum (NQF). "NQF Patient Reported Outcomes (PROs) in Performance Measurement." January 2013. Accessed February 23, 2016. [http://www.qualityforum.org/Projects/nr/Patient\\_Reported\\_Outcomes/Patient\\_Reported\\_Outcomes.aspx](http://www.qualityforum.org/Projects/nr/Patient_Reported_Outcomes/Patient_Reported_Outcomes.aspx)

# General Framework for Discussion of PROs

1. Initial prioritization of PROs based on patient/stakeholder feedback about what is important, irrespective of facility practices/influence
2. ***Identification of the prioritized PROs (from step 1) that patients/stakeholders believe are attributable to facility practices/influence***
3. ***Identification of PROs from first two discussion steps that meet criteria of evidence and actionability***
4. Identify if there are existing PRO-Measures that capture the topics/domains prioritized in steps 1-3

# Evaluating Attributability and Evidence

- Identification of the prioritized PROs (from step 1) that patients/stakeholders believe are attributable to facility practices/influence
- Identification of PROs from first two discussion steps that meet criteria of evidence and actionability

# Evaluating Attributability and Evidence: Patient Reported Outcome Topic Areas

## Patient Experience of Care at Dialysis Clinic

- Treatment Experience (defined several ways)
  - interaction with staff and patients
  - staff competency, education and professionalism
  - on-time, smooth, streamlined clinic proceedings
  - clinic safety, cleanliness, hygiene practices
- Continuity of care among providers
- Coordination of care (medical services as well as psychosocial/emotional support services)
- Clinician communication (caring, respect, cultural competence)
- Staff understanding of patient goals
- Quality of care (general)
- Satisfaction with patient health care and services
- Symptoms (non-specific) being addressed

# Evaluating Attributability and Evidence: Patient Reported Outcome Topic Areas

## Patient Education and Engagement

- Diet/ nutritional education
- Health risk behaviors
- Disease knowledge
- Patient empowerment
- Patient engagement (in care, in clinic) and patient activation (in care)
- Coping skills with chronic disease (via psychosocial-emotional support services)
- Adequate modality education and options (including option for conservative care without dialysis) so that “right patient has right modality”



# Evaluating Attributability and Evidence: Patient Reported Outcome Topic Areas

## Life goals\*

- Being able to meet life goals/ living the life that patients want to live
- Patients determine what is most important to them (work, family, other considerations)
- Independence (defined in several ways: personal living activities, medical aids, work capacity, dependence on medical substances, financial)
- Adjustment (societal, life)

\*life goals/ aspirations defined in multiple ways, including: to live as normal a life as possible, to have access to modalities that allow patients to adjust dialysis to their lives, to achieve what is important to them [patients], to facilitate desired social interactions, to maximize longevity to pursue aspirations (including transplant)

# Evaluating Attributability and Evidence: Patient Reported Outcome Topic Areas

## HRQoL

- Quality of Life (general)
- Health-related quality of life (focus on health and disease burden, functional health)
- HRQOL - Role functioning (physical and social)
- Healthy days at home (independence)
  - HRQoL-Psychological/ Emotional
  - Psychological adjustment (worry and stress)
- Well-being
- Emotional issues (anxiety and depression)
- Energy/Vitality and Fatigue

# Evaluating Attributability and Evidence: Patient Reported Outcome Topic Areas

## Symptoms and Symptom Management\*

- Post-dialysis fatigue
- Time-to-recovery after dialysis
- Cramping
- Fluid management
- Sleep disruption
- Nutritional status

*\*Interest in symptoms as biomarkers but no specifics here*

# Other Topics Identified

## *Clinical Outcomes*

- *Bloodstream Infections*
- *Presence and burden of multiple conditions*
- *Catheter rates for in the elderly population especially for those chronic units who has a high population*
- *Anemia Management issues on the elderly chronic setting*
- *Mortality and comorbidities*
- *Hospitalizations and readmissions*

# Prioritization of Patient Reported Outcome Topics

Candidate Measure Concepts

# Un-Prioritized Topics Identified

- HRQOL
  - Symptoms/Recovery Time, Fatigue, Cramping, Lack of Appetite
  - Care Burden
  - Mental Health
    - Depression, Anxiety
  - Physical Functioning
  - Sexual Function
  - Social Functioning
  - Sleep
- Life Goals
- Patient Activation/Engagement
  - Education on Modality
- Patient Safety

# Public Comment

4:45pm – 5:00pm (ET)

