

# Report on Patient-Reported Outcomes (PROs)

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

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## Executive Summary

The Centers for Medicare & Medicaid Services (CMS) tasked the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) with developing recommendations that investigate avenues for acquiring the evidence, data, and infrastructure necessary to implement patient-centered measures which capture care that is “responsive to the needs, values, and expressed preferences of individual patients.” There are six domains of patient-centered care as defined by the Institute of Medicine (IOM): respect for patients’ values, preferences and needs; information communication and education; coordination of care; relief of suffering through provision of physical comfort and emotional support (e.g., palliative care) (Cavanaugh 2015 citing National Research Council 2001).

Patient-reported outcomes (PROs) fall under the umbrella of patient-centered outcomes. PROs include health-related quality of life (HRQoL), patient experience of care and other measures based on patient self-report of their health status, well-being and experience with health care delivery. Patient-reported outcomes (PROs) are defined as “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 2013; U.S. Food and Drug Administration 2009).

The main objectives of this report are the following: identify what PRO measures exist; report stakeholder feedback on existing PROs and their suggestions for future PRO investigation; and determine what data are available to support future development, testing, and implementation of these measures.

To complete this work, UM-KECC conducted an environmental scan for PRO measures; held conference calls with multiple stakeholders; and disseminated a broad-based email blast to the renal community, including patient groups, requesting feedback on PRO measures that are considered important to patients, including identifying existing PRO measures, and potential data sources. UM-KECC conducted calls with stakeholder representatives from dialysis patient organizations, dialysis provider organizations, academic and renal professional organizations, and individuals with expertise in development of PRO instruments and measures.

The environmental scan identified existing measures and measure topics specific to the end-stage renal disease (ESRD) population as well as non-ESRD and non-dialysis care settings. UM-KECC included measures from other settings in the scan results if they could be adapted to the chronic dialysis setting.

UM-KECC bases the recommendations in this report on the potential to adapt existing measures for future testing, and data collection feasibility, as well as consideration of longer-term investigation of PRO metric development.

## Common Themes that Emerged from Stakeholder Feedback

- PROs are regarded as important and there is significant interest in further work in this area.
- Both patients and providers expressed concerns about the existing ICH-CAHPS and KDQoL-36 measures. These include survey burden (due to administration frequency and length, and unnecessary questions); low response rates; and limited actionability for providers.
- Feedback was mixed about the level of evidence to support most of the current measures to be used as quality measures; stakeholders emphasized that measures need to be reliable, valid, and practical for implementation.
- Patient and provider perspectives diverge on important PROs:
  - Patient groups specified that they cared about a combination of both health-related outcomes as well as facility operational characteristics.
  - Providers stated that health-related outcomes were important, and that facility characteristics like cleanliness or staff attentiveness are issues that have been addressed or can be easily remedied, but should not be included in performance measures of care quality.
- Providers and patients stated that PRO measures and assessments should incorporate patients' goals for their care in order to reflect outcomes important to the individual patient.
- Use one instrument or shorter instrument(s) to measure PROs.
- There is consensus that more work is needed for development of PRO measures, owing to the complexities in defining and measuring PROs and data collection sources.
- Some patients and providers expressed interest in recovery time as a PRO, and similarly, a measure of patient experience of treatment.

## Recommendations

UM-KECC presents recommendations for developing PRO measures in the short-term, intermediate, and long-term. Long-term steps reflect input from stakeholders who requested a more comprehensive and longer-term approach to developing PRO measures in order to overcome some of the current limitations they noted about the ICH-CAHPS and KDQoL-36.

- Short-term steps: Two topic areas for PRO development are HRQoL and recovery time. Both would be the focus of a technical expert panel (TEP) in 2017.
  - CMS should also determine the feasibility of requiring submission of summary QoL data, as facilities are already collecting these data per the 2008 Conditions for Coverage (CfCs) and Interpretive Guidance for CfC 494.90 (patient plan of care-psychosocial status). The heterogeneity of existing QoL instruments used in the ESRD setting creates an initial barrier to immediate implementation of a HRQoL measure. Further stakeholder input

will be needed to assess the consistency of QoL data collected from different instruments.

- Evidence on recovery time is limited. The TEP will be charged with determining whether further development is warranted.
  
- Intermediate steps: Conduct further examination of the individual items in the ICH-CAHPS and subscales from one of the existing QoL instruments. Gather patient and other stakeholder input from providers to determine support for reporting of individual ICH-CAHPS items and subscales of one of the existing QoL instruments. Measures based on these individual items would require extensive testing of psychometric properties and measure reliability and validity. CMS should also investigate the disease-specific QoL instrument (Ware et al., 2016) as another potential PRO measure, recognizing obstacles related to using a proprietary instrument (e.g., may require permission and/or cost).
  
- Long-term steps: Investigate development of measure concepts suggested by stakeholders for which there is limited evidence or testing. For example: patient experience of treatment; patient rating of the facility; incorporating patient goals and values into outcomes assessment; patient education; and features of facility operations (transportation, access to a social worker at the facility, wait-time before dialysis, cleanliness, etc.).

## Summary

Stakeholders acknowledged existing PROs are primarily limited to the ICH-CAHPS (collected and implemented) and the QoL/KDQoL-36 (collected but not reported). Stakeholders interviewed for this project believe that gaps remain in understanding how to use these results to improve clinical care from both the patient and provider perspective. Patients and providers also diverged in their priorities for meaningful PROs. Patients valued metrics that provide them with practical information about facilities, and inform them about clinical quality outcomes. Providers emphasized PROs that are clinically actionable and that are reliable and valid. Most stakeholders noted that the survey burden and low response rates are limitations of the existing ICH-CAHPS and KDQoL-36. Several providers also raised questions about the definition of PROs. For example, they reported definitions may vary based on the patient or provider perspective. They placed great emphasis on capturing the individual patient's perspective and priorities for his/her care and clinical outcomes, which are not measured in the current ICH-CAHPS and KDQoL-36 metrics.

## Project Overview

CMS tasked UM-KECC with developing recommendations to investigate avenues for acquiring the evidence, data, and infrastructure necessary to implement patient-centered measures. These measures capture patient-centered care that is “responsive to the needs, values, and expressed preferences of individual patients” (Cavanaugh 2015 citing National Research Council 2001). There are six domains of patient-centered care as defined by the Institute of Medicine (IOM): respect for patients’ values, preferences and needs; information communication and education; coordination of care; relief of suffering through provision of physical comfort and emotional support (e.g., palliative care) (Cavanaugh 2015 citing National Research Council 2001).

Patient-reported outcomes (PROs) fall under the umbrella of patient-centered outcomes. PROs are defined as “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 2013; U.S. Food and Drug Administration 2009). PROs include health-related quality of life (HRQoL), patient experience of care, such as the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems survey (ICH-CAHPS) and other measures based on patient self-report of health status, well-being, and experience with health care delivery.

The main objectives of this report are the following: identify what PRO measures exist; report stakeholder feedback on existing PROs and their suggestions for future PRO investigation; and determine what data are available to support future development, testing, and implementation of these measures.

To complete this work, UM-KECC conducted an environmental scan for PRO measures; held conference calls with multiple stakeholders; and disseminated a broad-based email blast to the renal community, including patient groups, requesting feedback on PRO measures that are considered important to patients, including identifying existing PRO measures, and potential data sources.

## Environmental Scan Summary

The environmental scan identified existing measures and measure topics specific to the end-stage renal disease (ESRD) population as well as non-ESRD and non-dialysis care settings. UM-KECC included measures from other settings in the scan results if they could be adapted to the chronic dialysis setting.

UM-KECC consulted the following sources: National Quality Forum (NQF) database ([www.qualityforum.org/](http://www.qualityforum.org/)) and the Patient-Centered Outcomes Research Institute (PCORI) website (<http://www.pcori.org>).

The NQF database features measures and specifications that have been submitted for endorsement by NQF (see Appendix). We also scanned PCORI study abstracts to identify relevant PRO topic areas. The essential principle of PCORI and its funded studies is direct patient engagement in patient-centered research. This principle emphasizes the active role of patients in designing and executing studies that examine interventions and outcomes that are important to patients. As a result, all of the studies on

patient-centered outcomes include patients as partners in the research, from study inception to conclusion and dissemination, ensuring that patient perspectives are reflected throughout the process.

Finally, we consulted selected published studies on PROs. We focused primarily on several more recent studies that examined health-related quality of life and experience of care within the chronic dialysis population. Several studies did not focus on this population, but offered useful insights on PRO topic areas and issues that arose in the stakeholder interviews.

## **NQF Database**

### ***Disease-Specific Quality of Life: ESRD and other Chronic Diseases***

We identified several patient-experience of care and health-related QoL measures. The NQF measure derived from the Kidney Disease Quality of Life (KDQoL-36) survey (NQF 0260) was endorsed in 2007, but was not recommended for endorsement in the current 2016 maintenance review cycle due to the limited evidence linking the process of administering the survey to health outcomes. The measure reports the portion of eligible patients that received the KDQoL-36 survey. However, the measure does not report measure scores from the composite or individual components that make-up the KDQoL-36, which is regarded as a limitation. Finally, a QoL measure for patients with chronic obstructive pulmonary disease (NQF 0700) assesses the percentage of patients with improved health-related quality of life scores.

### ***Patient Experience with Care: ICH-CAHPS and Related Measures***

The ICH-CAHPS (NQF 0258, endorsed in 2008) is a validated instrument that measures patient experience with care (limited to in-center hemodialysis patients). It is implemented in the CMS ESRD Quality Incentive Program (QIP) and beginning in fall 2016, the three global measures and three composite measures are reported on the CMS Dialysis Facility Compare (DFC) website.

In addition to the ICH-CAHPS, UM-KECC identified several other CAHPS based measures (see Appendix for complete list). These are the global and composite measures of patient experience. The following experience of care metrics are based on the family of the CAHPS measures developed for different care settings or conditions, such as hospital (NQF 0166); home health (NQF 0517); health care plan (NQF 0006); and experience of care and health outcomes (ECHO) survey (for behavioral health, managed care versions; NQF 0008).

The scan also identified other patient and care giver experience with care measures that included family evaluation of hospice care (NQF 0208); documentation of a discussion of spiritual and religious concerns with the patient, or concerns that the patient did not want to discuss (NQF 1647); and consumer assessments and reports of end-of-life care (NQF 1632). These measures capture other aspects of patient and caregiver experiences that also may be pertinent PROs for the chronic dialysis setting.

### ***Patient Education***

Two patient education awareness measures developed for the ESRD setting were originally time-limited endorsed in 2007, but the endorsement was removed in 2012 (NQF 0320; 0324). These measures report the percentage of patients that had documentation of receiving information from their provider on

renal replacement therapy modalities. Each measure assessed patient education at the physician and facility level, respectively.

### **Patient-Centered Outcomes Research Institute**

We scanned the collection of existing studies funded by the Patient-Centered Outcomes Research Institute (PCORI) to identify PRO-related topics focused on outcomes for kidney disease patients or other outcomes identified as important by stakeholders in the renal community.

PCORI is an independent nongovernmental organization authorized under the Affordable Care Act in 2010. PCORI funds evidence-based, patient-centric research “to improve the quality and relevance of evidence available to help patients, caregivers, clinicians, employers, insurers, and policy makers make informed health decisions.” PCORI studies use a patient-centered approach by involving every key stakeholder, including patients, providers, researchers, and other stakeholders (see [www.pcori.org](http://www.pcori.org) for more background information on PCORI).

All PCORI supported studies place patients at the center of investigation, and many define outcomes from the patient perspective. For example, funded studies examine factors important to patients when evaluating treatment or health care outcomes; use approaches to comparing different treatment interventions in a way that directly incorporates the patient perspective for evaluating trade-offs; rely on patient involvement in setting treatment and care goals; report health-related quality of life for certain diseases and conditions; examine patient experience of care; test implementation of PROs in clinical care; examine the impact of patient illness on caregivers; and develop strategies for tailoring information to better target underserved communities.

There are several PCORI funded studies that examine patient-centered outcomes relevant to the chronic dialysis population. For example, one study is testing an intervention to improve informed decision making and patient engagement for chronic kidney disease (CKD) patients progressing toward end-stage kidney failure (Boulware, 2015). The interventions include providing (1) tools to physicians to better engage patients in treatment decision making, (2) a kidney transition care specialist who helps navigate patients through decisions about their renal replacement treatment, and (3) education on what patients should expect from their treatment. Two other PCORI funded studies similarly focus on strategies directly incorporating patient preferences into treatment decisions. One study on cancer patients collects information on specific symptoms burdensome for patients, in order to tailor treatment regimens that will ameliorate troubling symptoms impairing quality of life (Basch 2016). Similarly, one study is examining how to incorporate PROs into treatment plans, and specifically, to understand whether patients think the information they provide in questionnaires will help better engage them and whether they see a positive result in developing their care plans and enhancing self-care strategies (Scholle 2014). The study is also collecting input from physicians to examine how they use patients’ health self-reports, and whether physicians can translate patient self-reports into actionable information for clinical decision making. Another study is testing the effect of peer mentoring programs for patients and caregivers of patients progressing toward end-stage kidney failure (Ghahramani 2014). The goal is to determine how peer mentoring support results in better preparation of patients and their caregivers for renal replacement therapy and specifically equipping them with education and support to

make informed decisions that better suit their needs. The study seeks to understand how peer mentoring improves patients' quality of life and ameliorates caregiver burden.

In their study, Cook et al. test strategies to reduce disparities among minority patients by improving the incorporation of their treatment preferences into care plans for depression and type 2 diabetes (Cook et al., 2016). They examine the sociocultural context and the impact of patients' past negative experiences with health care providers.

Mehrotra and colleagues examine treatment options for depression among hemodialysis patients by testing the effect of patients choosing from a range of behavioral and medication-based therapies (Mehrotra 2014). The end goal is to improve patients' ability to select from evidence-based treatments that also reflect treatment outcomes important to them. See Appendix for the list of relevant PCORI studies funded since 2012.

## **Selected Peer Reviewed Literature**

### ***Health-Related Quality of Life Outcomes and Symptom Burden***

Research studies assessing HRQoL as primary end points or secondary outcomes associated with clinical outcomes in the chronic dialysis population or CKD-non-dialysis population use one of several HRQoL instruments developed over the last few decades. The most widely used is the Medical Outcomes Study (MOS) SF-36 developed by RAND (see Ware et al, 1994) and validated in the general population. Other instruments include the generic SF-12 (a subset of the SF-36), which requires licensing for use. The original KDQoL was developed in 1994 (Hays, et al., 1994). It contained the original generic SF-36 items/subscales. Later the KDQoL was revised in KDQoL SF Version 1.3, which still retained the SF-36, but fewer renal disease-specific items. The KDQoL-36 is the current version, which includes the SF-12 subscales and fewer (24) renal specific items compared to the earlier KDQoL SF Version 1.3. The "Choices for Healthy Outcomes in Caring for End-Stage Renal Disease (CHOICE) Study Health Experience Questionnaire (CHEQ)" was developed and validated in the dialysis population. It contains the SF-36, plus additional renal-specific items clinically sensitive to dialysis modality and dialysis dose (Wu et al 2003). The SF-36, CHEQ, and KDQoL SF have all been validated in the chronic dialysis population. See Mitema and Jaar (2016) for further details on these and other HRQoL instruments used to assess specific psychosocial or physical symptoms.

Hays et al. (1994) developed and originally validated the KDQoL. The original long form contained 134 items. Input from patients identified both physical and psychosocial symptoms as primary concerns, including low energy and lack of strength. Strong reliability was observed in 18 of 19 multi-item scales while 14 of 19 multi-item scales were statistically significantly correlated with the number of hospital days in the last 6 months. The number of medications was correlated with 9 of the 19 scales. Hays et al. reported that their results supported the reliability and validity of the long form KDQoL (Hays et al., 1994).

A systematic review by Flythe et al., (2015) demonstrates the heterogeneity of HRQoL instruments developed for research and interventional studies in the dialysis population (13 dialysis-specific instruments and 10 developed in the non-dialysis population). They evaluated instruments for recall

period, completion time, and number of physical items assessed. Flythe et al., found that the physical symptom instruments most frequently assess 2-3 physical symptoms and have different recall periods. The study found that instruments most frequently measured fatigue, shortness of breath, insomnia, nausea and vomiting, and appetite. The KDQoL-36 was among the instruments with the longest completion time. Flythe observes that many of the instruments have not undergone extensive reliability and validity testing (Flythe et al., 2015).

Lacson et al., (2010) compared the properties of the SF-36 and SF-12 physical component summary (PCS) and mental component summary (MCS) scores, concluding both sets of summary scores demonstrate reliability and validity for the chronic dialysis population. Moreover, they suggest the summary scores generated from the SF-12 would be sufficient for use in assessing patient QoL. Wu and colleagues (2003) developed the Choices for Healthy Outcomes in Caring for ESRD Health Experience Questionnaire (CHEQ) that uses the SF-36 core subscales and supplements these with kidney disease-specific items sensitive to dialysis modality and dialysis dose. They observed improvement in the SF-36 PCS for peritoneal dialysis (PD) patients, with validity and reliability testing demonstrating good performance. These results are from an observational study, which is subject to bias introduced by confounding of patient clinical characteristics. It is unclear to what extent CHEQ was used in other studies or implemented by any facilities for quality measurement.

Several multi-center interventional trials in the chronic dialysis population included HRQoL as a primary or secondary outcome, most using the MOS SF-36 or its subsets. Results vary between the tested interventions and associations with HRQoL. For example, the Frequent Hemodialysis Network (FHN) trial (Chertow/FHN Study Group, 2010; also see Jhamb et al., 2011) used the PCS as part of one composite primary end point in the study's comparison of daily (6 times weekly) vs. conventional thrice weekly dialysis. The authors reported statistically significant but clinically modest improvement in the PCS for patients who received six hemodialysis sessions per week compared to controls. The HEMO trial, evaluating both higher Kt/V targets and high flux dialyzer membranes compared to controls, similarly did not find clinically meaningful associations between the experimental interventions and the PCS (Eknoyan et al., 2002; Unruh et al., 2004). Trials testing anemia management interventions in the CKD non-dialysis population targeting high versus intermediate target hemoglobin provide mixed results, generally demonstrating marginal clinically meaningful effect sizes or no differences (Singh, et al., 2006; Drüeke et al, 2008; Pfeffer et al, 2009). In addition, most anemia trials have been criticized for a limitation in study blinding that makes interpretation of QoL outcomes difficult (Singh et al., 2006). The Canadian Erythropoietin (EPO) Study (British Medical Journal, 1990), a small, blinded, multicenter trial, included patients on chronic dialysis treated with placebo, low-dose EPO, or high-dose EPO. This trial used older QoL instruments and demonstrated small, statistically significant improvements in fatigue and physical function PROs, but only between the placebo and low-dose EPO groups. Of note, the achieved mean hemoglobin in the placebo group was distinctly lower than the achieved hemoglobin concentrations for most prevalent U.S. dialysis patients over the last decade.

A few observational studies report associations between clinical outcomes and health-related QoL, for example, ESRD patients with lower health-related QoL scores are at higher risk of hospitalization and mortality (Mapes et al, 2003; Kalantar-Zadeh et al, 2001). Measures of health-related quality of life may

be indicative of the symptom burden of patients with multiple chronic diseases. For example, one study demonstrates the disease-specific attribution of symptoms using a standardized shorter proprietary QoL instrument (Ware et al., 2016).

One consistent theme emerging in PRO studies is that patients prioritize specific psychosocial factors and physical symptom burden (see Urquhart-Secord 2016). For example, patients' decisions about modality and treatment options are driven by the goal of achieving minimal disruption to their lives, such as avoiding clinical complications and symptoms that impede day-to-day living. Specific factors include:

1. Fatigue/energy
2. Sleep issues
3. Cramping
4. Survival (defined as coping with their disease and treatment)
5. Ability to travel
6. Ability to work
7. Convenience of home dialysis
8. Dialysis free time
9. Impact on family
10. Anxiety/stress
11. Decrease in blood pressure
12. Lack of appetite/taste

There is also increasing emphasis by funding agencies and research groups for patient participation in research to identify what is meaningful to them. Examples include PCORI studies or other vehicles for obtaining patient feedback and participation in PRO development (Basch et al., 2013; Dahlerus et al., 2016). Moreover, outcomes important to patients and the definitions they assign may not align with outcomes that clinicians deem are important. For example, in their study examining patient and caregiver priorities for hemodialysis outcomes, Urquhart-Secord et al. reported that only one clinical outcome (decrease in blood pressure) was in the top 10 patient priorities list, while patients ranked mortality lower in importance than clinicians (Urquhart-Secord, et al., 2016, p.444).

### *Patient Experience with Care*

Patient experience with care measures, such as the ICH-CAHPS, reflect the overall experience of health care delivery from the patient's perspective. Some stakeholders express concerns about the ICH-CAHPS for performance reporting, for example, due to low response rates and response bias (Gabbay et al., 2014; Richardson et al, 2014). Richardson et al., (2015) found that respondents to a facility patient satisfaction survey tended to be healthier, and more compliant with their treatment, therefore caution is warranted in relying on patient experience surveys like the ICH-CAHPS as assessments of provider quality in programs such as the ESRD QIP (also Richardson 2014). Other studies and reviews suggest the ICH-CAHPS is an important source of patients' own care experiences (Cavanaugh 2016; Cavanaugh 2015; Weidmer et al., 2014; Wood et al., 2014). Cavanaugh's 2016 review of studies on ICH-CAHPS and

hospital CAHPS challenged some of the concerns about survey burden, limited actionability, association with clinical care quality (including individual providers and facility settings), among others. For example, Cavanaugh (2016) cited several studies demonstrating the relationship of patient experience of care with clinical care quality, but recognized overall that the current body of evidence is still limited. Cavanaugh also noted that while providers have concerns about actionability, these overlook the intent of the ICH-CAHPS (and CAHPS), which is to give patients and caregivers meaningful information that they can use to select providers. Additionally, one study reported that the ICH-CAHPS provides a reliable and valid measurement of patient experiences of care, while noting the limitation of over representation of certain respondent subgroups (Weidmer et al., 2014.). Wood and colleagues demonstrated moderate reliability of the nephrologist and quality of care ICH-CAHPS composites. They also found that waiting time at the facility and provider-to-patient ratios were related to patients' reported experience of care (Wood et al., 2014, pp. 1101-1102).

A recent synthesis of dialysis patient experience of care studies identified four broad patient concerns: a new dialysis-dependent self; a restricted life; regaining control; and relationships with health professionals (Reid et al., 2016). The authors suggest these themes provide a framework for understanding stages of hemodialysis patient experience with care that providers can use to inform interventions for improving aspects of the patient experience that matter most. Paying attention to how dialysis care impacts patients' goals and day-to-day living can lead to identifying ways to improve care and outcomes that matter to patients.

Finally, there is increasing attention to patient-written reviews, such as Yelp reviews of facility care experiences. A recent study assesses the association between Yelp reviews and the CAHPS measures evaluating patient experience with hospital care. Findings suggest an overall correlation across several dimensions of the CAHPS (Ranard et al., 2016). This suggests that patient-reported experience matters to patients as it comes from their "peers" (e.g., also see Winterbottom et al., 2012). This could be because patients feel that other patients fully understand concerns about how treatment impacts one's life.

## Stakeholder Input

UM-KECC gathered stakeholder input from a broad cross section of the renal community between December 2015 and July 2016. Telephone interviews were conducted with stakeholder representatives from dialysis patient organizations, dialysis provider organizations, academic and renal professional organizations, a patient education organization, and individuals with expertise in development of PROs and instruments.

UM-KECC held individual conference calls with the following:

### Patient Advocacy Organizations

- National Kidney Foundation: Tonya Saffer, MPH, Senior Health Policy Director
- Renal Support Network: Lori Hartwell, President and Founder
- Dialysis Patient Citizens: Jackson Williams, JD, MPA, Director of Government Affairs
- American Association of Kidney Patients: Paul Conway, President

### **Patient Education Organization**

- Medical Education Institute: Dori Schatell, MS, Executive Director

### **Nephrologists and Dialysis Providers**

- Yale New Haven Health System: Alan Kliger, MD, Senior Vice President Medical Affairs and Chief Quality Officer, and Fredric Finkelstein, MD, Section Chief of Nephrology at the Hospital of St. Raphael
- Fresenius Medical Care: Franklin Maddux, MD, Chief Medical Officer and Executive Vice President for Clinical and Scientific Affairs
- DaVita: Allen Nissenson, MD, FACP, Chief Medical Officer, and Steven Brunelli, MD, MSCE, Vice President and Medical Director of Health Economics and Outcomes Research
- Dialysis Clinic, Inc.: Michelle Richardson, PharmD, FCCP, BCPS, Director, Outcomes Monitoring Program, and Klemens Meyer, MD, Medical Director
- Satellite: Brigitte Schiller, MD, Chief Medical Officer, Sumi Sun, Director of Applied Research and Data Analysis, MPH, and Sheila Doss-McQuitty, Director of Clinical Programs and Research, MBA, RN, CNN
- U.S. Renal Care: Stan Lindenfeld, MD, Senior Vice President & Chief Medical Officer, Ninfa Alvarado, BSN, Director of Clinical Projects, Joanne Zimmerman, RN, CNN, Vice President, Clinical Services, Johnie Flotte, RN, Vice President of Clinical Services

### **Professional Association/Researchers**

- American Society of Nephrology Policy Board: John Sedor, MD, FASN, Daniel Weiner, MD, FASN, Wolfgang Winkelmayr, MD, PhD, MPH, Suzanne Watnick, MD, Mark Lukaszewski, ASN Policy Associate
- John Ware Research Group Inc: John Ware, PhD, University of Massachusetts Medical School

### **Renal Community**

- Kidney Care Partners: Franklin Maddux, MD, KCP Chairman, Kathleen J. Lester, JD, MPH, KCP Counsel, Robyn Y. Nishimi, PhD, KCP Consultant

In addition to telephone interviews, UM-KECC collected input from the community through a public email blast in spring 2016 requesting feedback on PROs and available data. We received a range of suggestions on the existing PROs, including suggestions to expand the currently limited universe of measures to include measures directly capturing patient experiences (beyond the global ICH-CAHPS) and outcomes that reflect patients' priorities (see Appendix). Finally, both the National Kidney Foundation (NKF) and Dialysis Patient Citizens (DPC) provided summary results of respective surveys they separately conducted with patients. Both surveys elicited patient and caregiver feedback on information related to facilities and care delivery that they feel are important.

Comments from stakeholders highlighted the importance of PROs, overall gaps in PROs and data, limitations in existing metrics, and challenges in developing new metrics.

## Stakeholder Input on Existing PROs and Patient Centric Measures

### *Quality of Life/KDQoL-36*

HRQoL featured prominently in the feedback received from patient groups, QoL industry experts, and providers. A few provider stakeholders made the important distinction that the QoL/KDQoL-36 was derived from the provider perspective, reflecting outcomes that clinicians have identified as important for clinical management.

Patient participants did not specifically mention the overall QoL scores from the KDQoL-36 (or other QoL instruments), but rather referenced topics related to specific PROs/symptoms measured through the individual question items in the SF-36 and KDQoL-36. For example, several patients identified fatigue, cramping, ability to travel, and dietary restrictions as treatment effects that are important to patients because of how they impact and limit their overall well-being and ability to lead as normal a life as possible. This suggests patients want to know about specific markers related to quality of life, but it is unclear whether the summary scores typically used to assess QoL (mental component and physical component scores) would be as important to know as the subscales and individual items that make up the overall composite scores.

An expert on QoL metrics provided feedback that described a proprietary instrument they developed that assesses QoL using a shorter instrument that reduces the survey burden on patients and provides actionable information to clinicians. The instrument (QoL Disease Impact Scale, QDIS<sup>®</sup>) assesses disease-specific impact on QoL using standardized questions that differ only in their attribution of symptom burden to a specific disease. The scale was developed in response to the gaps in current disease-specific QoL or generic HRQoL instruments.

Provider stakeholders (nephrologists, renal nurses, and dialysis organizations) reported KDQoL data are collected and reviewed with patients by their social workers and used to determine if a referral is necessary for a certain area of care (physical therapy, or mental health). Stakeholders observed that enlisting social workers who are particularly skilled at taking time to go through results with each patient to help develop a plan of care is critical for enhancing the actionability of the QoL results. This suggests that beyond collecting the data, social workers and clinicians can incorporate the KDQoL-36 into patient care. A few stakeholders also noted operational challenges. Some clinicians stated that the KDQoL-36 is actionable for individual patients, but it is not actionable or useful for public reporting, for example, for reporting the average facility-level summary score. Some providers indicated that examining QoL/KDQoL-36 scores longitudinally would be valuable.

Providers also shared several limitations in particular. The overall KDQoL-36 mental component and physical component summary scores may not be clear indicators of quality of care, however some of the individual elements of the KDQoL-36 may be more relevant and actionable as measures, such as the question about whether the patient experiences cramps. Another concern was that while providers are required to administer the survey per the CMS regulations, this could adversely impact patient-provider relationships if patients feel they are being pressured to complete the survey. Respondents indicated

that another limitation was that current QoL assessments do not assess how effectively patient-prioritized outcomes are met.

### *ICH-CAHPS*

Feedback from patient groups and providers consistently noted several limitations of the ICH-CAHPS, including general survey burden, low response rates from patients due to survey length, survey layout, increased frequency of administration for reporting purposes (semi-annually), some cases of patients feeling pressured to complete the survey, and relevance of ICH-CAHPS to clinical care. Moreover, there was concern about the usability of the current ICH-CAHPS measures as the DFC reports only the six summary measures. For example, several stakeholders felt that while some question items may be of value, there are also many that do not seem relevant or important to every patient. Discussions with patient groups suggested that certain individual experiences with care processes or outcomes, such as whether facility staff show respect and listen to “me” as a patient, are attentive to “me”, and facility cleanliness are areas that patients do care about. These are individual items within the ICH-CAHPS but are not reported separately. This may be an area of future patient focus group or TEP discussion given these data are already collected and patients have expressed interest in these topic areas.

Provider stakeholders reported that some patients may be unclear about the usefulness of the ICH-CAHPS surveys. Providers said that many patients view them as important measures, but others feel that the burden of the survey outweighs any benefit or importance. They felt that the ICH-CAHPS could be more actionable if the instrument was streamlined and if facilities received results in a timelier manner, for example, before the next round of the required semi-annual administration. One provider stakeholder group expressed a preference that facilities should be able to review anonymized individual level results of patients so they could effectively identify, design, and implement potential interventions. Another notable limitation identified by stakeholders is that the ICH-CAHPS measures do not apply to patients on home therapies (home hemodialysis [HD] or PD).

One of the main themes expressed among providers is that while patients are being surveyed about experiences of care (and quality of life), it was less clear how facilities and providers use these data to engage patients and improve their care. One stakeholder noted that while the KDQoL-36 is actionable, that is not the case with the ICH-CAHPS, because it is too broad and not individually patient centric. Another felt that facilities should not ask patients to fill out surveys if they are not going to use that information. Similarly, one patient group we spoke with suggested that patients may better understand the value of the surveys they are asked to complete, such as the ICH-CAHPS, if it is clear that collection of these data can benefit other patients by providing information about patients’ experiences with facility care.

There was generally strong consensus that incorporating the patient perspective is a critical ingredient for actionable and meaningful patient-driven measures. This requires direct patient input into metrics. For example, one provider recommended meeting with a typical patient to go through the ICH-CAHPS questionnaire to get their input in order to directly understand the patient perspective about which items are important and the interpretability of all items in the survey.

Consensus was mixed about how specifically the ICH-CAHPS measure should be improved or streamlined. Some stakeholders indicated that since the ICH-CAHPS is one of the few implemented measures of PROs, some improvements would be beneficial to reduce survey burden, and make results actionable. While there was some agreement the ICH-CAHPS should be revised, there was no clear consensus on what or how to revise the survey.

### ***Pain and Depression PRO Measures***

Patient reported pain and depression outcomes are a subset of PROs captured in two existing metrics assessing screening for pain and depression. Some provider stakeholders expressed support for measuring patient-reported pain and depression, but currently, some noted these measures have limited actionability or accountability. One stakeholder stated that the depression and pain screening results need to be actionable, otherwise, the time it takes to merely report on whether screening was done limits translating this information into actionable interventions and improving care. Several stakeholders said the goal is that providers act on the results of these assessments by documenting that patients are at risk and that facilities/providers are taking action.

One of the patient stakeholders expressed concerns with the pain PRO measure adopted in QIP. They said this could lead to medication therapies that rely on opioids for pain management. An unintended consequence would be patient dependence on opioid medications and addiction. Overall, patient stakeholders indicated that the current pain and depression screening measures were not a top priority for them.

### ***Impact of Public Reporting***

Several providers stated that an unintended consequence of public reporting and incentive programs (DFC; QIP) is that providers spend too much time reporting data and trying to achieve good scores, which detracts from time devoted to directly addressing patient symptoms and overall patient care. In short, clinical management focuses on the requirement to report data and achieve high scores, instead of paying greater attention to individualized patient care. Stakeholders identified this as a limitation of the information provided in the current ICH-CAHPS and KDQoL-36 data, because they do not allow providers to drill down and address specific patient issues. Several expressed that providers and facilities should be assessed on the basis of documentation that they are taking action to address health outcomes for their patients and have a care plan in place.

While noting limitations of the existing KDQoL-36 and ICH-CAHPS, one stakeholder expressed concerns about further adding to the existing survey and data collection burden by creating new measures for public reporting. They felt that, instead, a first step should be to consider revisions to the existing KDQoL and ICH-CAHPS, or to evaluate what other PROs could be developed from existing CMS data sources.

### ***Other Patient Reported and Patient-Centric Outcome Topics***

Patient and provider stakeholders suggested other potential measure topics on what is meaningful to patients and potentially actionable by dialysis providers. Most have limited evidence and testing owing to the challenges of measurement and data collection. Additionally, attention to PROs, while recognized as important, is still a developing focus area within the chronic dialysis setting. As noted earlier,

definitions of patient-reported and other patient-centric outcomes also vary between patients and providers. Outcomes identified by patients include both clinical and non-clinical outcomes, whereas providers focused on clinical outcomes. Finally, several provider stakeholders described internal pilot initiatives they have implemented or are developing that assess patient-centric outcomes, including PROs.

Suggestions from the renal community in response to the email information request were generally consistent with feedback in the stakeholder interviews:

- Incorporating patient goals and values into assessment of outcomes
- Patients select their own measures based on their own care priorities
- Treatment experience and recovery time
- Ability to work, go to school, travel
- Enhanced patient education; patient empowerment
- Features of facility operations (transportation, access to a social worker at the facility, wait-time before dialysis, cleanliness)
- Facility/staff communication (staff attentiveness/respect); collaboration with the care team
- Symptoms being effectively addressed (pain, cramping, fatigue, depression, nausea, sleep, etc.)
- Functional status (exercise capacity, ability to perform activities of daily living)
- End-of-life planning; palliative care
- Information about kidney transplant (referral and waiting list metrics)
- Patient Reported Outcomes Measurement Information System (PROMIS®) initiative

Further details are provided in the next section on several topics that emerged across all stakeholder feedback.

### ***Incorporating Patient Goals and Patient Engagement***

Both patients and providers repeatedly stated that PRO quality measures should directly incorporate individual patient values and priorities for care. One stakeholder explained that outcomes should be defined through the “lens” (i.e., direct perspective) of the patient, taking into account that individual patients have different goals for their care that are not necessarily captured in population-level metrics. Outcomes that are patient-driven need to reflect these individualized goals. For example, these may reflect individual goals for living with minimal disruption to day-to-day life by treatment (dialysis); longer life expectancy in order to realize their personal and family goals; or a treatment plan that is targeted to providing comfort, but not necessarily longevity. Several studies further reinforce the importance and variation in identifying factors that are important to individual patients when considering treatment options (Morton et al., 2011; Wuerth et al., 2002; Dahlerus et al., 2016).

The feedback from providers spanned a range of patient-driven goals. One provider stated that it is important to recognize patients’ different goals (for example, patients receiving rehabilitative versus palliative dialysis care). Reporting clinical measures without adjusting for patient goals may have unintended consequences. For example, nursing home patients are much different than actively working dialysis patients and are expected to have different goals for their treatment. If subpopulations could be identified by patient goals, then targets could be set based on the desired outcome for that patient (or patient subpopulation). The utility and purpose of PROs may differ by patient subpopulations

that have different clinical management needs. The challenge of instituting PROs as a quality measure is to capture these individualized patient goals and priorities, while the measure also fulfills criteria for reliable and valid measurement.

Finally, various stakeholders supported the incorporation of patient empowerment and patient voices into care plans. One related suggestion to enhancing patient empowerment was through a measure of patient activation that uses strategies to encourage patients to be active partners in their care (e.g., see Hibbard, 2008).

### *Treatment Experience and Recovery Time*

One patient stakeholder expressed strong interest in the development of a patient experience of treatment measure. They stated that how patients feel after treatment has a large impact on their daily life, which is important for their health and QoL. The measure would focus on whether treatment is tolerable or intolerable (see Appendix for mock-up provided by the stakeholder). The stakeholder stated that an experience of dialysis treatment measure would be preferred over KDQoL-36 and would be more actionable. The stakeholder stated that experience of dialysis treatment may be more directly in the facility's control, while QoL outcome measures include several factors that are beyond the facility's control. Several of the individual elements included in an experience of treatment survey correspond with items on the KDQoL-36, suggesting that both are measuring conceptually similar PROs. They differ in that the experience of treatment survey is intended to be administered after each dialysis treatment. A measure administered after each treatment would very likely preclude administration by a third party vendor, and instead rely on direct facility administration. However, that could be seen as increasing burden for the facility depending on its length and whether it was made mandatory. An additional concern to consider is that administration after each treatment, at the facility, could mute reporting of complications if patients feel uncomfortable reporting problems to facility staff.