# ESRD Patient Reported Outcomes (PRO)

Technical Expert Panel  
Day Two: May 24, 2017



# Agenda: May 24, 2017

- 9:00 – 10:45 Identify Candidate PRO Measure Concepts
- 10:45 – 11:00 *BREAK*
- 11:00 – 12:00 Continue Discussion
- 12:00 – 1:00 *LUNCH*
- 1:00 – 2:30 TEP Recommendations and Meeting Wrap-up
- 2:30 – 3:00 Public Comment Period
- 3:00 Meeting Adjourns

# Recap of Day One Discussions

- Recap of candidate PRO Measure Concepts identified on Day One

# Un-Prioritized Topics Identified

- HRQOL
  - Symptoms/Recovery Time, Fatigue, Cramping, Lack of Appetite
  - Care Burden
  - Mental Health
    - Depression, Anxiety
  - Physical Functioning
  - Sexual Function
  - Social Functioning
  - Sleep
- Life Goals
- Patient Activation/Engagement
  - Education on Modality
- Patient Safety

# General Framework for In-Person Meeting Discussion

1. Initial prioritization of PROs based on patient/stakeholder feedback about what is important, irrespective of facility practices/influence
2. Identification of the prioritized PROs (from step 1) that patients/stakeholders believe are attributable to facility practices/influence
3. Identification of PROs from first two discussion steps that meet criteria of evidence and actionability
4. ***Identify if there are existing PRO-Measures that capture the topics/domains prioritized in steps 1-3***

# What Candidate Measure Concepts can be Supported by existing PRO-Measures

# Measure Concepts Supported by Existing Instruments

- Do any of the existing PRO Measures support the candidate measure concepts?

# Lunch

12:00-1:00

# TEP Recommendations and Meeting Wrap-up

- The TEP Strongly Recommends the principle of PRO measures that capture patient centered care (Individualization) for all dialysis modalities
- Two Broad New Topic Areas of Interest that were identified: (1) Assessment of Patient Goals and (2) Assessment of Overall Patient Safety. One Existing Topic Area that was identified was Health Related Quality of Life.
- KDQOL-36 was not believed to be an effective PRO measure for comparing facility performance
- Other Generic and Disease Specific Health-related Quality of Life measures were not ruled out but additional considerations of important and actionable domains would drive clinic processes
- The Following Items were recognized as important but were tabled:
  - Patient Experience of Care
  - Transplant Recipients
- It is critical for PROs to meet accepted current standards of measurement science.



# Areas of Evidence and Questions to be Answered

- What are Existing PRO Measures that capture goals?
- Are there Existing PRO Measures that capture safety?
- What are the right domains to be included in a future HRQoL?

# Un-Prioritized Topics Identified

- HRQOL
  - Symptoms/Recovery Time, Fatigue, Cramping, Lack of Appetite
  - Care Burden
  - Mental Health
    - Depression, Anxiety
  - Physical Functioning
  - Sexual Function
  - Social Functioning
  - Sleep
- Life Goals
- Patient Activation/Engagement
  - Education on Modality
- Patient Safety

# Public Comment

2:30pm – 3:00pm (ET)