Several stakeholders identified recovery time post-dialysis as a potential PRO measure. One stakeholder proposed to assess recovery time by asking patients, "How long does it take you to recover after dialysis?" One dialysis provider has started to collect recovery time data from patients and reported receiving positive feedback from patients as a result. Other provider stakeholders stated that recovery time should be part of routine assessment, but the lack of an objective measurement of recovery time presents challenges for facilities. The indicator is inherently subjective in how each patient determines the time it takes them to recover. Individual patients may differ as to what is an acceptable recovery time, for example some may say two hours while others say twelve hours. Stakeholders suggested more evidence would be necessary before using recovery time as a quality measure.

Published evidence on recovery time remains limited based on a review of the current literature. The two most notable studies report associations between recovery time and health-related QoL outcomes. One small study (46 patients) in Canada validated a one-question instrument ("How long does it take you to recover from a dialysis session?") based on the associations with individual components of health-related QoL (Lindsay et al., 2006). A larger study reported an association between shorter recovery time and higher quality of life physical component and mental component summary scores; and longer recovery time with higher morbidity and mortality. The authors note that more research is

needed to build the strength of evidence for clinical interventions that impact recovery time and subsequent improvement in quality of care (Rayner et al., 2014). In addition, one small observational study conducted in Italy found that recovery time was independently associated with the number of fatigue symptoms reported by patients (Bossola et al., 2013). Further testing and validation are needed to assess the psychometric properties of a recovery time survey instrument and its use to support a PRO performance measure.

Finally, and similar to recovery time, one stakeholder referenced a “health days at home” patient-reported quality measure, a measure outlined in MedPAC’s 2015 report to Congress (MedPAC, 2015).

One stakeholder cautioned implementation of additional PRO instruments, such as recovery time or patient experience of treatment. This could further increase the respective survey and reporting burden expressed by patients and providers. Alternatives that reduce the burden need to be considered, for example, by tailoring surveys to topic areas most relevant to the patient and his/her comorbidity burden.

### *Individual Measure Topics Captured in Existing ICH-CAHPS and KDQoL-36*

In discussions with multiple dialysis patient organizations, several measure topics that were recommended such as cleanliness, reporting on modality choice, respect shown by staff, or symptoms like fatigue, are related to existing items on the respective ICH-CAHPS or KDQoL-36 instruments. Several stakeholders also wanted to see measures developed that either include or are specific to the home HD and PD populations. One stakeholder recommended creating a modality measure that scored how many treatments a facility offered (for example: 3 out of 4 modality options were offered to a patient); another suggestion was a measure for whether facilities offered modality education and a full range of modality options to patients. This also included information on transplant referral and patient understanding of transplantation as an option. The stakeholder also proposed measuring factors listed by the SONG initiative such as fatigue, ability to travel, and impact on family (see Tong et al., 2015).

Some patient stakeholders identified specific measures of facility operations, such as a measure of the ratio of doctors, nurses, social workers, and dieticians to patients; attentiveness of staff; and whether patients felt respected by staff. Patients have reported that the dialysis technicians may not be respectful or well-trained in placing needles, for example. Other measures or items patient stakeholders identified included: caregivers being part of the care and decision-making process; distance from facility to patient’s home; transportation services; facility cleanliness; impact on caregivers; staff education/training; and support groups for ESRD patients.

Several stakeholders commented that it would be important to review how existing PROs (i.e., ICH-CAHPS, KDQoL-36) could be retooled or revised before developing additional new PRO measures. One stakeholder suggested use of the Patient-Reported Outcomes Measurement Information System® (PROMIS) measures as an alternative to the existing KDQoL-36 and ICH-CAHPS. PROMIS item banks are standardized across diseases, and allow for different administration methods that can reduce the burden on patients and providers (Alonso et al., 2013). The instruments are available to clinicians and researchers for assessment of patient-reported symptoms and other health-related QoL outcomes.

Similar to the SF-12, SF-36, and KDQoL, domains include emotional distress (e.g., anxiety, depression, anger); fatigue; pain; psychosocial impact, and physical function. A few PROMIS domains measured are disease- or condition-specific (e.g., for cancer; chronic pain; depression; gastrointestinal conditions; smoking cessation). Currently, there is no PROMIS instrument developed and validated specifically for the chronic dialysis population. However, in at least one study, PROMIS measure items have been applied to assessing health-related QoL in the pediatric CKD population (Selewski et al., 2014).

### *Using PRO/PCO Information Effectively*

There was general consensus that making PROs meaningful to patients and actionable to providers relies on using PRO results with patients as part of clinical care. Incorporating results into clinical care shows patients how information from surveys they complete is used to improve their care and may result in better patient response rates and engagement in care, which was observed by other assessments of PRO measures (Breckenridge et al., 2015). In another example, one dialysis provider reported that survey response rates were low when facilities did not bring the results back to patients. One patient organization explained that patients might not see the frequency of surveys as a burden if they feel they are contributing to the improved treatment outcomes of other patients in terms of dialysis care practices. They felt the problem might not be with the survey instruments, but with how the instruments are being administered and in what ways results are being reported or used.

One of the biggest challenges for PROs is to ensure they are reliable and practical for implementation and usable by both patients and providers. Another challenge is how measurement of PROs will be able to quantify subjective experiences within quality metrics, reinforcing the need for careful examination of reliable and valid psychometric properties. One stakeholder explained that many of the current PRO measures are checklists and do not address the importance of understanding patient goals. A few stakeholders also mentioned survey fatigue and the proliferation and complexity of existing DFC quality measures. The concern was that patients already have a difficult time understanding the existing clinical measures, so caution is needed before developing additional measures to report. Finally, several mentioned the influence of socioeconomic status, sociodemographics, and cultural competency in patient/clinician interactions, and that these should be accounted for in PRO measures.

### *Patient Survey Results*

Representatives from two patient advocacy organizations, the National Kidney Foundation (NKF), and Dialysis Patient Citizens (DPC), shared responses from feedback they received from patients and members. The feedback identified several factors that patients felt were important in helping choose a facility and assessing overall facility quality of care.

NKF conducted a survey with 821 patient members (see the Appendix for NKF survey results). Surveys asked patients and caregivers to rate items as important to patients and caregivers when choosing a dialysis facility. The following were rated as of highest importance to patients:

- “How safely the care is delivered (free from medical errors, proper infection control precautions, protection of vascular access)”
- “How clean the facility is”

- “How safe and comfortable patients feel to voice concerns about their care to dialysis facility staff (no fear of retribution for issuing complaints)”
- “How satisfied patients are with the care they receive”
- “How satisfied patients are with the attention the staff gives them at the facility”

DPC conducted an initial survey with patients (both DPC members and non-members) to identify the “most important measures when determining the quality of a dialysis facility.” Next, a follow-up focus group with 24 participants identified these priority areas: staff respect/listening; patient education; dialysis adequacy; infection control; transplant referral access; QoL-cramping, feeling washed out; healthy days at home; anemia management. See the Appendix for the DPC comment letters to CMS.

These survey results suggest that PROs and patient-centric measures that are important to patients include both aspects of facility operations and staff and patient interactions, along with several clinical quality outcomes. This is important to note as it indicates patients do care about clinical outcomes, in addition to other aspects of dialysis facility care operations. Finally, a recurring theme in some of the patient feedback received is the value of patient written reviews of dialysis facilities, akin to “Yelp” reviews.

## Data Availability

Assessment of data availability was limited to the QoL/KDQoL-36, and ICH-CAHPS. As part of the CMS Conditions for Coverage (CfC; CMS 2008), CfC 494.90, Patient Plan of Care-psychosocial needs monitoring, facilities are required to administer a quality of life survey to their patients annually. Many facilities use the KDQoL-36. While this survey is not required by these regulations, it is strongly implied in the Interpretive Guidance (CMS ESRD Surveyor Training Interpretive Guidance, 2008). Currently, dialysis facilities are not required to submit QoL data. Collection and use of the data occurs as part of facility Interdisciplinary Team assessment and care planning and Quality Assurance & Performance Improvement (QAPI) activities, which are reviewed as part of the facility survey and certification process.

As part of discussions with stakeholders, UM-KECC determined potential sources for obtaining summary QoL data for a subset of facilities. Future discussion with dialysis providers would need to be conducted to determine the feasibility of an arrangement whereby the organization would provide future access to its summary QoL data for testing purposes. Additionally, the KDQoL-36 data collected as part of the KDQoL-36 Complete® service to facilities would potentially be available for purchase. These data are from about 1,000 facilities that are part of small and independent dialysis organizations. Finally, the DOPPS Practice Monitor publishes the summary PCS and MCS data for a sample of DOPPS facilities. Annual data are from August 2010 to December 2015 (US-DOPPS Practice Monitor, October 2016). We note these data are collected from in-center hemodialysis patients only, and are limited to the summary annual scores aggregated across the DOPPS Practice Monitor participating facilities.

The ICH-CAHPS data for the three global and three composite measures (computed from individual survey items) are publically reported on DFC as of October 2016. Additional investigation is needed to determine whether CMS would have access to the complete ICH-CAHPS data that are collected and the feasibility of reporting individual ICH-CAHPS on DFC. This may depend on whether other Compare sites

are also reporting individual CAHPS items, since CMS aims for consistency across its Compare sites for similar measures.

## Conclusion and Recommendations

There was consensus that the ICH-CAHPS, and the QoL/KDQoL-36 that are collected but not reported, primarily reflect the existing set of PROs in ESRD but gaps remain in the actionability of how to use these results to improve clinical care from both the patient and provider perspective. Patients and providers also diverged in their priorities for meaningful PROs. Patients valued metrics that provide them practical information about facilities, in addition to knowing about clinical quality outcomes. Providers emphasized PROs that are clinically actionable and that are reliable and valid as performance measures. All stakeholders noted that the survey burden and resulting low response rates are limitations of the existing ICH-CAHPS and KDQoL-36. Great emphasis was placed on capturing the individual patient's perspective and priorities for care, which are not directly measured in the current ICH-CAHPS and KDQoL-36 metrics.

Key take away messages from stakeholders include:

- PROs are regarded as important and there is significant interest in further work in this area.
- Both patients and providers expressed concerns about the existing ICH-CAHPS and KDQoL-36 measures. These include survey burden (due to administration frequency and length, and unnecessary questions); low response rates; and limited actionability for providers.
- Feedback was mixed about the level of evidence to support most of the current measures to be used as quality measures; stakeholders emphasized that measures need to be reliable, valid, and practical for implementation.
- Patient and provider perspectives diverge on important PROs:
  - Patient groups specified that they cared about a combination of both health-related outcomes as well as facility operational characteristics.
  - Providers stated that health-related outcomes were important, and that facility characteristics like cleanliness or staff attentiveness are issues that have been addressed or can be easily remedied, but should not be included in performance measures of care quality.
- Providers and patients stated that PRO measures and assessments should incorporate patients' goals for their care in order to reflect outcomes important to the individual patient.
- Use one instrument or shorter instrument(s) to measure PROs.
- There is consensus that more work is needed for development of PRO measures, owing to the complexities in defining and measuring PROs and data collection sources.
- Some patients and providers expressed interest in recovery time as a PRO, and similarly, a measure of patient experience of treatment.

## Recommendations

Feedback from stakeholders highlighted concerns about the existing KDQoL and ICH-CAHPS measures. However, we recognize that at this time these represent the existing measures of PROs for the chronic

dialysis setting. The recommendations presented here focus on short, intermediate, and long-term steps CMS can take to further the goal of reporting on PROs. Finally, input from stakeholders was suggestive of the need for a more comprehensive and longer term approach to developing PRO measures in order to overcome the current concerns and limitations identified for existing PROs.

- **Short-term steps:** Two topic areas for PRO development are HRQoL and recovery time. Both would be the focus of a TEP in 2017.
  - CMS should also determine the feasibility of requiring submission of summary QoL data as facilities are already collecting these data per the 2008 Conditions for Coverage (CfCs) and Interpretive Guidance for CfC 494.90 (patient plan of care-psychosocial status). The heterogeneity of existing QoL instruments used in the ESRD setting creates an initial barrier to immediate implementation of a HRQoL measure. Further stakeholder input will be needed to assess the consistency of QoL data collected from different instruments.
  - Evidence on recovery time is limited. The TEP will be charged with determining whether further development is warranted.

There are several advantages to proceeding with HRQoL as a short-term step: 1) CMS requires administration of a QoL survey per the 2008 CfCs and Interpretive Guidance for CfC 494.90 (patient plan of care-psychosocial status), which implies use of KDQoL-36; 2) there is an existing data infrastructure for collection of HRQoL data due to the CfC requirement for assessing HRQoL. Related to points 1 and 2, there is broad community familiarity with assessing HRQoL. Potential limitations of proceeding with HRQoL include the heterogeneity of existing QoL instruments in the ESRD setting, which could limit immediate implementation. For example, instruments include: MOS-SF-36; MOS-SF-12; KDQoL/KDQoL-SF/KDQoL SF-1.3/KDQoL-36; CHEQ, as well as other symptom-specific instruments. It is possible some dialysis providers are using adaptations of the KDQoL, SF-36, or SF-12, thereby further increasing the heterogeneity of what is currently used to collect HRQoL data. Second, many of the studies assessing HRQoL (ESRD; non-ESRD) use PCS and MCS scores derived from SF-36 or SF-12 subscales, not the KDQoL subscales. Clinical actionability is another potential obstacle. Results from studies are mixed with small or no improvements observed between some treatment groups, including the few randomized controlled trials in the CKD non-dialysis and CKD-dialysis populations that include HRQoL as an end point or secondary outcome. Any differences in HRQoL scores may not be clinically meaningful.

Based on stakeholder input and a review of the literature, a recovery time measure offers several advantages: It is a simple and low burden measure and patients and providers identified it as important. However, there is limited evidence on recovery time as an actionable and quantifiable measure; patient clinical and demographic characteristics could potentially confound the measure; and the measure would still require extensive testing.

- **Intermediate steps:** Conduct further examination of the individual items in the ICH-CAHPS and subscales from one of the existing QoL instruments. Gather patient and other stakeholder input from providers to determine support for reporting of individual ICH-CAHPS items and subscales of one of the existing QoL instruments. Measures based on these individual items would require

extensive testing of psychometric properties and measure reliability and validity. CMS should also investigate the disease-specific QoL instrument (Ware et al., 2016) as another potential PRO measure, recognizing the obstacle of using a proprietary instrument (e.g., may require permission and/or fee).

As part of an intermediate step, a TEP should examine the individual patient-level items collected both on the QoL/KDQoL and ICH-CAHPS and consider whether these would be meaningful to report. Testing will also be needed to evaluate reporting of individual items. Patients and consumers have expressed interest in greater reporting of PROs related to symptom burden and experience of care. Data may be more readily available as part of the required submission of ICH-CAHPS data. We would also need to determine whether these individual item level data would be available for evaluation. Finally, patient and other stakeholder input will also be needed to determine whether the individual items are meaningful and useful to patients, and would be considered actionable by providers.

- **Long-term steps:** Investigate development of measure concepts suggested by stakeholders for which there is limited evidence or testing. For example: patient experience of treatment; patient rating of the facility; incorporating patient goals and values into outcomes assessment; patient education; features of facility operations (transportation, access to a social worker at the facility, wait-time before dialysis, cleanliness, etc.).

Finally, several of the stakeholders interviewed expressed interest in providing further input and supporting CMS's work in the arena of PROs and other patient-driven measures. A few also shared interest in future collaboration in work examining cultural competency and cultural understanding as these relate to defining PROs.

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## Order of Appendices

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# **End Stage Renal Disease (ESRD) Quality Measure Development, Maintenance, and Support Patient Reported Outcomes Measure Scan**

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## List of NQF Measures related to Patient Reported Outcomes (PROs)

### End Stage Renal Disease PROs

<b>Measure Title</b>	<b>NQF # 0258 CAHPS In-Center Hemodialysis Survey</b>
<b>Measure Developer</b>	Centers for Medicare & Medicaid Services
<b>Measure Description</b>	<p>Comparison of services and quality of care that dialysis facilities provide from the perspective of ESRD patients receiving in-center hemodialysis care. Patients will assess their dialysis providers, including nephrologists and medical and non-medical staff, the quality of dialysis care they receive, and information sharing about their disease.</p> <p>Three measures:  a. M1. Nephrologists’ Communication and Caring  b. M2: Quality of Dialysis Center Care and Operations  c. M3: Providing Information to Patients</p> <p>Three Global items:  a. M4: Rating of the nephrologist  b. M5: Rating of dialysis center staff  c. M6: Rating of the dialysis facility</p> <p>The first three measures are created from six or more questions from the survey that are reported as one measure score. The three global items use a scale of 0 to 10 to measure the respondent’s assessment</p>
<b>Numerator</b>	Each measure encompasses the responses for all questions included in the particular measure. Missing data for individual survey questions are not included in the calculations. Only data from a "completed survey" is used in the calculations. The measures score averages the proportion of those responding to each answer choice in all questions. Each global rating will be scored based on the number of respondents in the distribution of top responses- e.g, the percentage of patients rating the facility a “9” or “10” on a 0 to 10 scale (with 10 being the best).