# Appendix

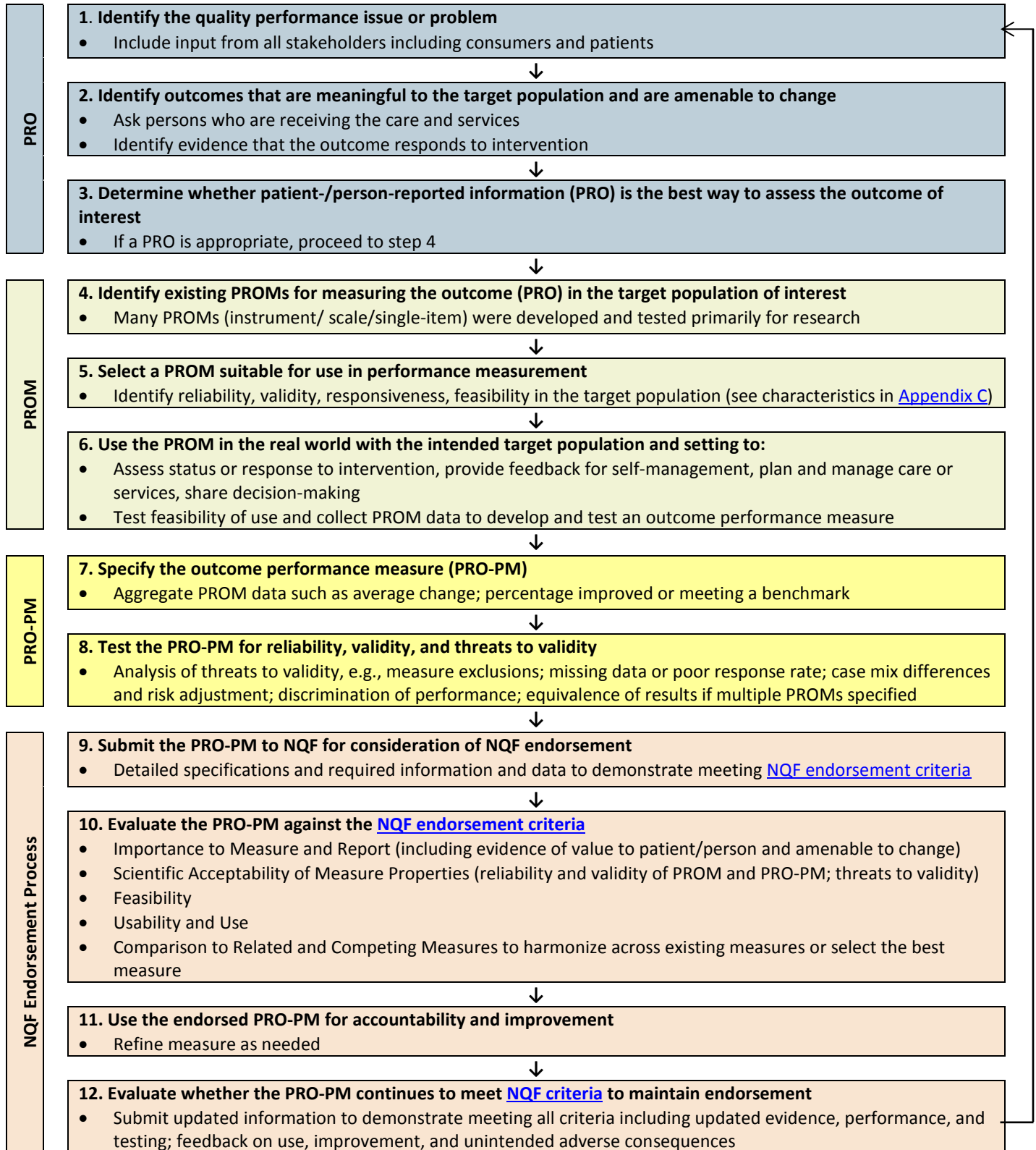
## ***Exhibit 1: NQF Report Figure***

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Exhibit 1 includes Figure 2: Pathway from PRO to NQF-endorsed PRO-PM from the “NQF Patient Reported Outcomes (PROs) in Performance Measurement” report published in January 2013 by NQF. Exhibit 1 is provided on the next page. The reference and link are provided below.

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](http://www.qualityforum.org/Projects/n-r/Patient-Reported_Outcomes/Patient-Reported_Outcomes.aspx)

**Figure 2. Pathway from PRO to NQF-endorsed PRO-PM**



## ***Exhibit 2: KDQoL-36 Instrument***

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Exhibit 2 is the KDQoL-36 Instrument, which is provided on the next page. The KDQoL-36 was developed by the RAND Corporation and can be viewed at this link- [https://www.rand.org/health/surveys\\_tools/kdqol.html](https://www.rand.org/health/surveys_tools/kdqol.html).

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# Your Health – *and* – Well-Being

## Kidney Disease and Quality of Life (KDQOL™-36)

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.



***Thank you for completing these questions!***



# **Study of Quality of Life For Patients on Dialysis**

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## **What is the purpose of the study?**

This study is being carried out in cooperation with physicians and their patients. The purpose is to assess the quality of life of patients with kidney disease.

## **What will I be asked to do?**

For this study, we want you to complete a survey today about your health, how you feel and your background.

## **Confidentiality of information?**

We do not ask for your name. Your answers will be combined with those of other participants in reporting the findings of the study. Any information that would permit identification of you will be regarded as strictly confidential. In addition, all information collected will be used only for purposes of the study, and will not be disclosed or released for any other purpose without your prior consent.

## **How will participation benefit me?**

The information you provide will tell us how you feel about your care and further understanding about the effects of medical care on the health of patients. This information will help to evaluate the care delivered.