<b>Denominator</b>	<p>Patients with ESRD receiving in-center hemodialysis at sampled facility for the past 3 months or longer are included in the sample frame. The denominator for each question is the sample members that responded to the particular question.</p> <p>Proxy respondents are not allowed. Only complete surveys are used. A complete survey is defined as a one where the sampled patient answered at least 50 percent of the questions that are applicable to all sample patients, which defines the completeness criteria.</p>
<b>Exclusions</b>	<p>Exclusions:</p> <ul style="list-style-type: none"> <li>a. Patients less than 18 years of age</li> <li>b. Patients not receiving dialysis at sampled facility for 3 months or more</li> <li>c. Patients who are receiving hospice care</li> <li>d. Any surveys completed by a proxy (mail only mode or mixed mode)</li> <li>e. Any ineligible patients due to death, institutionalization, language barrier, physically or mentally incapable.</li> </ul>
<b>NQF Endorsed</b>	Endorsed in 2007
<b>Clinical Condition</b>	Renal
<b>Risk Adjusted</b>	Yes
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/0258">http://www.qualityforum.org/QPS/0258</a>

## Global and Composite sub-items from NQF #0258 (ICH-CAHPS)

Measure Title	Global or Composite	Link
In-center hemodialysis patients' experiences: percentage of in-center hemodialysis patients who reported how often their nephrologist cared and communicated well.	Composite	<a href="https://www.qualitymeasures.ahrq.gov/summaries/summary/49939">https://www.qualitymeasures.ahrq.gov/summaries/summary/49939</a>
In-center hemodialysis patients' experiences: percentage of in-center hemodialysis patients who reported how often they were satisfied with the quality of dialysis center care and operations.	Composite	<a href="https://www.qualitymeasures.ahrq.gov/summaries/summary/49941">https://www.qualitymeasures.ahrq.gov/summaries/summary/49941</a>
In-center hemodialysis patients' experiences: percentage of in-center hemodialysis patients who reported whether specified information was provided to them.	Composite	<a href="https://www.qualitymeasures.ahrq.gov/summaries/summary/49942">https://www.qualitymeasures.ahrq.gov/summaries/summary/49942</a>
In-center hemodialysis patients' satisfaction with care: in-center hemodialysis patients' overall ratings of their dialysis center staff.	Global	<a href="https://www.qualitymeasures.ahrq.gov/summaries/summary/49944">https://www.qualitymeasures.ahrq.gov/summaries/summary/49944</a>
In-center hemodialysis patients' satisfaction with care: in-center hemodialysis patients' overall ratings of their dialysis center.	Global	<a href="https://www.qualitymeasures.ahrq.gov/summaries/summary/49945">https://www.qualitymeasures.ahrq.gov/summaries/summary/49945</a>
In-center hemodialysis patients' satisfaction with care: in-center hemodialysis patients' overall ratings of their kidney doctors.	Global	<a href="https://www.qualitymeasures.ahrq.gov/summaries/summary/49943">https://www.qualitymeasures.ahrq.gov/summaries/summary/49943</a>

## End Stage Renal Disease PROs (continued)

<b>Measure Title</b>	<b>NQF # 0260 Assessment of Health-related Quality of Life (Physical &amp; Mental Functioning) <i>Note: measure currently under maintenance review</i></b>
<b>Measure Developer</b>	Witten and Associates, LLC
<b>Measure Description</b>	Percentage of eligible dialysis patients who complete a health-related quality of life assessment with or without assistance using the KDQOL-36 (36-question survey that assesses patients' functioning and well-being) at least once during a calendar year.
<b>Numerator</b>	Number of eligible (not excluded) individuals with ESRD (ICD-10 N18.6) on dialysis who complete a KDQOL-36 with or without assistance at least once per calendar year
<b>Denominator</b>	Number of individuals with ESRD (ICD-10 N18.6) on peritoneal dialysis, in-center hemodialysis, and home hemodialysis treated by the dialysis facility during the calendar year minus those dialysis patients who meet exclusion criteria.
<b>Exclusions</b>	Patients with ESRD (ICD-10 N18.6) on dialysis who are <18 years old; who are unable to complete the survey due to mental status that could invalidate the results; who are non-English speaking/reading and no native language translation or interpreter is available; or who have been on dialysis for <3 months. A patient who declines to complete one survey but completes one survey during the calendar year is counted as having a completed survey.
<b>NQF Endorsed</b>	Endorsed in 2007
<b>Clinical Condition</b>	Renal, Renal: End Stage Renal Disease (ESRD)
<b>Risk Adjusted</b>	No
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/0260">http://www.qualityforum.org/QPS/0260</a>

<b>Measure Title</b>	<b>NQF # 0320 Patient Education Awareness—Physician Level</b>
<b>Measure Developer</b>	Kidney Care Quality Alliance
<b>Measure Description</b>	Percentage of a physician’s end stage renal disease (ESRD) patients aged 18 years and older with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period.
<b>Numerator</b>	Number of patients from the denominator with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period.
<b>Denominator</b>	All ESRD patients aged 18 years and older.
<b>Exclusions</b>	None.
<b>NQF Endorsed</b>	Endorsed 2007; Endorsement Removed 2012
<b>Clinical Condition</b>	Palliative Care and End-of-Life Care, Renal, Renal: End Stage Renal Disease (ESRD)
<b>Risk Adjusted</b>	No
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/0320">http://www.qualityforum.org/QPS/0320</a>

<b>Measure Title</b>	<b>NQF #0324 Patient Education Awareness—Facility Level</b>
<b>Measure Developer</b>	Kidney Care Quality Alliance
<b>Measure Description</b>	Percentage of end stage renal disease (ESRD) patients aged 18 years and older with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period.
<b>Numerator</b>	Number of patients from the denominator with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period.
<b>Denominator</b>	All ESRD patients aged 18 years and older receiving renal replacement therapy.
<b>Exclusions</b>	None.
<b>NQF Endorsed</b>	Endorsed 2007; Endorsement Removed 2012
<b>Clinical Condition</b>	Palliative Care and End-of-Life Care, Renal, Renal: End Stage Renal Disease (ESRD)
<b>Risk Adjusted</b>	No
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/0324">http://www.qualityforum.org/QPS/0324</a>

## PROs: Other Conditions and Care Settings

<b>Measure Title</b>	<b>NQF # 0700 Health-related Quality of Life in COPD patients before and after Pulmonary Rehabilitation</b> <i>Note: measure currently under maintenance review</i>
<b>Measure Developer</b>	American Association of Cardiovascular Pulmonary Rehabilitation
<b>Measure Description</b>	The percentage of patients with COPD enrolled in pulmonary rehabilitation (PR) who are found to increase their health-related quality of life score (HRQOL).
<b>Numerator</b>	Number of patients with clinician diagnosed COPD who have participated in PR and have been found to increase their HRQOL score by 1.0 points, as measured by the Chronic Respiratory Disease Questionnaire (CRQ), or a similar tool, at the beginning and the end of PR.
<b>Denominator</b>	All patients with COPD, during the reporting period, who are enrolled in a PR program.
<b>Exclusions</b>	Inability to read and/or write in order to complete the self-administered CRQ, or presence of cognitive or neuropsychiatric impairment that impairs the patient's ability to answer the CRQ (or similar tool).
<b>NQF Endorsed</b>	Initially Endorsed in 2011
<b>Clinical Condition</b>	Respiratory, Respiratory: Chronic Obstructive Pulmonary Disease (COPD)
<b>Risk Adjusted</b>	No
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/0700">http://www.qualityforum.org/QPS/0700</a>

<b>Measure Title</b>	<b>NQF # 0208 Family Evaluation of Hospice Care</b>
<b>Measure Developer</b>	National Hospice and Palliative Care Organization
<b>Measure Description</b>	<p>Derived from responses to 17 items on the Family Evaluation of Hospice Care (FEHC) survey presented as a single score ranging from 0 to 100 and is an indication of the hospice's overall performance on key aspects of care delivery.</p> <p>Target Population: The FEHC survey is an after-death survey administered to bereaved family caregivers of individuals who died while enrolled in hospice. Timeframe: The survey measures family member's perception of the quality of hospice care for the entire enrollment period, regardless of length of service. The computed hospice level performance score is calculated with once a quarter year.</p>
<b>Numerator</b>	The numerator is the sum total of the weighted incidence of problem scores occurring in response to 17 specific items on each survey. The 17 questions focus on the following aspects of hospice care: symptom management, communication, provision of information, emotional support and care coordination.
<b>Denominator</b>	The denominator represents the number of surveys with responses for at least 14 of the 17 questions required to compute the composite score in the FEHC survey.
<b>Exclusions</b>	If a survey has responses to fewer than 14 of the 17 FEHC survey questions included in calculation of the composite score, then a composite score will not be calculated for that survey and the survey will not be included in the calculation of a composite score for the hospice.
<b>NQF Endorsed</b>	Endorsed in 2009
<b>Clinical Condition</b>	Cancer, Cardiovascular, Gastrointestinal (GI), Infectious Diseases (ID), Infectious Diseases (ID): HIV/AIDS, Neurology, Palliative Care and End-of-Life Care, Renal, Respiratory: Chronic Obstructive Pulmonary Disease (COPD), Respiratory: Dyspnea, Respiratory: Pneumonia
<b>Risk Adjusted</b>	No
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/0208">http://www.qualityforum.org/QPS/0208</a>

<b>Measure Title</b>	<b>NQF #0209 Comfortable Dying: Pain Brought to a Comfortable Level Within 48 Hours of Initial Assessment</b> <i>Note: measure currently under maintenance review</i>
<b>Measure Developer</b>	National Hospice and Palliative Care Organization
<b>Measure Description</b>	Number of patients who report being uncomfortable because of pain at the initial assessment (after admission to hospice services) who report pain was brought to a comfortable level within 48 hours.
<b>Numerator</b>	Patients whose pain was brought to a comfortable level (as defined by patient) within 48 hours of initial assessment (after admission to hospice services).
<b>Denominator</b>	Patients who replied "yes" when asked if they were uncomfortable because of pain at the initial assessment (after admission to hospice services).
<b>Exclusions</b>	"Inclusions: Patients are eligible if they: Report they are uncomfortable because of pain at the initial assessment (after admission to hospice services); Are able to communicate and understand the language of the person asking the question; Are able to self-report; and Are at least 18 years of age or older."
<b>NQF Endorsed</b>	Endorsed in 2009
<b>Clinical Condition</b>	Cancer, Cardiovascular, Gastrointestinal (GI), Infectious Diseases (ID), Musculoskeletal, Neurology, Palliative Care and End-of-Life Care, Renal, Respiratory: Chronic Obstructive Pulmonary Disease (COPD)
<b>Risk Adjusted</b>	No
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/0209">http://www.qualityforum.org/QPS/0209</a>

<b>Measure Title</b>	<b>NQF #1623 Bereaved Family Survey</b>
<b>Measure Developer</b>	Department of Veterans Affairs / Hospice and Palliative Care
<b>Measure Description</b>	<p>The purpose of this measure is to assess families' perceptions of the quality of care that Veterans received from the VA in the last month of life. The BFS consists of 19 items (17 structured and 2 open-ended). The BFS items were selected from a longer survey that was developed and validated with the support of a VA HSR&amp;D Merit Award and have been approved for use by the Office of Management and Budget.</p> <p>Seventeen items in the survey have predefined response options and ask family members to rate aspects of the care that the Veteran received from the VA in the last month of life. These items cover areas of care such as communication, emotional and spiritual support. Two additional items are open-ended and give family members the opportunity to provide comments regarding the care the patient received.</p> <p>A growing body of research has underscored the degree to which end-of-life care in the United States needs to be improved. The challenges of end-of-life care are particularly significant in the U.S. Department of Veterans Affairs Health Care system because the VA provides care for an increasingly older population with multiple comorbid conditions. In FY2000, approximately 104,000 enrolled Veterans died in the U.S., and approximately 27,200 Veterans died in VA facilities. At least 30% of the Veterans are over age 65 now, and 46% will be over 65 by 2030. Therefore, it is clear that the number of deaths in VA facilities will increase substantially as the World War II and Korean War Veterans age. These demographic trends mean that, like other healthcare systems, the VA will face substantial challenges of providing care to Veterans near the end-of-life.</p> <p>The VA has addressed this challenge aggressively in the last 5 year, however the VA has not yet developed and implemented measures of the quality of end-of-life care it provides to Veterans. There are at least 3 reasons why adoption of a quality measurement tool is essential. First, it would make it possible to define and compare the quality of end-of-life care at each VA facility and to identify opportunities for improvement. Second, facilities and VISNs (geographic service divisions within the VA system) would be able to monitor the effectiveness of efforts to improve care locally and nationally, and would enable monitoring of the impact of the Comprehensive End of Life Care Initiative, ensuring that expenditures are producing improvements in care. Third, it will help the VA to recognize those facilities that provide outstanding end-of-life care, so that successful processes and structures of care can be identified and disseminated throughout the VA.</p> <p>The BFS's 17 close-ended items ask family members to rate aspects of the care that the Veteran received from the VA in the last month of life. These items cover areas of care such as communication, emotional and spiritual support, pain management and personal care needs. Two additional items (not used in scoring) are open-ended and give family members the opportunity to provide comments regarding the care the patient received. The BFS has undergone extensive development and has been pilot-tested for all inpatient deaths in Q4FY2008 in seven</p>

	VISNs (1, 2, 4, 5, 8, 11, and 22). As of October 1, 2009, Q1FY2010, all inpatient deaths in all VISNs were included in the project.
<b>Numerator</b>	The numerator is comprised of completed surveys (at least 12 of 17 structured items completed), where the global item question has an optimal response. The global item question asks "Overall, how would you rate the care that [Veteran] received in the last month of life" and the possible answer choices are: Excellent, Very good, Good, Fair, or Poor. The optimal response is Excellent.
<b>Denominator</b>	The denominator consists of all inpatient deaths for which a survey was completed (at least 12 of 17 structured items completed), excluding: 1) deaths within 24 hours of admission (unless the Veteran had a previous hospitalization in the last month of life); 2) deaths that occur in the Emergency Department (unless the Veteran had a prior hospitalization of at least 24 hours in the last 31 days of life); 3) deaths that occur in the operating room; and 4) deaths due to suicide or accidents. Additional exclusion criteria include: 1) Veterans for whom a family member knowledgeable about their care cannot be identified (determined by the family member's report); or contacted (no current contacts listed or no valid addresses on file); 2) absence of a working telephone available to the family member.
<b>Exclusions</b>	<ul style="list-style-type: none"> <li>- Veterans for whom a family member knowledgeable about their care cannot be identified (determined by family member's report)</li> <li>- Absence of a current address and/or working telephone number for a family member or emergency contact.</li> <li>- Deaths within 24 hours of admission without a prior hospitalization of last least 24 hours in the last 31 days of life.</li> <li>- Deaths that occur in the operating room during an outpatient procedure.</li> <li>- Deaths due to a suicide or accident</li> <li>- Surveys in which less than 12 items were answered.</li> </ul>
<b>NQF Endorsed</b>	Endorsed 2012; Endorsement Removed 2014
<b>Clinical Condition</b>	Palliative Care and End-of-Life Care
<b>Risk Adjusted</b>	No
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/1623">http://www.qualityforum.org/QPS/1623</a>

<b>Measure Title</b>	<b>NQF #1632 CARE - Consumer Assessments and Reports of End of Life</b>
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<b>Measure Developer</b>	Center for Gerontology and Health Care Research
<b>Measure Description</b>	<p>The CARE survey is mortality follow back survey that is administered to the bereaved family members of adult persons (age 18 and older) who died of a chronic progressive illness receiving services for at least 48 hours from a home health agency, nursing homes, hospice, or acute care hospital. The survey measures perceptions of the quality of care either in terms of unmet needs, family reports of concerns with the quality of care, and overall rating of the quality of care. The time frame is the last 2 days of life up to last week of life spent in a hospice, home health agency, hospital, or nursing home.</p> <p>The survey is based on structured literature review, (1) cognitive testing, (2) pre-test, (2) and national survey of the quality of end of life care. (3) The conceptual model is patient focused, family centered care (1) that posits that high quality care at the end of life is obtained when health care institutions: 1) provide the desired level of symptom palliation and emotional support; 2) treat the patient with respect; 3) promote shared decision making; 4) attend to the needs of caregivers for information and skills in providing care for the patient; 5) provide emotional support to the family before and after the patient’s death- and 6) coordinates care across settings of care and health care providers.</p> <p>We are asking NQF approval for a single composite derived from the survey items that is presented as single score that varies from 0 to 100. This score indicates an institution quality of care end of life care in the last week of life.</p> <p>This is the “parent” survey of the Family Evaluation of Hospice Care Survey (4-7) that my colleagues and I have collaborated with the National Hospice and Palliative Care Organization to create a self-administered survey that is used widely by hospices in the USA and other nations. With the proposed development of accountable care organizations and other potential innovations in health care financing, we recognized the need for an instrument that would allow the comparisons across place of care when there is one entity coordinating and/or financing the care for population of decedents. We have decided to submit the telephone based survey for NQF consideration based on the void of validated measures to capture consumer perceptions (i.e, bereaved family members) of the quality of care at the end of life across place of care. This submission is not meant to be competitive with the existing NQF endorsed Family Evaluation of Hospice Care survey.</p> <p>This new proposed measure for NQF consideration consists of the survey which has six domains and the new creation of 0-100 composite score that is composed of 14 of 17 core items.</p> <p>1. Teno JM, Casey VA, Welch L, Edgman-Levitan S. Patient-Focused, Family-Centered End-of-Life Medical Care:</p>

	<p>Views of the Guidelines and Bereaved Family Members. J Pain Symptom Manage-Special Section on Measuring Quality of Care at Life's End II. 2001 Sep 2001;22(3):738-751.</p> <p>2. Teno JM, Clarridge B, Casey V, Edgman-Levitan S, Fowler J. Validation of Toolkit After-Death Bereaved Family Member Interview. J Pain Symptom Manage. 2001 Sep 2001;22(3):752-758.</p> <p>3. Teno JM, Clarridge BR, Casey V, et al. Family perspectives on end-of-life care at the last place of care. JAMA. 2004 Jan 7 2004;291(1):88-93.</p> <p>4. Rhodes RL, Mitchell SL, Miller SC, Connor SR, Teno JM. Bereaved family members' evaluation of hospice care: what factors influence overall satisfaction with services? J Pain Symptom Manage. 2008 Apr 2008;35(4):365-371.</p> <p>5. Mitchell SL, Kiely DK, Miller SC, Connor SR, Spence C, Teno JM. Hospice care for patients with dementia. J Pain Symptom Manage. 2007 Jul 2007;34(1):7-16.</p> <p>6. Rhodes RL, Teno JM, Connor SR. African American bereaved family members' perceptions of the quality of hospice care: lessened disparities, but opportunities to improve remain. J Pain Symptom Manage. 2007 Nov 2007;34(5):472-479.</p> <p>7. Connor SR, Teno J, Spence C, Smith N. Family Evaluation of Hospice Care: Results from Voluntary Submission of Data Via Website. J Pain Symptom Manage. 2005 Jul 2005;30(1):9-17.</p>
<b>Numerator</b>	The numerator of the total of bereaved family member reports of concerns with the quality of care in the last 2-7 days of life at that institutional setting. Respondent reports of concerns with the quality of care, their self-efficacy in basic tasks of caregiving, or unmet needs that indicate an opportunity to improved end of life care provided by either a nursing home, hospital, hospice, or home health agency.
<b>Denominator</b>	Non-traumatic deaths and deaths from chronic progressive illnesses based on ICD 9/10 codes are included. A list will be provided as technical appendix to the proposed survey. Note the survey is for only persons that died with the following services or location of care: nursing home, hospital, hospice, or home health agency
<b>Exclusions</b>	We excluded deaths due to accidents, trauma, during surgery, lethal injection, acute overwhelming infections, and from complications of pregnancy. If there are more than 3 items missing, than a composite score will not be calculated.
<b>NQF Endorsed</b>	Endorsed 2012; Endorsement Removed 2014
<b>Clinical Condition</b>	Palliative Care and End-of-Life Care
<b>Risk Adjusted</b>	No
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/1632">http://www.qualityforum.org/QPS/1632</a>

<b>Measure Title</b>	<b>NQF # 1647 Percentage of hospice patients with documentation in the clinical record of a discussion of spiritual/religious concerns or documentation that the patient/caregiver did not want to discuss. <i>Note: measure currently under maintenance review</i></b>
<b>Measure Developer</b>	Deyta, LLC
<b>Measure Description</b>	This measure reflects the percentage of hospice patients with documentation of a discussion of spiritual/religious concerns or documentation that the patient/caregiver/family did not want to discuss.
<b>Numerator</b>	Number of patient with clinical record documentation of spiritual/religious concerns or documentation that the patient/family did not want to discuss.
<b>Denominator</b>	Total number of patient's discharged from hospice care during the designated reporting period.
<b>Exclusions</b>	Testing has only been done with the adult population, but there is no reason to believe that this wouldn't be applicable to all hospice patients.
<b>NQF Endorsed</b>	Endorsed in 2012
<b>Clinical Condition</b>	Palliative Care and End-of-Life Care
<b>Risk Adjusted</b>	No
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/1647">http://www.qualityforum.org/QPS/1647</a>