## **Do I have to take part?**

You do not have to fill out the survey and you can refuse to answer any question. Your decision to participate will not affect your opportunity to receive care.

# Your Health

This survey includes a wide variety of questions about your health and your life. We are interested in how you feel about each of these issues.

1. In general, would you say your health is: [Mark an  in the one box that best describes your answer.]

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? [Mark an  in a box on each line.]

Yes, limited a lot	Yes, limited a little	No, not limited at all
--------------------------	-----------------------------	------------------------------

2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf .....  1..... 2..... 3

3. Climbing several flights of stairs .....  1..... 2..... 3

**During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?**

Yes	No
▼	▼

4. Accomplished less than you would like.....  1..... 2

5. Were limited in the kind of work or other activities .....  1..... 2

**During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?**

Yes	No
▼	▼

6. Accomplished less than you would like.....  1..... 2

7. Didn't do work or other activities as carefully as usual .....  1..... 2

**8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

**These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.**

**How much of the time during the past 4 weeks...**

		A good			
All	Most	bit	Some	A little	None
of the	of the	of the	of the	of the	of the
time	time	time	time	time	time
▼	▼	▼	▼	▼	▼

9. Have you felt calm and peaceful?.....  1..... 2..... 3..... 4..... 5..... 6
10. Did you have a lot of energy? .....  1..... 2..... 3..... 4..... 5..... 6
11. Have you felt downhearted and blue? .  1..... 2..... 3..... 4..... 5..... 6

**12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?**

All	Most	Some	A little	None
of the	of the	of the	of the	of the
time	time	time	time	time
▼	▼	▼	▼	▼
<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

# Your Kidney Disease

How true or false is each of the following statements for you?

Definitely true ▼	Mostly true ▼	Don't know ▼	Mostly false ▼	Definitely false ▼
-------------------------	---------------------	--------------------	----------------------	--------------------------

13. My kidney disease interferes too much with my life .....

1 .....  2 .....  3 .....  4 .....  5

14. Too much of my time is spent dealing with my kidney disease.....

1 .....  2 .....  3 .....  4 .....  5

15. I feel frustrated dealing with my kidney disease.....

1 .....  2 .....  3 .....  4 .....  5

16. I feel like a burden on my family .....

1 .....  2 .....  3 .....  4 .....  5

**During the past 4 weeks, to what extent were you bothered by each of the following?**

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

- |   |                            |       |                            |       |                            |       |                            |       |                            |
|---|----------------------------|-------|----------------------------|-------|----------------------------|-------|----------------------------|-------|----------------------------|
| <b>17.</b> Soreness in your muscles?.....                 | <input type="checkbox"/> 1 | ..... | <input type="checkbox"/> 2 | ..... | <input type="checkbox"/> 3 | ..... | <input type="checkbox"/> 4 | ..... | <input type="checkbox"/> 5 |
| <b>18.</b> Chest pain? .....                              | <input type="checkbox"/> 1 | ..... | <input type="checkbox"/> 2 | ..... | <input type="checkbox"/> 3 | ..... | <input type="checkbox"/> 4 | ..... | <input type="checkbox"/> 5 |
| <b>19.</b> Cramps?.....                                   | <input type="checkbox"/> 1 | ..... | <input type="checkbox"/> 2 | ..... | <input type="checkbox"/> 3 | ..... | <input type="checkbox"/> 4 | ..... | <input type="checkbox"/> 5 |
| <b>20.</b> Itchy skin?.....                               | <input type="checkbox"/> 1 | ..... | <input type="checkbox"/> 2 | ..... | <input type="checkbox"/> 3 | ..... | <input type="checkbox"/> 4 | ..... | <input type="checkbox"/> 5 |
| <b>21.</b> Dry skin?.....                                 | <input type="checkbox"/> 1 | ..... | <input type="checkbox"/> 2 | ..... | <input type="checkbox"/> 3 | ..... | <input type="checkbox"/> 4 | ..... | <input type="checkbox"/> 5 |
| <b>22.</b> Shortness of breath?.....                      | <input type="checkbox"/> 1 | ..... | <input type="checkbox"/> 2 | ..... | <input type="checkbox"/> 3 | ..... | <input type="checkbox"/> 4 | ..... | <input type="checkbox"/> 5 |
| <b>23.</b> Faintness or dizziness?.....                   | <input type="checkbox"/> 1 | ..... | <input type="checkbox"/> 2 | ..... | <input type="checkbox"/> 3 | ..... | <input type="checkbox"/> 4 | ..... | <input type="checkbox"/> 5 |
| <b>24.</b> Lack of appetite?...                           | <input type="checkbox"/> 1 | ..... | <input type="checkbox"/> 2 | ..... | <input type="checkbox"/> 3 | ..... | <input type="checkbox"/> 4 | ..... | <input type="checkbox"/> 5 |
| <b>25.</b> Washed out or drained?.....                    | <input type="checkbox"/> 1 | ..... | <input type="checkbox"/> 2 | ..... | <input type="checkbox"/> 3 | ..... | <input type="checkbox"/> 4 | ..... | <input type="checkbox"/> 5 |
| <b>26.</b> Numbness in hands or feet?.....                | <input type="checkbox"/> 1 | ..... | <input type="checkbox"/> 2 | ..... | <input type="checkbox"/> 3 | ..... | <input type="checkbox"/> 4 | ..... | <input type="checkbox"/> 5 |
| <b>27.</b> Nausea or upset stomach?.....                  | <input type="checkbox"/> 1 | ..... | <input type="checkbox"/> 2 | ..... | <input type="checkbox"/> 3 | ..... | <input type="checkbox"/> 4 | ..... | <input type="checkbox"/> 5 |
| <b>28<sup>a</sup>.</b> (Hemodialysis patient only)        |                            |       |                            |       |                            |       |                            |       |                            |
| Problems with your access site? ...                       | <input type="checkbox"/> 1 | ..... | <input type="checkbox"/> 2 | ..... | <input type="checkbox"/> 3 | ..... | <input type="checkbox"/> 4 | ..... | <input type="checkbox"/> 5 |
| <b>28<sup>b</sup>.</b> (Peritoneal dialysis patient only) |                            |       |                            |       |                            |       |                            |       |                            |
| Problems with your catheter site?..                       | <input type="checkbox"/> 1 | ..... | <input type="checkbox"/> 2 | ..... | <input type="checkbox"/> 3 | ..... | <input type="checkbox"/> 4 | ..... | <input type="checkbox"/> 5 |

# Effects of Kidney Disease on Your Daily Life

Some people are bothered by the effects of kidney disease on their daily life, while others are not. How much does kidney disease bother you in each of the following areas?

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

29. Fluid restriction?....  1 .....  2 .....  3 .....  4 .....  5
30. Dietary restriction?.....  1 .....  2 .....  3 .....  4 .....  5
31. Your ability to work around the house? .....  1 .....  2 .....  3 .....  4 .....  5
32. Your ability to travel? .....  1 .....  2 .....  3 .....  4 .....  5
33. Being dependent on doctors and other medical staff?.....  1 .....  2 .....  3 .....  4 .....  5
34. Stress or worries caused by kidney disease? .....  1 .....  2 .....  3 .....  4 .....  5
35. Your sex life? .....  1 .....  2 .....  3 .....  4 .....  5
36. Your personal appearance? .....  1 .....  2 .....  3 .....  4 .....  5

*Thank you for completing these questions!*

## ***Exhibit 3: PROMIS Scale v1.2 - Global Health Mental 2a 09062016***

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Exhibit 3 includes the PROMIS Scale v1.2 - Global Health Mental 2a 09062016 (version). The full set of PROMIS item banks and forms are available at <http://www.healthmeasures.net/explore-measurement-systems/promis/obtain-administer-measures>.

Exhibit 3 is provided on the next page.



## Global Health – Mental 2a

Please respond to each question or statement by marking one box per row.

		Excellent	Very good	Good	Fair	Poor
Global04	In general, how would you rate your mental health, including your mood and your ability to think? .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
Global05	In general, how would you rate your satisfaction with your social activities and relationships?.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1

## ***Exhibit 4: PROMIS SF v1.0 - Fatigue 8a 5-16-2016***

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Exhibit 4 includes the PROMIS SF v1.0 - Fatigue 8a 5-16-2016 (version). The full set of PROMIS item banks and forms are available at <http://www.healthmeasures.net/explore-measurement-systems/promis/obtain-administer-measures>.

Exhibit 4 is provided on the next page.

## Fatigue – Short Form 8a

Please respond to each question or statement by marking one box per row.