<b>Measure Title</b>	<b>NQF # 0517 CAHPS® Home Health Care Survey (experience with care)</b>
<b>Measure Developer</b>	Centers for Medicare & Medicaid Services
<b>Measure Description</b>	The Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Home Health Care Survey, also referred as the "CAHPS Home Health Care Survey" or "Home Health CAHPS" is a standardized survey instrument and data collection methodology for measuring home health patients' perspectives on their home health care in Medicare-certified home health care agencies. AHRQ and CMS supported the development of the Home Health CAHPS to measure the experiences of those receiving home health care with these three goals in mind: (1) to produce comparable data on patients' perspectives on care that allow objective and meaningful comparisons between home health agencies on domains that are important to consumers, (2) to create incentives for agencies to improve their quality of care through public reporting of survey results, and (3) to enhance public accountability in health care by increasing the transparency of the quality of care provided in return for public investment. As home health agencies begin to collect these data and as they are publicly reported, consumers will have information to make more informed decisions about care and publicly reporting the data will drive quality improvement in these areas.
<b>Numerator</b>	The numerator statement is that each measure encompasses the responses for all questions in the particular measure. Missing data for individual survey questions are not included in the calculations. Only data from a completed survey are used in the calculations. The measure scores averages the proportion of those responding to each answer choice in all questions. Each global rating is scored based on the number of the respondents in the distribution of top responses, such as the percentage of patients rating a home health agency with a 9 or a 10, where 10 is the highest quality responses on a scale from 0 to 10.
<b>Denominator</b>	The following are eligible to be included in the HHCAHPS Survey: patients who are at least 18 years old in the sample period, patients who are known to be alive, patients who received at least 2 home health visits during a 2-month look back period, patients who have not been selected for the monthly sample during any month in the current quarter or during the 5 months immediately prior to the sample month, patients who are not receiving hospice care, patients who do not have maternity as the primary reason for their home health care, patients who have not requested no publicity status, and patients with a condition or illness residing in a state with regulations and laws prohibiting the release of information for patients with that condition. HHCAHPS Surveys may be completed by proxy respondents who are family and friends of the home health patients but who do not work for home health agency being assessed by the patient respondent.
<b>Exclusions</b>	Numerator and Denominator Exclusions: <ul style="list-style-type: none"> <li>•Patients under 18 years of age at any time during their stay are excluded.</li> <li>•Patients who died during the sample month are excluded.</li> </ul>

	<ul style="list-style-type: none"> <li>•Patients who received fewer than 2 visits from home health agency personnel during a 2-month look-back period are excluded. (Note that the 2-month look-back period is defined as the 2-months prior to and including the last day in the sample month.)</li> <li>•Patients have been previously selected for the HHCAHPS sample during any month in the current quarter, or during the last 5 months, are excluded.</li> <li>•Patients who are currently receiving hospice, or are discharged to hospice, are excluded.</li> <li>•Maternity patients are excluded.</li> <li>•“No publicity” status patients are excluded.</li> <li>•Patients receiving only non-skilled (aide) care are excluded.</li> </ul>
<b>NQF Endorsed</b>	Endorsed in 2009
<b>Clinical Condition</b>	N/A
<b>Risk Adjusted</b>	Yes
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/0517">http://www.qualityforum.org/QPS/0517</a>

<b>Measure Title</b>	<b>NQF # 0726 Patient Experience of Psychiatric Care as Measured by the Inpatient Consumer Survey (ICS)</b>
<b>Measure Developer</b>	National Assoc. of State Mental Health Program Directors Research Institute, Inc. (NRI)
<b>Measure Description</b>	<p>The Patient Experience of Psychiatric Care as Measure by the Inpatient Consumer Survey (ICS) was developed to gather patient’s evaluation of their inpatient psychiatric care. The survey is composed of the following six individual measures or domains:</p> <p>Measure #1: Outcome of care- The receipt of mental healthcare services should enable patients to effectively deal with their illness and with social situations. Patient’s report of the effectiveness of the organization in enabling this improvement is an important dimension of the quality of care of the organization. The following questions of the ICS pertain to the Outcome of care domain: Q1. I am able to deal with crisis.; Q2. My symptoms are not bothering me as much.; Q4. I do better in social situations.; and Q5. I deal more effectively with daily problems.</p> <p>Measure #2: Dignity- The provision of mental healthcare services should be in an atmosphere where patients feel respected and treated with dignity. Patient’s report of the effectiveness of the organization in providing this respectful exchange is an important dimension of the quality of care of the organization. The following questions of the ICS pertain to the Dignity domain: Q6. I was treated with dignity and respect.; Q7. Staff here believe that I can grow, change and recover.; Q8. I felt comfortable asking questions about my treatment and medications.; and Q9. I was encouraged to use self-help/support groups.</p> <p>Measure #3: Rights- The provision of mental healthcare services should be in an atmosphere where patients feel that they can express disapproval with conditions or treatment and receive an appropriate response from the organization. Patient’s report of the effectiveness of the organization in providing this respectful exchange is an important dimension of the quality of care of the organization. The following questions of the ICS pertain to the Rights domain: Q13. I felt free to complain without fear of retaliation.; Q14. I felt safe to refuse medication or treatment during my hospital stay.; and Q15. My complaints and grievances were addressed.</p> <p>Measure #4: Participation in treatment- Patient’s involvement in the treatment process and the coordination of discharge planning with their doctors or therapist from the community are enabling activities that strengthen patient’s ability to care for themselves. Patient’s report of the effectiveness of the organization in supporting this level of involvement is an important dimension of the quality of care of the organization. The following questions of the ICS pertain to the Participation in treatment domain: Q16. I participated in planning my discharge.; Q17. Both I and my doctor or therapist from the community were actively involved in my hospital treatment plan.; and Q18. I had the opportunity to talk with my doctor or therapist from the community prior to discharge.</p>

	<p>Measure #5: Hospital environment - The provision of mental healthcare services should be in an environment conducive to patients feeling safe and enabling patients to focus on recovering from their illness. The following questions of the ICS pertain to the Hospital environment domain: Q19. The surroundings and atmosphere at the hospital helped me get better.; Q20. I felt I had enough privacy in the hospital.; Q21. I felt safe while in the hospital.; and Q22. The hospital environment was clean and comfortable.</p> <p>Measure #6: Empowerment - The provision of mental healthcare services should be in an atmosphere where patients feel that they, interactively with their doctors and therapist, learn more about their illness and about their treatment options and are encouraged to determine their best plan to recovery. Patient's report of the effectiveness of the organization in enabling this respectful, compassionate, and supportable encounter among patients and healthcare professionals is an important dimension of the quality of care of the organization. The following questions pertain to the Hospital empowerment domain: Q25. I had a choice of treatment options.; Q26. My contact with my doctor was helpful.; and, Q27. My contact with nurses and therapist was helpful.</p> <p>Question 28, "If I had a choice of hospitals, I would still choose this one", is considered as the anchor item utilized to measure overall satisfaction with the mental healthcare service received. This question does not pertain to any of the six measures/domains of the ICS.</p> <p>Each measure is scored as the percentage of patients (adolescents aged 13-17 and adults aged 18 and older) at time of discharge or at annual review who respond positively to the domain on the survey for a given month. Survey questions are based on a standard 5-point Likert scale, evaluated on a scale from strongly disagree to strongly agree.</p> <p>As a note, the words domain and measure are used interchangeably during the application.</p>
<b>Numerator</b>	<p>Number of patients who respond positively to the domain (outcome of care, dignity, rights, participation in treatment, hospital environment, and empowerment.) Each domain is calculated separately.</p> <p>Six domains are embedded in the ICS. Hospitals can choose to participate in any of the six performance measures, one for each domain. The outcome of care domain includes questions about the effect of the hospital stay on the patient's ability to deal with their illness and with social situations. The dignity domain includes questions about the quality of interactions between staff and patients that highlight a respectful relationship. The rights domain includes questions about the ability of patients to express disapproval with conditions or treatment and receive an appropriate response from the organization. The participation in treatment domain includes questions about</p>

	patient's involvement in their hospital treatment as well as coordination with the patient's doctor or therapist from the community. The hospital environment includes questions about feeling safe in the hospital and the aesthetics of the hospital. The empowerment domain includes questions about patients having a choice of treatment options and about the helpfulness of their contact with their doctor or therapist.
<b>Denominator</b>	Number of patients completing at least 2 questions included in the domain. Domains (or measures) include outcome of care, dignity, rights, participation in treatment, hospital environment, and empowerment.
<b>Exclusions</b>	There are no exclusions from target population. All patients discharged and patients on annual treatment review should be given the opportunity to respond to the survey.
<b>NQF Endorsed</b>	Endorsed in 2011
<b>Clinical Condition</b>	Behavioral Health, Behavioral Health: Other Serious Mental Illness
<b>Risk Adjusted</b>	No
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/0726">http://www.qualityforum.org/QPS/0726</a>

<b>Measure Title</b>	<b>NQF #0006 Consumer Assessment of Healthcare Providers and Systems (CAHPS) Health Plan Survey, Version 5.0 (Medicaid and Commercial)</b>
<b>Measure Developer</b>	Agency for Healthcare Research and Quality
<b>Measure Description</b>	<p>The CAHPS Health Plan Survey is a standardized survey instrument which asks enrollees to report on their experiences accessing care and health plan information, and the quality of care received by physicians. HP-CAHPS Version 4.0 was endorsed by NQF in July 2007 (NQF #0006). The survey is part of the CAHPS family of patient experience surveys and is available in the public domain at <a href="https://cahps.ahrq.gov/surveys-guidance/hp/index.html">https://cahps.ahrq.gov/surveys-guidance/hp/index.html</a>.</p> <p>The survey's target population includes individuals of all ages (18 and older for the Adult version; parents or guardians of children aged 0-17 for the Child version) who have been enrolled in a health plan for a specified period of time (6 months or longer for Medicaid version, 12 months or longer for Commercial version) with no more than one 30-day break in enrollment.</p> <p>The CAHPS Adult Health Plan Survey has 39 items, and the CAHPS Child Health Plan Survey has 41 core items. Ten of the adult survey items and 11 of the child survey items are organized into 4 composite measures, and each survey also has 4 single-item rating measures. Each measure is used to assess a particular domain of health plan and care quality from the patient's perspective.</p> <p>Measure 1: Getting Needed Care (2 items)  Measure 2: Getting Care Quickly (2 items)  Measure 3: How Well Doctors Communicate (4 items in Adult survey &amp; 5 items in Child survey)  Measure 4: Health Plan Information and Customer Service (2 items)  Measure 5: How People Rated Their Personal Doctor (1 item)  Measure 6: How People Rated Their Specialist (1 item)  Measure 7: How People Rated Their Health Care (1 item)  Measure 8: How People Rated Their Health Plan (1 item)</p>
<b>Numerator</b>	<p>We recommend that CAHPS Health Plan Survey items and composites be calculated using a top-box scoring method. The top-box score refers to the percentage of patients whose responses indicated that they "always" received the desired care or service for a given measure.</p> <p>The top box numerator for each of the four Overall Ratings items is the number of respondents who answered 9 or 10 for the item- with a 10 indicating the "Best possible."</p>

<b>Denominator</b>	The measure's denominator is the number of survey respondents who answered the question. The target population for the survey includes all individuals who have been enrolled in a health plan for at least 6 (Medicaid) or 12 (Commercial) months with no more than one 30-day break in enrollment. Denominators will vary by item and composite.
<b>Exclusions</b>	Individuals are excluded from the survey target population if: <ol style="list-style-type: none"> <li>1) They were not continuously enrolled in the health plan (excepting an allowable enrollment lapse of less than 30 days).</li> <li>2) Their primary health coverage is not through the plan.</li> <li>3) Another member of their household has already been sampled.</li> <li>4) They have been institutionalized (put in the care of a specialized institution) or are deceased.</li> </ol>
<b>NQF Endorsed</b>	Endorsed in 2007
<b>Clinical Condition</b>	N/A
<b>Risk Adjusted</b>	Yes
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/0006">http://www.qualityforum.org/QPS/0006</a>

<b>Measure Title</b>	<b>HCAHPS (NQF #0166)</b>
<b>Measure Developer</b>	Centers for Medicare & Medicaid Services
<b>Measure Description</b>	<p>HCAHPS (NQF #0166) is a 32-item survey instrument that produces 11 publicly reported measures:</p> <p>7 multi-item measures (communication with doctors, communication with nurses, responsiveness of hospital staff, pain control, communication about medicines, discharge information and care transition); and</p> <p>4 single-item measures (cleanliness of the hospital environment, quietness of the hospital environment, overall rating of the hospital, and recommendation of hospital)</p>
<b>Numerator</b>	<p>The HCAHPS Survey asks recently discharged patients about aspects of their hospital experience that they are uniquely suited to address. The core of the survey contains 21 items that ask “how often” or whether patients experienced a critical aspect of hospital care, rather than whether they were “satisfied” with their care. Also included in the survey are four screener items that direct patients to relevant questions, five items to adjust for the mix of patients across hospitals, and two items that support Congressionally-mandated reports. Hospitals may include additional questions after the core HCAHPS items.</p> <p>HCAHPS is administered to a random sample of adult inpatients between 48 hours and six weeks after discharge. Patients admitted in the medical, surgical and maternity care service lines are eligible for the survey; HCAHPS is not restricted to Medicare beneficiaries. Hospitals may use an approved survey vendor or collect their own HCAHPS data if approved by CMS to do so. HCAHPS can be implemented in four survey modes: mail, telephone, mail with telephone follow-up, or active interactive voice recognition (IVR), each of which requires multiple attempts to contact patients. Hospitals must survey patients throughout each month of the year. IPPS hospitals must achieve at least 300 completed surveys over four calendar quarters.</p> <p>For full details, see the current HCAHPS Quality Assurance Guidelines, V.9.0, pp. 49-55, at <a href="http://www.hcahpsonline.org/qaguidelines.aspx">http://www.hcahpsonline.org/qaguidelines.aspx</a></p>
<b>Denominator</b>	<p>Eligibility for the HCAHPS Survey</p> <p>The HCAHPS Survey is broadly intended for patients of all payer types who meet the following criteria:</p> <p>Eighteen (18) years or older at the time of admission</p> <p>Admission includes at least one overnight stay in the hospital</p> <ul style="list-style-type: none"> <li>• An overnight stay is defined as an inpatient admission in which the patient’s admission date is different from the patient’s discharge date. The admission need not be 24 hours in length. For example, a patient had an overnight</li> </ul>

	<p>stay if he or she was admitted at 11:00 PM on Day 1, and discharged at 10:00 AM on Day 2. Patients who did not have an overnight stay should not be included in the sample frame (e.g., patients who were admitted for a short period of time solely for observation; patients admitted for same day diagnostic tests as part of outpatient care). Non-psychiatric MS-DRG/principal diagnosis at discharge</p> <p>Note: Patients whose principal diagnosis falls within the Maternity Care, Medical, or Surgical service lines and who also have a secondary psychiatric diagnosis are still eligible for the survey.</p> <p>Alive at the time of discharge</p> <p>Note: Pediatric patients (under 18 years old at admission) and patients with a primary psychiatric diagnosis are ineligible because the current HCAHPS instrument is not designed to address the unique situation of pediatric patients and their families, or the behavioral health issues pertinent to psychiatric patients.</p>
<b>Exclusions</b>	<p>There is a two-stage process for determining whether a discharged patient can be included in the HCAHPS Sample Frame. The first stage is to determine whether the discharged patient meets the HCAHPS eligibility criteria, listed above. If the patient meets the eligibility criteria, then a second set of criteria is applied:</p> <p>Exclusions from the HCAHPS Survey</p> <p>Patients who meet the eligible population criteria outlined above are to be included in the HCAHPS Sample Frame. However, there are a few categories of otherwise eligible patients who are excluded from the sample frame. These are:</p> <ul style="list-style-type: none"> <li>“No-Publicity” patients – Patients who request that they not be contacted (see below)</li> <li>Court/Law enforcement patients (i.e., prisoners); this does not include patients residing in halfway houses</li> <li>Patients with a foreign home address (the U.S. territories – Virgin Islands, Puerto Rico, Guam, American Samoa, and Northern Mariana Islands are not considered foreign addresses and therefore, are not excluded)</li> <li>Patients discharged to hospice care (Hospice-home or Hospice-medical facility)</li> <li>Patients who are excluded because of state regulations</li> <li>Patients discharged to nursing homes and skilled nursing facilities</li> </ul> <p>“No-Publicity” patients are defined as those who voluntarily sign a “no-publicity” request while hospitalized or who directly request a survey vendor or hospital not to contact them (“Do Not Call List”). These patients should be</p>

excluded from the HCAHPS Survey. However, documentation of patients' "no-publicity" status must be retained for a minimum of three years.

Court/Law enforcement patients (i.e., prisoners) are excluded from HCAHPS because of both the logistical difficulties in administering the survey to them in a timely manner, and regulations governing surveys of this population. These individuals can be identified by the admission source (UB-04 field location 15) "8 – Court/Law enforcement," patient discharge status code (UB-04 field location 17) "21 – Discharged/transferred to court/law enforcement," or patient discharge status code "87 – Discharged/transferred to court/law enforcement with a planned acute care hospital inpatient readmission." This does not include patients residing in halfway houses.

Patients with a foreign home address are excluded from HCAHPS because of the logistical difficulty and added expense of calling or mailing outside of the United States (the U.S. territories - Virgin Islands, Puerto Rico, Guam, American Samoa, and Northern Mariana Islands are not considered foreign addresses and therefore, are not excluded).

Patients discharged to hospice care are excluded from HCAHPS because of the heightened likelihood that they will expire before the survey process can be completed. Patients with a "Discharge Status" of "50 – Hospice – home" or "51 – Hospice – medical facility" would not be included in the sample frame. "Discharge Status" is the same as the UB-04 field location 17.

Some state regulations place further restrictions on patients who may be contacted after discharge. It is the responsibility of the hospital/survey vendor to identify any applicable regulations and to exclude those patients as required by law or regulation in the state in which the hospital operates.

Patients discharged to nursing homes and skilled nursing facilities are excluded from HCAHPS. This applies to patients with a "Discharge Status" (UB-04 field location 17) of:

"03 – Skilled nursing facility"

"61 – SNF Swing bed within hospital"

"64 – Certified Medicaid nursing facility"

"83 – Skilled nursing facility with a planned acute care hospital inpatient readmission"

"92 – Certified Medicaid nursing facility with a planned acute care hospital inpatient readmission"

Hospitals/Survey vendors must retain documentation that verifies all exclusions and ineligible patients. This documentation is subject to review.

	<p>Note: Patients must be included in the HCAHPS Survey sample frame unless the hospital/ survey vendor has positive evidence that a patient is ineligible or fits within an excluded category. If information is missing on any variable that affects survey eligibility when the sample frame is constructed, the patient must be included in the sample frame.</p> <p>Patients Discharged to Health Care Facilities</p> <p>Patients discharged to health care facilities other than nursing homes (e.g., long-term care facilities, assisted living facilities and group homes), who are deemed eligible based on the above criteria, must be included in the HCAHPS sample frame. Patients residing in halfway homes, who are deemed eligible, must be included in the HCAHPS sample frame. CMS is aware that contacting patients residing in these facilities may be difficult. Nevertheless, hospitals/survey vendors must attempt to contact all patients in the sample in accordance with HCAHPS protocols.</p> <p>Note: Patients discharged to nursing homes and skilled nursing facilities are excluded from HCAHPS Survey administration. This applies to patients with a “Discharge Status” (UB-04 field location 17) of. “03 – Skilled nursing facility,” “61– SNF Swing bed within hospital” “64 – Certified Medicaid nursing facility,” “83 – Skilled nursing facility with a planned acute care hospital inpatient readmission,” and “92 – Certified Medicaid nursing facility with a planned acute care hospital inpatient readmission.”</p>
<b>NQF Endorsed</b>	Endorsed in 2010
<b>Clinical Condition</b>	Behavioral Health
<b>Risk Adjusted</b>	Case-mix adjustment
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/0166">http://www.qualityforum.org/QPS/0166</a> <a href="http://www.qualitymeasures.ahrq.gov/content.aspx?id=48510&amp;search=%23%239743">http://www.qualitymeasures.ahrq.gov/content.aspx?id=48510&amp;search=%23%239743</a>

<b>Measure Title</b>	<b>NQF #0005- CAHPS Clinician &amp; Group Surveys (CG-CAHPS)-Adult, Child</b>
<b>Measure Developer</b>	Agency for Healthcare Research and Quality
<b>Measure Description</b>	<p>The Consumer Assessment of Healthcare Providers and Systems Clinician &amp; Group Survey (CG-CAHPS) is a standardized survey instrument that asks patients to report on their experiences with primary or specialty care received from providers and their staff in ambulatory care settings over the preceding 12 months.</p> <p>The survey includes standardized questionnaires for adults and children. All questionnaires can be used in both primary care and specialty care settings. The adult survey is administered to patients aged 18 and over. The child survey is administered to the parents or guardians of pediatric patients under the age of 18. Patients who have had at least one visit during the past 12-months are eligible to be surveyed.</p> <p>CG-CAHPS Survey Version 1.0 was endorsed by NQF in July 2007 (NQF #0005). The development of the survey is through the CAHPS consortium and sponsored by the Agency for Healthcare Research and Quality. The survey is part of the CAHPS family of patient experience surveys and is available in the public domain at <a href="https://cahps.ahrq.gov/surveys-guidance/cg/about/index.html">https://cahps.ahrq.gov/surveys-guidance/cg/about/index.html</a>.</p> <p>The Adult CG-CAHPS Survey includes one global rating item and 39 items in which 13 items can be organized into three composite measures and one global item for the following categories of care or services provided in the medical office:</p> <ol style="list-style-type: none"> <li>1. Getting Timely Appointments, Care, and Information (5 items)</li> <li>2. How Well Providers Communicate With Patients (6 items)</li> <li>3. Helpful, Courteous, and Respectful Office Staff (2 items)</li> <li>4. Overall Rating of Provider (1 item)</li> </ol> <p>The Child CG-CAHPS Survey includes one global rating item and 54 items in which 24 items can be organized into five composite measures and one global item for the following categories of care or services provided in the medical office:</p> <ol style="list-style-type: none"> <li>1. Getting Timely Appointments, Care, and Information (5 items)</li> <li>2. How Well Providers Communicate With Patients (6 items)</li> <li>3. Helpful, Courteous, and Respectful Office Staff (2 items)</li> <li>4. Overall Rating of Provider (1 item)</li> </ol>

	<p>5. Provider’s Attention to Child’s Growth and Development (6 items)</p> <p>6. Provider’s Advice on Keeping Your Child Safe and Healthy (5 items)</p>
<b>Numerator</b>	<p>We recommend that CG-CAHPS Survey items and composites be calculated using a top-box scoring method. The top box score refers to the percentage of patients whose responses indicated that they “always” received the desired care or service for a given measure.</p> <p>The top box numerator for the Overall Rating of Provider is the number of respondents who answered 9 or 10 for the item, with 10 indicating “Best provider possible”.</p> <p>For more information on the calculation of reporting measures, see How to Report Results of the CAHPS Clinician &amp; Group Survey, available at <a href="https://cahps.ahrq.gov/surveys-guidance/cg/cgkit/HowtoReportResultsofCGCAHPS080610FINAL.pdf">https://cahps.ahrq.gov/surveys-guidance/cg/cgkit/HowtoReportResultsofCGCAHPS080610FINAL.pdf</a>.</p>
<b>Denominator</b>	<p>The measure’s denominator is the number of survey respondents. The target populations for the surveys are patients who have had at least one visit to the selected provider in the target 12-month time frame. This time frame is also known as the look back period. The sampling frame is a person-level list and not a visit-level list.</p> <p>For more information on the calculation of reporting measures, see How to Report Results of the CAHPS Clinician &amp; Group Survey, available at <a href="https://cahps.ahrq.gov/surveys-guidance/cg/cgkit/HowtoReportResultsofCGCAHPS080610FINAL.pdf">https://cahps.ahrq.gov/surveys-guidance/cg/cgkit/HowtoReportResultsofCGCAHPS080610FINAL.pdf</a>.</p>
<b>Exclusions</b>	<p>The following are excluded when constructing the sampling frame:</p> <ul style="list-style-type: none"> <li>• Patients that had another member of their household already sampled.</li> <li>• Patients who are institutionalized (put in the care of a specialized institution) or deceased.</li> </ul>
<b>NQF Endorsed</b>	Endorsed in 2007
<b>Clinical Condition</b>	N/A
<b>Risk Adjusted</b>	Yes
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/0005">http://www.qualityforum.org/QPS/0005</a>

<b>Measure Title</b>	<b>NQF #0008 (CAHPS) Experience of Care and Health Outcomes (ECHO) Survey (behavioral health, managed care versions) (Composite Measure) <i>Note: measure currently under maintenance review</i></b>
<b>Measure Developer</b>	Agency for Healthcare Research and Quality - Federal Government Agency [U.S.]
<b>Measure Description</b>	52- questions including patient demographic information. The survey measures patient experiences with behavioral health care (mental health and substance abuse treatment) and the organization that provides or manages the treatment and health outcomes. Level of analysis: health plan- HMO, PPO, Medicare, Medicaid, commercial
<b>Numerator</b>	N/A
<b>Denominator</b>	N/A
<b>Exclusions</b>	N/A
<b>NQF Endorsed</b>	Endorsed in 2007
<b>Clinical Condition</b>	Behavioral Health
<b>Risk Adjusted</b>	Case-mix adjustment
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/0008">http://www.qualityforum.org/QPS/0008</a> <a href="http://www.ahrq.gov/cahps/surveys-guidance/echo/instructions/index.html">http://www.ahrq.gov/cahps/surveys-guidance/echo/instructions/index.html</a> <a href="http://www.ahrq.gov/sites/default/files/wysiwyg/cahps/surveys-guidance/echo/about/21_contents_echo_kit.pdf">http://www.ahrq.gov/sites/default/files/wysiwyg/cahps/surveys-guidance/echo/about/21_contents_echo_kit.pdf</a>

<b>Measure Title</b>	<b>NQF #0010 Young Adult Health Care Survey (YAHCS) <i>Note: measure currently under maintenance review</i></b>
<b>Measure Developer</b>	Child and Adolescent Health Measurement Initiative - Nonprofit Organization
<b>Measure Description</b>	<p>The Young Adult Health Care Survey (YAHCS) is a survey of adolescents 14-18 years of age that assesses how well the health care system provides adolescents with recommended preventive care. The YAHCS assesses the provision of private and confidential care, experience of care, helpfulness of care provided, and the following aspects of preventive care:</p> <ul style="list-style-type: none"> <li>• Preventive screening and counseling on risky behaviors.</li> <li>• Preventive screening and counseling on sexual activity and sexually transmitted diseases (STDs).</li> <li>• Preventive screening and counseling on weight, healthy diet, and exercise.</li> <li>• Preventive screening and counseling on emotional health and relationship issues.</li> <li>• Private and confidential care.</li> <li>• Helpfulness of counseling.</li> <li>• Communication and experience of care.</li> <li>• Health information.</li> </ul> <p>The YAHCS has been used to assess health care quality at the national, State, geographic, county, and health plan levels. English and Spanish versions of the YAHCS are available free of charge on CAHMI's web site (<a href="http://www.cahmi.org">http://www.cahmi.org</a>), and additional information is available at the Child Healthcare Quality Toolbox: <a href="http://www.ahrq.gov/choolbx/measure7.htm">www.ahrq.gov/choolbx/measure7.htm</a></p> <p>Please contact CAHMI staff at <a href="mailto:cahmi@ohsu.edu">cahmi@ohsu.edu</a> for more information.</p>
<b>Numerator</b>	N/A
<b>Denominator</b>	N/A
<b>Exclusions</b>	N/A
<b>NQF Endorsed</b>	Endorsed in 2007
<b>Clinical Condition</b>	N/A
<b>Risk Adjusted</b>	N/A
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/0010">http://www.qualityforum.org/QPS/0010</a> <a href="http://www.qualitymeasures.ahrq.gov/content.aspx?id=27452">http://www.qualitymeasures.ahrq.gov/content.aspx?id=27452</a>

<b>Measure Title</b>	<b>NQF # 1896 Language services measure derived from language services domain of the C-CAT <i>Note: measure currently under maintenance review</i></b>
<b>Measure Developer</b>	American Medical Association - Medical Specialty Society
<b>Measure Description</b>	0-100 measure of language services related to patient-centered communication, derived from items on the staff and patient surveys of the Communication Climate Assessment Toolkit (C-CAT)
<b>Numerator</b>	Language services component of patient-centered communication: an organization should determine what language assistance is required to communicate effectively with the population it serves, make this assistance easily available and train its workforce to access and use language assistance resources.
<b>Denominator</b>	There are two components to the target population: staff (clinical and nonclinical) and patients. Sites using this measure must obtain at least 50 staff responses and at least 100 patient responses, including at least 50 patients who prefer to speak a language other than English with their doctor.
<b>Exclusions</b>	Staff respondents who do not have direct contact with patients are excluded from questions that specifically address patient contact. Patient respondents who report a preference for speaking English with doctors are excluded from items that pertain to translation and interpretation services, as they are unlikely to have utilized these services.
<b>NQF Endorsed</b>	Endorsed in 2012
<b>Clinical Condition</b>	N/A
<b>Risk Adjusted</b>	No
<b>Link</b>	<a href="http://www.qualityforum.org/QPS/1896">http://www.qualityforum.org/QPS/1896</a> <a href="https://www.qualitymeasures.ahrq.gov/summaries/summary/49859/communication-climate-mean-score-for-the-language-domain-on-the-patient-or-pediatric-survey-and-staff-survey">https://www.qualitymeasures.ahrq.gov/summaries/summary/49859/communication-climate-mean-score-for-the-language-domain-on-the-patient-or-pediatric-survey-and-staff-survey</a>

## Appendix: List of Relevant PCORI Studies funded since 2012

**Project Title:** A Multicentric Randomized Pragmatic Trial to Compare the Effectiveness of Fingolimod versus Dimethyl-Fumarate on Patient Overall Disease Experience in Relapsing-Remitting Multiple Sclerosis: Novel Data to Inform Decision Makers

**Principal Investigator:** Silvia Rossi, MD, PhD

**Year(s) Funded:** 2016

**Project Summary:** The expansion of the treatment landscape in multiple sclerosis (MS) has increased the complexity of treatment decisions. Oral therapies have been shown to offer benefits with regard to clinical relapse prevention, when compared with placebo in pivotal trials. The clinical efficacy of these therapies over traditional injectable drugs has been demonstrated for fingolimod and presumed for dimethyl-fumarate; however, which is the best oral therapy for controlling suboptimal responders or naive patients has never been assessed. Choosing the right therapy for the right patient is challenging for the clinician and crucial for the patient, but it is often driven only by medical personal experience, indirect comparative data, drug availability, and cost concerns.

Randomized head-to-head trials are the best method for evaluating the efficacy of different treatments and to help the clinicians and the patients in health decision making. There is, however, a lack of head-to-head clinical trials. These experiments employ comprehensive designs to control for most, if not all, sources of bias, by means of randomization, blinding, allocation concealment, and so on. Although the above experimental design, if correctly applied, leads to well-controlled trials with statistically credible results, the applicability of these results to real-life practice may be questionable. Here we aim to perform the first pragmatic trial in MS, assessing in a randomized and everyday clinical setting the superiority of fingolimod or dimethyl-fumarate in terms of effectiveness and patient-centered outcomes.

Patient overall disease experience will be considered for the first time as the most important outcome. In fact, in addition to classical “no evidence of disease activity” (NEDA), a new composite NEDA, taking account of patient point of view and quality of life, will be proposed. If, traditionally, both clinical trials and routine medical care have relied on outcomes assessed by healthcare professionals, then here we want to focus also on the importance of self-evaluation of health, thus growing participation of individuals in their own care. The availability of comparative data from routine practice will help policymakers efficiently allocate resources and manpower, and will drive patients and clinicians in shared and informed health decisions.

**Link:** <http://www.pcori.org/research-results/2016/multicentric-randomized-pragmatic-trial-compare-effectiveness-fingolimod>

**Project Title:** A Patient-Centered Framework to Test the Comparative Effectiveness of Culturally and Contextually Appropriate Program Options for Latinos with Diabetes from Low-Income Households

**Principal Investigator:** Janet Page-Reeves, MA, PhD

**Year(s) Funded:** 2016

**Project Summary:** Background and Significance: Diabetes is a national health problem, yet Latinos from low-income households are at greater risk. Although guidelines recommend that patients learn self-management strategies, many are not able to do so effectively and cannot control their diabetes. Studies show that culturally competent self-management programming can help, but patients told us that not all programs sufficiently respect patients’ cultural values or account for their socioeconomic

limitations.

**Study Aims:** This project will compare two models for culturally competent diabetes self-management programming. Our hypothesis is that the program model that best considers patient culture and accommodates patient socioeconomic circumstances will have the best outcomes.

**Study Design.** We have designed the research to follow PCORI's scientific requirements. We have completed calculations to make sure that enough people will participate so that our findings will be scientifically meaningful. We will gather data about patients at each of the programs. We made a detailed project timeline with specific accomplishments that include both scientific and engagement activities. We assembled a research team with the expertise and experience in patient-engaged research necessary for the proposed study, and we have support from both our university and our community partners. We also have included many opportunities for paid patient participation.

**Things We Compare:** We will compare two diabetes self-management program models used by many Latino patients from low-income households in Albuquerque, New Mexico:

1. The Diabetes Self-Management Support Empowerment Model
2. The Chronic Care Model

**Study Population:** Our patient advisors told us that gathering data from individuals alone does not account for important social aspects of Latino patients' lives, so we will recruit patients and ask them to invite someone close to them to participate too. Patients will be individuals who consider themselves to be Latino and who are from low-income households. We will recruit 240 patient-caregiver pairs through the two sites.

**Primary Outcome:** The primary outcome to be measured is improved capacity for diabetes self-management, measured as diabetes knowledge and patient activation or the ability to put that knowledge into action.

**Secondary Outcome:** The secondary outcome to be measured is successful diabetes self-management measured through reduced A1c, body mass index (BMI), and depression. We will also consider two exploratory clinical measures: 1) patient body composition and 2) patient stress levels, measured using hair samples, to identify levels of cortisol as a biological marker for chronic stress.

**Methods:** We will use statistical calculations to make sure that the things we are comparing are differences in program design and not differences in individual patient characteristics. We will compare whether the programs improve diabetes health knowledge, ability to act, A1c, BMI, body composition, and depression and stress control, and we will determine which program is best.

**Link:** <http://www.pcori.org/research-results/2016/patient-centered-framework-test-comparative-effectiveness-culturally-and>

**Project Title:** Development and Evaluation of a Patient-Centered Approach to Assess Quality of Care: Patient-Reported Outcomes-based Performance Measures (PRO-PMs)

**Principal Investigator:** Ethan Basch, MD, MS

**Year(s) Funded:** 2016

**Project Summary:** It may be surprising to adults diagnosed with cancer to learn that the quality of care

they receive is evaluated with administrative data, such as hospital readmission rates, and not the level of symptoms they are experiencing. Yet, research consistently shows that symptoms, such as pain, and quality of life are among the highest priorities to adults with cancer and caregivers. Adults making treatment decisions will likely find it useful to have reports on how well prospective practices control their patients' symptoms, and clinicians will likely find it useful to compare their symptom management to that of their colleagues. Therefore, we have designed a study to develop and evaluate a patient-centered approach to assessing quality of care.

A multidisciplinary and multi-institutional research team has been assembled to carry out the study. Patient investigators are from three organizations: Research Advocacy Network, Patients and Partners, and the Cancer Information and Support Network. Key state and national organizations are also part of the team (American Society of Clinical Oncology, National Committee for Quality Assurance, and Minnesota Community Measurement). Clinicians, health system leaders, and researchers are also team members.

In Aim 1, we are proposing 115 in-depth interviews with our stakeholder groups nationally (adults with cancer, caregivers, clinicians, health system leaders, and researchers). Adults being treated for cancer will be interviewed to elicit feedback about their cancer care experiences, symptoms, and impressions of using PRO questionnaires to measure quality of care. Clinicians, health system leaders, and researchers will be asked about barriers to implementing patient-reported outcomes (PRO) questionnaires in their practices and impressions of PRO questionnaires as a way to measure quality. In Aim 2, we are proposing to conduct systematic literature reviews to collect all available questionnaires that adults with cancer can use to report their symptoms, toward assessing quality of care. We will then evaluate the questionnaires to find the most promising ones to test in clinics. Questionnaires will be evaluated on how they were developed, how well the questionnaire performs for identifying individuals with problematic symptoms, how long it is, and which languages are available. In Aim 3, we are proposing to test the symptom questionnaires in nationwide clinics (California, Connecticut, Florida, Minnesota, North Carolina, and Texas) to collect data on a variety of individuals and experiences. Adults with cancer who are receiving chemotherapy will fill out brief symptom questionnaires on a tablet computer in the clinic or at home. If an individual is too sick or does not have computer experience, a research assistant will call and ask the questions over the phone. A caregiver or loved one can also complete the questionnaire for the patient. We are hypothesizing that offering choices for ways to complete the questionnaire (web-based, phone calls, or caregiver reports) will increase the number of adults with cancer who complete the symptom questionnaire. We also think the sample will be more representative of adults with low to high symptoms during cancer treatment.

We anticipate that this study is going to be high-impact and will improve quality of care for adults being treated for cancer in the future, because the patient voice will become part of the process for evaluating how well care was provided. The measurement approaches we develop will be immediately used by the state and national organizations that are partners on this proposal. The proposed research advancements for use in cancer treatment settings will provide a broader model for use in other health conditions.

**Link:** <http://www.pcori.org/research-results/2016/development-and-evaluation-patient-centered-approach-assess-quality-care>

**Project Title:** Electronic Patient Reporting of Symptoms during Outpatient Cancer Treatment: A US National Randomized Controlled Trial

**Principal Investigator:** Ethan Basch, MD, TRD

**Year(s) Funded:** 2016

**Project Summary:** Patients with metastatic cancer frequently experience symptoms that cause distress, disability, and lead to urgent care visits. These symptoms often go unrecognized and unaddressed by clinicians even though there are many interventions that can provide relief. Sometimes this happens because patients do not have the opportunity to discuss symptoms at an office visit; sometimes the symptoms occur between visits.