**During the past 7 days...**

		Not at all	A little bit	Somewhat	Quite a bit	Very much
HI7	I feel fatigued .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
AN3	I have trouble <u>starting</u> things because I am tired.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

**In the past 7 days...**

FATEXP41	How run-down did you feel on average? ...	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
FATEXP40	How fatigued were you on average? .....	1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
FATEXP35	How much were you bothered by your fatigue on average?.....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
FATIMP49	To what degree did your fatigue interfere with your physical functioning? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

**In the past 7 days...**

		Never	Rarely	Sometimes	Often	Always
FATIMP3	How often did you have to push yourself to get things done because of your fatigue? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
FATIMP16	How often did you have trouble finishing things because of your fatigue? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

## ***Exhibit 5: PROMIS-29 Profile v2.0 12-21-2016***

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Exhibit 5 includes the PROMIS-29 Profile v2.0 12-21-2016 (version). The full set of PROMIS item banks and forms are available at <http://www.healthmeasures.net/explore-measurement-systems/promis/obtain-administer-measures>.

Exhibit 5 is provided on the next page.

## PROMIS–29 Profile v2.0

Please respond to each question or statement by marking one box per row.

<b><u>Physical Function</u></b>		<b>Without any difficulty</b>	<b>With a little difficulty</b>	<b>With some difficulty</b>	<b>With much difficulty</b>	<b>Unable to do</b>
PFA11	Are you able to do chores such as vacuuming or yard work? .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFA21	Are you able to go up and down stairs at a normal pace? .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFA23	Are you able to go for a walk of at least 15 minutes? .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
PFA53	Are you able to run errands and shop? .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
<b><u>Anxiety</u></b>						
<b>In the past 7 days...</b>		<b>Never</b>	<b>Rarely</b>	<b>Sometimes</b>	<b>Often</b>	<b>Always</b>
EDANX01	I felt fearful .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX40	I found it hard to focus on anything other than my anxiety .....	1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX41	My worries overwhelmed me .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDANX53	I felt uneasy .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
<b><u>Depression</u></b>						
<b>In the past 7 days...</b>		<b>Never</b>	<b>Rarely</b>	<b>Sometimes</b>	<b>Often</b>	<b>Always</b>
EDDEP04	I felt worthless .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDDEP06	I felt helpless .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDDEP29	I felt depressed .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
EDDEP41	I felt hopeless .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
<b><u>Fatigue</u></b>						
<b>During the past 7 days...</b>		<b>Not at all</b>	<b>A little bit</b>	<b>Somewhat</b>	<b>Quite a bit</b>	<b>Very much</b>
HI7	I feel fatigued .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
AN3	I have trouble <u>starting</u> things because I am tired .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5

## PROMIS–29 Profile v2.0

### Fatigue

**In the past 7 days...**

**Not at all    A little bit    Somewhat    Quite a bit    Very much**

FATEXP41	How run-down did you feel on average? ...	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
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FATEXP40	How fatigued were you on average? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
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### Sleep Disturbance

**In the past 7 days...**

**Very poor    Poor    Fair    Good    Very good**

Sleep109	My sleep quality was .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
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**In the past 7 days...**

**Not at all    A little bit    Somewhat    Quite a bit    Very much**

Sleep116	My sleep was refreshing.....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
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Sleep20	I had a problem with my sleep .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
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Sleep44	I had difficulty falling asleep .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
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### Ability to Participate in Social Roles and Activities

**Never    Rarely    Sometimes    Usually    Always**

SRPPER11 _CaPS	I have trouble doing all of my regular leisure activities with others .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
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SRPPER18 _CaPS	I have trouble doing all of the family activities that I want to do .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
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SRPPER23 _CaPS	I have trouble doing all of my usual work (include work at home) .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
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SRPPER46 _CaPS	I have trouble doing all of the activities with friends that I want to do .....	<input type="checkbox"/> 5	<input type="checkbox"/> 4	<input type="checkbox"/> 3	<input type="checkbox"/> 2	<input type="checkbox"/> 1
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### Pain Interference

**In the past 7 days...**

**Not at all    A little bit    Somewhat    Quite a bit    Very much**

PAININ9	How much did pain interfere with your day to day activities? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
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PAININ22	How much did pain interfere with work around the home? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
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PAININ31	How much did pain interfere with your ability to participate in social activities? .	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
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PAININ34	How much did pain interfere with your household chores? .....	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5
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# PROMIS-29 Profile v2.0

## Pain Intensity

### In the past 7 days...

Global07

How would you rate your pain on average?.....

0  
No  
pain

1

2

3

4

5

6

7

8

9

10

**Worst pain  
imaginable**