One solution to this problem is to enable patients to report their own symptoms electronically at regular intervals. Patient reports of severe symptoms can then trigger clinicians to respond with interventions ranging from advice to prescriptions or triage for evaluation. Prior studies have found most patients willing and able to self-report symptoms during cancer care, and clinicians find this information valuable. Preliminary data suggest this approach leads to better patient quality of life, avoids emergency room (ER) and hospital visits, and may lengthen survival.

Many healthcare systems are currently considering if and how to integrate patient-reported outcomes (PROs), like symptoms, into care delivery; however, before it can be concluded that it is indeed worthwhile to ask patients to self-report PROs systematically, a multicenter study that includes a diverse group of patients and establishes the size of benefits and burdens is necessary.

A national randomized trial is proposed to address these questions. In the trial's intervention arm, patients will regularly self-report 12 common symptoms from the National Cancer Institute's validated PRO-CTCAE and PROMIS questionnaire systems. Patients will have the option to choose reporting via the web or an automated telephone system for up to 12 months. Email alerts will be triggered to nurses when patients report severe or worsening symptoms. Nurses and patients will be provided with evidence-based symptom management recommendations. In the trial's control arm, nurses and patients will be provided with symptom management recommendations, but there will be no self-reporting of symptoms. Outcomes include physical function; quality of life; survival; ER/hospital visits; and perspectives about relative benefits and burdens from patients, clinicians, and national organizations.

This trial is proposed in partnership with three national patient organizations and two major US oncology professional organizations. The trial will be conducted through the Alliance for Clinical Trials in Oncology, a national research network of oncology practices. The trial will be led by a multistakeholder team, including established PRO researchers, patients, and clinicians. Purposeful enrolment will include patients from diverse racial, ethnic, geographic, and educational backgrounds.

We hypothesize that the PRO intervention will yield clinical benefits that stakeholders perceive to outweigh the burdens of implementation. The study's results could prompt fundamental changes to symptom management practices in oncology.

**Link:** <http://www.pcori.org/research-results/2016/electronic-patient-reporting-symptoms-during-outpatient-cancer-treatment-us>

**Project Title:** Improving Methods of Incorporating Racial/Ethnic Minority Patients' Treatment Preferences into Clinical Care

**Principal Investigator:** Benjamin Cook, PhD, MPH

**Year(s) Funded:** 2016

**Project Summary:** Past attempts at eliciting patient preferences have not taken into account the prior

negative experiences of the patient and his or her family and community. This may lead minority patients to prefer different treatment options or no treatment at all. Eliciting preferences without sufficient context may result in treatment plans centered on incomplete preferences information. A mismatch between treatment and patient preferences worsens health outcomes via lower patient engagement, poorer adherence, and higher attrition. We propose to develop a new method that more accurately elicits patient preferences and to apply this method for depression and type II diabetes.

The objectives are to leverage the power of a more thorough method that asks patients what matters in treatment and includes patient feedback about prior experiences, and to understand patient and provider perspectives on incorporating preferences questions into clinical care, and how this could help improve treatment plan setting and engagement in care.

In Aim 1, we develop and test a conceptual model of adaptive patient preferences for depression and type II diabetes. Our preferences elicitation procedure consists of conjoint analysis supplemented with additional survey questions to elicit individual, familial, community, and sociocultural factors that influence patient preferences. In Aim 2, in-depth follow-up interviews with survey respondents explore themes generated from the survey. In Aim 3, clinicians and health system stakeholders will discuss the results of the preferences elicitation procedure and the feasibility of adapting such procedures when co-developing a treatment plan for depression and diabetes.

Understanding patient preferences for care is crucial to understanding and measuring racial/ethnic disparities in treatment for depression and type II diabetes, and is especially important when a clinician and patient jointly develop treatment plans. Stemming from our primary outcome (relative value of treatment options in dollars) and secondary outcome (negative prior patient experiences), our research will yield a patient-centered process for improving preferences elicitation, and guidelines for providers to incorporate additional questions about patient preferences into the joint development of a treatment plan. We will disseminate our methodology and results to facilitate replication for other diseases. Patients and health system stakeholders will be integrally involved in the research team to ensure that the perspective of a diverse community of stakeholders (patients, clinicians, and patient advocates) are incorporated from the onset of the grant period in all three research aims. Patients and providers are also the focus of qualitative interviews that further inform research methodology and results.

**Link:** <http://www.pcori.org/research-results/2016/improving-methods-incorporating-raciaethnic-minority-patients-treatment>

**Project Title:** Monitoring and Peer Support to Improve Treatment Adherence and Outcomes in Patients with Overlap Chronic Obstructive Pulmonary Disease and Sleep Apnea via a Large PCORnet Collaboration (O2VERLAP)

**Principal Investigator:** David M. Mannino, MD

**Year(s) Funded:** 2016

**Project Summary:** Chronic obstructive pulmonary disease (COPD) and obstructive sleep apnea (OSA) are two major chronic conditions that impact the lives of millions of Americans. Separately, COPD and OSA contribute to the morbidity and mortality of hundreds of thousands of Americans every year, but OSA is prevalent in 10-15 percent of COPD patients in what is called overlap syndrome (OS). People with OS have an increased risk of death and more hospitalizations from complications of the diseases. Positive airway pressure therapy (PAP) and oxygen are two effective treatments for OS, but many people do not use them as prescribed and are not educated on good self-management practices. O2VERLAP is driven by a group of patient stakeholders who are motivated to participate in patient-centered research that

will inform better healthcare decisions and improve outcomes that matter the most to patients while exploring ways to build PCORnet's infrastructure through the conduct of exciting studies. The primary goal of O2VERLAP is to test the effectiveness of two strategies designed to improve adherence and patient outcomes in patients who use oxygen and PAP therapy: a proactive two-way interactive web-based platform guided by a peer and pro coach and a reactive referral to the same educational content without the support and two-way interaction. O2VERLAP will also collaborate with other PCORnet groups and external stakeholders to explore new models for stakeholder engagement, the use of new technologies, crowdsourcing methods in order to build PCO, and more.

O2VERLAP results will provide answers for clinicians seeking the best ways to remove barriers to treatment adherence and strategies for providing efficient educational and coaching platforms. The results will also help patients understand the benefits of their treatment. Additionally, the findings will help provide guidance for using social media, peer-to-peer support, and viral messaging to help recruit and enroll new participants, with the ultimate goal of improving the patient infrastructure for PCORnet and its Commons.

Collaboration within PCORnet unveiled the significant commonalities among many communities, especially COPD and OSA, such as breathing difficulties, anxiety, and depression, and the similar challenges faced in creating research infrastructure. O2VERLAP will contribute great insights to help directly address these challenges facing PCORnet networks: recruitment, retention, co-enrollment, collaboration, and sustainability. We have assembled a robust group of partners that are committed to participating in O2VERLAP to prioritize outcomes, develop the study protocols, cross recruit for the study, and create practical study dissemination strategies in addition to exploring best practices for cross-network governance structures, enrollment, data sharing, and more.

**Link:** <http://www.pcori.org/research-results/2016/monitoring-and-peer-support-improve-treatment-adherence-and-outcomes-patients>

**Project Title:** Continuation of the NephCure Kidney Network (Phase II)

**Principal Investigator:** Elizabeth L. Cope, MPH, PhD

**Year(s) Funded:** 2013 and 2015

**Project Summary:** Primary nephrotic syndrome (NS) is a collection of rare but serious kidney diseases that pose a substantial burden for those affected. Research has been challenged by the limited availability of high-quality data and barriers to patient participation. Accordingly, we established the NephCure Kidney Network (NKN) under Phase I of PCORnet to build a repository with detailed patient-reported outcomes (PRO) data to drive development of new clinical endpoints, patient preferences for participation to inform recruitment and retention strategies, and standardized clinical data to support study planning. Further, the NKN is composed of activated patients engaged in network governance, ensuring research conducted using this resource is responsive to their needs and priorities. Under Phase II, our team will further transform this valuable asset of rich clinical and PRO data from a vibrant and engaged patient community into a sustainable resource for conducting efficient and accurate research that will benefit the lives of those affected by NS.

The project team brings expertise in clinical nephrology, clinical research, epidemiology, health services research, patient advocacy, and data management. Poised for continued success, we will begin Phase II with:

1. a thriving body of NKN community leaders actively engaged in governance and operations,
2. a stable leadership team bringing expertise acquired in Phase I,
3. an expanded team of clinical co-investigators,
4. confirmed collaborations within and outside of PCORnet,
5. two recent funding awards,

6. three recent research proposal submissions, and
7. a robust plan for network sustainability.

In Phase II, we will:

1. ensure capacity for rapid ancillary study start-up capabilities;
2. deepen engagement to transform patients from subjects into collaborators;
3. leverage partnerships within and outside of PCORnet to grow the network to 1,500 patients;
4. consolidate the NKN's data management activities to enhance efficiency, flexibility, and usability;
5. build capacity for research by diversifying data streams and developing a computable phenotype for NS; and
6. execute a sustainability plan to ensure seamless support for ongoing operations and research.

The expansion of a network with research-ready interoperable data, a community of patients engaged as participants and partners, streamlined policies that support efficient research while protecting privacy, and strong collaborative ties to peer networks and research consortia will facilitate much-needed advances for patients with this rare and devastating condition. Success of this network will undoubtedly have broader applications to conditions with clinical overlap and to other rare diseases sharing similar barriers to research progress.

**Link:** <http://www.pcori.org/research-results/2015/continuation-nephcure-kidney-network>

**Project Title:** Enhancing the Cardiovascular Safety of Hemodialysis Care: A Cluster-randomized, Comparative Effectiveness Trial of Multimodal Provider Education and Patient Activation Interventions

**Principal Investigator:** Tiffany Veinot, MLIS, PhD

**Year(s) Funded:** 2015

**Project Summary:** When a person's kidneys stop working, he or she has end-stage renal disease (ESRD). Individuals with ESRD cannot live without either dialysis therapy—in which a machine performs the functions of the kidneys—or a kidney transplant. Dialysis must remove fluid as well as toxins in the blood. People with ESRD have a high risk for death, and the usual cause is cardiovascular disease.

Most people in the United States who have ESRD get hemodialysis therapy in a clinic for four hours at a time, three times a week. The stability of hemodialysis sessions varies, and many sessions become unstable from low blood pressure and other complications. Unstable dialysis sessions can result in negative symptoms, like fatigue.

Dialysis instability is an important patient safety problem. Session instability is linked to injury to the heart and other organs. Patients who have unstable dialysis sessions are more likely to end up in the hospital or die than are those who have stable sessions. Session instability is preventable. The main causes of instability are removal of fluid from a patient too fast or removal of too much fluid. Session instability results from many factors: decisions made by patients, decisions by healthcare providers, and dialysis clinic policies.

Presently, the way to best improve the safety of the heart and other organs during dialysis is not clear. Dialysis clinics approach this problem differently, and there is variation among clinics in how often hemodialysis sessions become unstable.

In partnership with the National Kidney Foundation and dialysis facilities, we will test two interventions designed to increase the stability of patient dialysis. One intervention, multimodal provider education, focuses on dialysis facility care teams. It includes team training, online education, and checklists.

Another intervention, patient activation, focuses on patients. It includes peer mentoring by trained ESRD patients. Mentors will hold with other patients multimedia-aided meetings that include skills instruction and role modeling. These interventions have been successful in hospital care and in chronic disease care, and we will adapt them to dialysis safety.

We will then conduct a study in 28 dialysis facilities in different parts of the United States. Seven facilities will get the provider education only; seven will get the patient activation intervention only; seven will get both interventions; and seven will get no interventions. We will test whether session stability improves in the facilities that get either intervention over the one-year intervention period. This study is expected to clarify whether these interventions can make dialysis safer for ESRD patients. This will inform hemodialysis care providers on whether to pursue provider-focused or patient-focused safety interventions, or both. People on hemodialysis will also have information to help them decide whether to become engaged in their safety, and the intervention will help them learn how to do so.

**Link:** <http://www.pcori.org/research-results/2015/enhancing-cardiovascular-safety-hemodialysis-care-cluster-randomized>

**Project Title:** Putting Patients at the Center of Kidney Care Transitions

**Principal Investigator:** Leigh E. Boulware, MD, MPH

**Year(s) Funded:** 2015

**Project Summary:** Background: Chronic kidney disease affects over 20 million adults in the United States. Over 115,000 patients develop complete kidney failure each year, devastating them and their families. When kidneys fail, patients need treatments (such as dialysis or a kidney transplant) to prolong their lives. Treatments are very different, and each has its own pros and cons, requiring patients' consideration. Unfortunately, doctors often are unsure of when is the best time to start preparing patients for kidney failure. In many cases, when kidney failure occurs, patients have no idea they are so sick, they have a very poor understanding of their treatments, and they feel blindsided. They also start kidney failure treatment under emergency circumstances, causing them to suffer and receive treatments they don't want.

**Objective:** We will change the health system to improve care patients receive as they transition through earlier stages of kidney disease toward kidney failure. We will study whether these changes lead to patients' improved health and well-being.

**Methods:** We will conduct our study in Geisinger Health System kidney specialty clinics. We will implement patient-centered kidney transitions care, which will: (1) give doctors tools to help them recognize when patients should prepare for kidney failure and help them support patients' early and informed treatment decisions; and (2) add a kidney transitions specialist to the healthcare team to help patients learn about kidney disease, learn self-care skills, make informed decisions, get psychosocial support, and coordinate their care. We will randomly assign four clinics to provide patient-centered kidney transitions care and four to provide their usual care. We will study differences in patients' outcomes among those treated in clinics providing patient-centered kidney transitions care compared with those treated in clinics providing usual care.

**Patient Outcomes:** Patients have told us that they want control over their disease transitions and to have the best quality of life possible. We will measure patients' empowerment, confidence with their self-care, their decisions to start self-care treatments for kidney failure, and their hospitalizations. We will also measure whether doctors record patients' treatment preferences in the medical record before

patients develop kidney failure.

**Patient and Stakeholder Engagement:** Our study responds to reports from hundreds of patients and caregivers who want better care. Patients and caregivers from around the country are part of our investigative team, and they will participate in all aspects of our study. We are also engaging key stakeholders in the kidney community, including patients, providers, payers, and regulators.

**Anticipated Impact:** If effective, patient-centered kidney transitions care will provide a model of care that can improve the lives of patients with kidney disease and their families across the United States.

**Link:** <http://www.pcori.org/research-results/2015/putting-patients-center-kidney-care-transitions>

**Project Title:** The Patient-Reported Outcomes Project of HCV-TARGET (PROP up TARGET)

**Principal Investigator:** Donna Evon, PhD

**Year(s) Funded:** 2015

**Project Summary:** Background: Newer, more effective medication regimens for chronic hepatitis C viral (HCV) infection are approved. For the first time, patients and providers will have more than one treatment option from which to choose. Deciding which treatment to choose may be challenging for patients, as regimens may be relatively similar on cure rates but may differ on other harms and benefits that matter to patients. Data collected from clinical drug trials do not provide all the answers, nor does the data represent the broad range of patients who will be treated in real-world clinical practice.

Meanwhile, HCV-TARGET is the largest international research network and clinical registry of patients undergoing treatment, and provides a unique opportunity to evaluate patient-reported outcomes in a diverse spectrum of patients treated in real-world clinical settings.

**Methods:** PROP up TARGET will be a prospective, observational cohort study of 1,600 patients infected with genotype 1 HCV and who initiate treatment at eight US liver centers. A HCV patient engagement group (HCV-PEG) and data derived from 45 patient interviews identified the top-priority information that affects patient decision making. Based on these informational needs of HCV patients, we will ask study participants to complete surveys to collect information on: (1) harms that may occur during treatment (side effects, poor functioning, out-of-pocket costs, difficulty with adherence); (2) benefits of treatment 3 months after it ends (do preexisting HCV symptoms and functioning improve?); and (3) longer-term toxicities and side effects that may occur up to 1 year after treatment ends. Participants will complete surveys at 5 time points: before treatment, twice during treatment, and 3 and 12 months after treatment. Our HCV-PEG members took, on average, 13 minutes to complete the surveys. Participants can answer surveys via three methods based on their preference: from their home-based computers, from a phone interview with our call center, or with the research coordinator at regularly scheduled visits with the liver doctor. All data will be entered into a web-based secure data management system. Our HCV-PEG indicated that it was reasonable to pay participants \$25 for the first three assessments and \$40 for the last two assessments.

**Patient Engagement:** Our research team includes patient partners (seven members of the HCV-PEG) and a patient advocacy organization- both will represent the patients' voices on the study steering committee.

PROP up TARGET is committed to collecting information to help patients and providers make more-informed treatment decisions. This study to compare two new all-pill treatments is the first head-to-head study of short-term and longer-term outcomes that were selected by patients with HCV, and will matter most to patients making future decisions about HCV treatment.

**Link:** <http://www.pcori.org/research-results/2015/patient-reported-outcomes-project-hcv-target-prop->

[target](#)

**Project Title:** Demonstrating Respect and Acceptable Consent Strategies: What Matters to Patients in PCOR?

**Principal Investigator:** Nancy Kass, ScD

**Year(s) Funded:** 2014

**Project Summary:** Background: Patient-centered outcomes research (PCOR) can improve the quality of medical care. Yet informed consent approaches developed for more experimental, riskier research may not be a good fit for PCOR, and are harder to do efficiently. This study will seek patients' views about the acceptability of four disclosure/consent approaches for PCOR, including shorter ways of telling patients about medical research. We also will see what patients think about ways of demonstrating respect to them in PCOR that extend beyond consent; namely, engagement, transparency, accountability (ETA).

**Objectives:** The specific aims of this study are:

- To assess patients' views about the importance of patient engagement (in ethics oversight of PCOR and in determining which types of disclosure/consent practices are appropriate for which studies), transparency (about which PCOR studies are happening and how they affect patients' medical care), and accountability (about how health care changes after a study is done) in showing respect to patients in PCOR
- To assess whether patients have more favorable attitudes toward shorter disclosure/consent approaches when studies have little impact on what matters to patients, including how their care is delivered and whether all treatments work well and are used regularly
- To see if patients like shorter, better disclosure/consent approaches when ETA practices are in place
- To see if patients like shorter, better disclosure/consent approaches most when ETA practices are in place and when studies don't change their care much, and when all treatments work well and are used regularly
- To see if patients' views on the above questions differ by income, ethnicity, gender, education, age, research experience or health status, or type of health system where they get care
- To make recommendations about next steps for actionable policies and practices

**Methods:** We will hold four focus groups and survey 800 patients from Johns Hopkins Healthcare and Geisinger Clinic. Focus groups will be held to make sure study materials are clear and cover topics important to patients. Patients will get different (randomly varied) versions of the survey so they each get one of four case examples of a PCOR study. Case studies will compare two treatments that are (1) more or (2) less similar to each other in ways that might matter to patients and (3) will or (4) won't also include engagement, transparency, and accountability. Patients will be asked what they think about four different disclosure/consent options for the study. Patients also will be asked their opinion on how risky and respectful the case is compared to usual care, trust, and background information.

**Patient Outcomes:** This study will show whether patients think shorter disclosure/consent approaches are appropriate, or under what conditions they think they are appropriate, related either to the type of study or whether other ways of showing them respect are in place.

**Link:** <http://www.pcori.org/research-results/2014/demonstrating-respect-and-acceptable-consent-strategies-what-matters-patients>

**Project Title:** Expanding PRO Assessment Integrated into Routine Clinical Care of Patients with HIV to New PROMIS Domains: Identifying Patient Priorities, Developing Cross-Walks with Legacy Instruments, and Evaluating Predictive Validity

**Principal Investigator:** Heidi M. Crane, MD, MPH

**Year(s) Funded:** 2014

**Project Summary:** Background: This study continues research work that integrates patient-reported outcomes (PRO) data into routine clinical care to optimize patient care and patient-centered outcomes research. We lead a PRO Measurement Information System (PROMIS) focused on PROs in routine clinical care for patients living with HIV (PLWH).

**Objectives:** Our goals are to identify PROMIS domains of highest priority to PLWH (Aim 1), co-calibrate legacy scales with PROMIS for high priority domains (Aim 2), and determine content validity and integrate the highest priority domains into routine clinical care for PLWH (Aim 3).

**Methods:** We will perform interviews and conduct focus groups for 200 or more PLWH (Aims 1 and 3) in English and Spanish at Centers for AIDS Research Network of Integrated Clinical Systems (CNICS) sites and collect PRO data from 9,000 or more clinical assessments from PLWH (Aims 2 and 3).

**Analytic Methods:** All methods will adhere to PROMIS standards. Aim 1 will involve analyses of survey data and qualitative assessment of themes. For Aim 2, we will use confirmatory factor analyses to determine whether PROMIS parameters are appropriate for PLWH and item response theory to evaluate measurement properties. For Aim 3, we will conduct individual and focus group interviews to evaluate completeness of PROMIS item banks, usefulness of short forms, and relevance of the computerized adaptive testing items. We will administer existing PROMIS items, new candidate items, and legacy scales to PLWH. We will capitalize on CNICS's diverse population to evaluate items for differential item functioning. We will evaluate predictive validity using CNICS's extensive clinical data.

**Patient and Stakeholder Engagement:** Patients are colleagues for all of our work. Patients will provide important feedback at every stage, from identifying domains to emphasize (Aim 1) to formulating, implementing, and refining dissemination plans. We have recruited three patient co-investigators. We will continue collaborations with Community Advisory Boards from three clinics.

**Patient Outcomes:** We will enhance patient care and PCOR by improving understanding of PROMIS-2 domains of highest priority to patients.

**Anticipated Impact:** Much more needs to be known about the use of PROMIS-2 scales in clinical care. This project will enhance our understanding of how to optimize PRO collection in clinical care to improve care and optimize PCOR.

**Link:** <http://www.pcori.org/research-results/2014/expanding-pro-assessment-integrated-routine-clinical-care-patients-hiv-new>

**Project Title:** Feasibility of Implementing Patient-Reported Outcome Measures

**Principal Investigator:** Sarah H. Scholle, DrPH, MPH

**Year(s) Funded:** 2014

**Project Summary:** Background: Patient-reported outcome measures (PROMs) are questionnaires that ask patients about their daily activities and feelings. These questions have been used in research to determine how well treatments affect patients but not in routine visits to doctors and clinics. We do not know how patients, doctors, and others on the care team would use the information or whether patients or their doctors would find it useful.

**Objectives:** Our goals are to:

Show how patients, doctors, and other members of their clinical care team can use PROMs in care planning

See how meaningful and valuable the use PROMs in care planning is to patients and their clinical care team

**Patient and Stakeholder Engagement:** Our team includes patients and experts in measuring the quality of health care and in gathering data from patients.

**Methods:** We will work with patients and healthcare teams to identify relevant questionnaires and to plan how to use these questionnaires to make care plans for patients. We will test these steps for 400 patients with diabetes at a starting point and again three months later. We will use the information to look at how patients' answers to the PROMs change from baseline to follow-up. We will interview patients and care team members to learn how the information is used and whether it is helpful in caring for one's self or in providing care.

**Outcomes.** This study will help us to understand how to evaluate healthcare teams' use of PROMs and to provide important information about how to use PROMs in the care of patients with chronic conditions. We will study whether usefulness of PROMs differs for people who have problems reading or understanding health information and for people of different cultural backgrounds.

**Anticipated Impacts:** If this study is successful, patients will have new ways to tell their healthcare teams about their health needs and get help in addressing those needs.

**Link:** <http://www.pcori.org/research-results/2014/feasibility-implementing-patient-reported-outcome-measures>

**Project Title:** Improving Advanced Cancer Patient-Centered Care by Enabling Goals of Care Discussions

**Principal Investigator:** Nina Bickell, MD, MPH

**Year(s) Funded:** 2014

**Project Summary:** Among advanced cancer patients, discussions about prognosis, goals of care (GoC), and end-of-life preferences improve patients' quality of life and reduce hospital and ICU admission rates. Yet, few patients know their chemotherapy treatments will not cure their disease, despite nearly all wishing to receive both positive and negative information. Currently, 37 percent of advanced cancer patients have GoC-clarifying discussions, and when they do, it is often in the last two months of life, when symptoms are uncontrollable and oncologists have no other treatments to offer. These discussions do not usually happen with the patient's personal oncologist. Current efforts to teach oncologists such skills are impractical- they require a lot of time away from the physicians' office practice and do not take into account job pressures. The goal of this study is to increase and improve GoC discussions for advanced cancer patients by training medical oncologists to conduct these discussions and evaluate their effects on patient satisfaction, receipt of care in line with preferences, aggressive care utilization, and oncologist communication skill.

The study team will train randomly selected oncologists to conduct GoC discussions. We will recruit 280 patients, half of whom will come from doctors receiving the intervention and the other half from control doctors. Patients will be surveyed at baseline within days of their GOC visit and at six months.

Oncologists will be audiotaped at baseline and after training is complete to assess practice and skill to conduct GoC discussions. Primary outcomes include patient-reported conduct of and satisfaction with the GoC discussion. Secondary outcomes include oncologist communication skills; feasibility of

performing GoC in the outpatient setting; receipt of care in line with preferences; and use of hospice, chemotherapy, or ICU in the last 30 days of life.

**Link:** <http://www.pcori.org/research-results/2014/improving-advanced-cancer-patient-centered-care-enabling-goals-care>

**Project Title:** Improving Patient Quality of Life and Caregiver Burden by a Peer-Led Mentoring Program for Patients with Chronic Kidney Disease and Their Caregivers

**Principal Investigator:** Nasrollah Ghahramani, MD, MS

**Year(s) Funded:** 2014

**Project Summary:** Chronic kidney disease is very common in the United States, and throughout the world. An increasing number of individuals are diagnosed with late stages of chronic kidney disease, which require treatment with either dialysis or kidney transplant. The number of individuals currently requiring such treatment in the United States is greater than 600,000. Patients with advanced kidney disease and their family members face many challenges in dealing with the disease and the decisions that relate to choice of treatment. Quite frequently, patients and their family members are faced with the need to decide on a treatment option without full awareness of all the options. In such cases, they might make choices with which they will not be satisfied. Poor satisfaction with treatment choice is likely to result in poor quality of life for the patients and increased sense of burden for the caregiver.

Receiving supportive mentoring from well-adjusted individuals who share similar experiences has had a positive influence on adjustment with some chronic diseases. Since 2004, the Kidney Foundation of Central Pennsylvania has conducted a program to formally train patients with kidney disease and their caregivers to become mentors for patients or caregivers who feel they might benefit from such mentoring. The program, the Patient and Family Partner Program (PFPP), was envisioned and designed by a patient with chronic kidney disease and has trained approximately 130 mentors.

In this study, patients with advanced chronic kidney disease and caregivers of such patients will be randomly assigned to one of three groups: (1) face-to-face PFPP—individuals will receive six months of PFPP peer-mentoring, along with an informational text; (2) online PFPP—individuals will receive six months of online peer-mentoring modeled after the PFPP program, along with an informational text; and (3) information-only control group—individuals will receive the text of the material provided to the other two groups. The study team's decision to include an online version is based on suggestions by previous participants who indicated that this would be convenient for individuals for whom distance and geographic location are major considerations of participation.

We expect that both face-to-face and online peer-mentorship programs will result in improved quality of life among patients with advanced kidney disease and decreased feeling of burden among caregivers of these patients. We also expect that mentorship will lead to improved engagement of patients in their own care.

**Link:** <http://www.pcori.org/research-results/2014/improving-patient-quality-life-and-caregiver-burden-peer-led-mentoring-program>

**Project Title:** Incorporating PROMIS Symptom Measures into Primary Care Practice

**Principal Investigator:** Kurt Kroenke, MD

**Year(s) Funded:** 2014

**Project Summary:** Background: Symptoms account for half of all outpatient encounters in the United

States, or more than 400 million clinic visits annually. In contrast to specific diseases, however, symptoms have received far less attention in research, training, and, consequently, patient care. Five symptoms that warrant special attention are the SPADE pentad (sleep problems, pain, anxiety, depression, and energy/fatigue). These symptoms are among the most prevalent, chronic, disabling, and undertreated symptoms in clinical practice, and they occur frequently in most medical and mental disorders. The SPADE pentad accounts for five of the seven areas assessed in the Patient-Reported Outcomes Measurement Information System (PROMIS) profile scales.

Objectives. The study's objectives are to.

1. Find out if providing PROMIS symptom scores to physicians improves the treatment of patients' symptoms, and if so, the degree to which symptoms improve
2. Find out from both patients and physicians the best way to use PROMIS symptom scores in improving care
3. Compare PROMIS symptom scores to other scales used for measuring patient symptoms

Methods: The study design will be a clinical trial involving 300 primary care patients who suffer from one or more of the five symptoms in the SPADE pentad. Participants will complete, prior to seeing their physician, the PROMIS-29 profile. Patients will then be randomly assigned to an intervention or control group. For patients in the intervention group, their physician will be given the PROMIS scores for the five symptoms. Control patients will complete the same pre-visit questionnaires but their physicians will not receive the PROMIS scores. All patients will be assessed three months later by a telephone interviewer who will re-administer the PROMIS-29 profile as well as ask questions about symptom-specific residual concerns and satisfaction. Also, 30–45 patients and 10–15 physicians will have more detailed interviews to find out the best way to use PROMIS scores to improve care for symptoms.

Anticipated Impact: We will learn, from both the patient and physician viewpoints, the usefulness of assessing symptoms with PROMIS measures and how to optimize the value of these symptom assessments. We will also determine whether a numerical or visual display of scores is optimal. Because the symptoms being evaluated in the PROMIS profile are common in most diseases, the study findings can improve care for patients seeing specialists as well primary care clinicians.

**Link:** <http://www.pcori.org/research-results/2014/incorporating-promis-symptom-measures-primary-care-practice>

**Project Title:** Making PROMIS Meaningful to Patients and Providers in Clinical Practice

**Principal Investigator:** Clifton Bingham, MD

**Year(s) Funded:** 2014

**Project Summary:** Background: Patient-reported outcomes (PROs) can help monitor symptoms, improve doctor-patient communication, detect new problems, and prompt treatment change. However, PROs must be viewed as relevant by patients and doctors and offer easily understood results. PROs in the Patient Reported Outcomes Measurement Information System (PROMIS) help researchers compare symptoms and function across different diseases. PROMIS may also help doctors and patients make better decisions about treatment, but first we need to learn how to use PROMIS for specific diseases. People with rheumatoid arthritis (RA) often live with pain, disability, and fatigue. Symptoms may vary from day to day. Early results from our ongoing PCORI study suggest that PROMIS can improve communication and identify troubling symptoms. But patients ask: How do I compare with other people with RA? Doctors ask: How do I know if my patient is better? Answers are needed to these and other

questions to make PROMIS results meaningful to patients and providers.

**Objectives:** This is the first study to bring patients and clinicians together to decide about the severity of symptoms and the amount of change that is important to consider when making treatment decisions.

Our specific goals are to:

1. confirm PROMIS measures are asking the right questions for RA,
2. identify how much change is meaningful, and
3. bring together patients and providers to determine symptom severity and identify when change is large enough to warrant treatment reconsideration.

**Methods:** People with RA will be interviewed in person and online to confirm that PROMIS PROs are relevant for RA. We will follow 280 RA patients over three visits to learn how results change when RA gets better or worse, and we will apply methods used in education and business to see whether doctors and patients agree about symptom severity and how much change is needed to suggest treatment reconsideration. We will evaluate the relevance, responsiveness, and appropriate reactions to PROMIS results, keeping in mind what is right for the patient.

**Patient and Stakeholder Engagement:** This study directly targets questions raised by current patients, patient research partners (PRPs), clinicians, and stakeholders. PRPs are key study members, helping to write the research proposal and think through our methods. PRPs will be involved in all study aspects including as Steering Committee members, by monitoring progress, and by working with other stakeholders. PRPs will create patient materials, review protocols and results, and tell others about the findings. In addition, we are working with eight stakeholders from patient organizations, health systems, payers, networks, government, and industry. They also helped write our proposal, will provide guidance, and will determine how others may benefit from our results.

**Anticipated Impact:** If successful, this approach can be applied to other diseases to make PROMIS and other PROs more meaningful for patients and doctors.

**Link:** <http://www.pcori.org/research-results/2014/making-promis-meaningful-patients-and-providers-clinical-practice>

**Project Title:** Measuring the Context of Healing: Using PROMIS in Chronic Pain Treatment

**Principal Investigator:** Carol Greco, PhD

**Year(s) Funded:** 2014

**Project Summary:** Background: Questions such as who improves with treatment, which treatments are most appropriate for whom, and do patients' perceptions influence outcomes, are highly relevant to patients and clinicians in making healthcare decisions. However, in most research studies, such questions are not addressed. This project focuses on these questions and will contribute to the understanding of treatment outcome differences based upon patients' views of themselves and their treatment.

**Methods:** We will administer Healing Encounters and Attitudes Lists (HEAL) and other Patient-Reported Outcomes Measurement Information System (PROMIS) computerized adaptive tests (CATs) to 200 patients who are starting treatment for chronic pain in integrative medicine and conventional medicine settings. Follow-up assessments will be completed two and four months after baseline testing.

Objectives: We aim to:

1. Evaluate whether the HEAL CATs predict chronic pain treatment outcomes
2. Examine heterogeneity of treatment effects based on HEAL and PROMIS scores in integrative and conventional medicine settings
3. Interview patients and their clinicians regarding the utility of HEAL, PROMIS, and a pain log for enhancing communication.

Patient Outcomes: We will evaluate factors that may predict which patients judge themselves to be improved, the same, or worsened. Some of the possible factors that may contribute to improvement include HEAL scores, emotional distress at baseline, or the preference for complementary and alternative medicine or conventional treatment. We are also interested in learning whether patients find the assessments to be clear and useful. A subset of 50 patients and approximately 10 clinicians will complete interviews about HEAL and PROMIS questions, and about the pain log developed by our patient advocacy group partner, the American Chronic Pain Association.

Anticipated Impact: By interviewing patients and their healthcare providers, we hope to determine the clarity and acceptability of HEAL and other assessments and to learn whether they enhance patient-provider communication in the clinical partnership.

**Link:** <http://www.pcori.org/research-results/2014/measuring-context-healing-using-promis-chronic-pain-treatment>

**Project Title:** The Comparative Impact of Patient Activation and Engagement on Improving Patient-Centered Outcomes of Care in Accountable Care Organizations

**Principal Investigator:** Stephen Shortell, MBA, MPH, PhD

**Year(s) Funded:** 2014

**Project Summary:** The study team will examine the delivery of care to patients with diabetes and cardiovascular diseases from 16 practices in healthcare organizations that receive incentives for improving the quality of patient care. Half of those will be far along in engaging patients in their care, and half will not be. We will see whether patients with diabetes or cardiovascular diseases who receive care from practices that more fully involve their patients have better clinical outcomes and satisfaction with their care than those that do not. We expect that these findings will help practices and patients to achieve better outcomes of care.

**Link:** <http://www.pcori.org/research-results/2014/comparative-impact-patient-activation-and-engagement-improving-patient>

**Project Title:** Treatment Options for Depression in Patients Undergoing Hemodialysis

**Principal Investigator:** Rajnish Mehrotra, MD, MS

**Year(s) Funded:** 2014

**Project Summary:** Patients whose kidneys fail generally require dialysis treatments to sustain life. Most patients undergo hemodialysis, a treatment that takes three to four hours and is performed in a dialysis facility three times a week. They need to make significant changes to their diet and are asked to take about 17 pills daily. The ability of patients to make such major adjustments in their lives is hampered by depression that affects almost one-quarter of such individuals. Yet many doctors do not offer depression treatment, and when offered, many dialysis patients are reluctant to accept it. This is, in part, because there are no studies that have adequately tested whether treatment for depression is effective in dialysis patients, or if there is any difference between the responses to the two most commonly available forms of treatment, psychotherapy and antidepressant drug therapy.

To fill this important gap in our knowledge, the study team proposes to undertake (1) a randomized

controlled clinical trial of 400 patients to test whether an engagement interview will result in a higher proportion of dialysis patients accepting treatment for depression and (2) a randomized controlled clinical trial of 180 patients to determine whether there is any difference in the likelihood of improvement of depressive symptoms with psychotherapy or drug therapy among dialysis patients with depression. Patients in these studies will be enrolled from 50 dialysis facilities in three metropolitan areas—Seattle, Dallas, and Albuquerque.

The research proposal has been developed with the support of patients, caregivers, and stakeholders to ensure that the findings from the study are relevant to them and can be readily implemented in day-to-day clinical practice. Hence, the engagement interview and psychotherapy will be delivered in a dialysis facility to ease the burden on patients, and the dose of the study drug will be changed in partnership with the study participants.

In addition to depressive symptoms, the effect of treatment on other meaningful outcomes such as fatigue and sleep will be determined. A single research assistant will ascertain the potential benefits of treatment by computer-assisted telephone interviewing with the patient at home. Upon completion of treatment in the clinical trial, each patient will be invited to undergo a semistructured interview to describe their experience with the intervention.

The two forms of depression treatment being tested in this clinical trial are very different from each other, and patients differ with regard to the treatment option preferable or available to them. Successful completion of the clinical trial will provide patients, caregivers, and other stakeholders with the information that they would need when faced with a diagnosis of depression in patients undergoing hemodialysis. This will allow patients to select evidence-based treatments to improve outcomes that are relevant to them.

**Link:** <http://www.pcori.org/research-results/2014/treatment-options-depression-patients-undergoing-hemodialysis>

**Project Title:** Bringing Care to Patients: A Patient-Centered Medical Home for Kidney Disease

**Principal Investigator:** Denise Hynes, MPH, PhD, RN

**Year(s) Funded:** 2013

**Project Summary:** Background: Patients with end-stage renal disease (ESRD) receive care from several different doctors at multiple locations. They often have other chronic diseases that require complex care and are at a higher risk for emergency room visits and hospitalizations. The patient-centered medical home (PCMH) model has been proposed as a solution to patients with complex needs such as those with ESRD. We will compare a PCMH model with usual care on ESRD patients and their caregivers.

Purpose: The purpose of this project is to compare a PCMH model of care with the usual care of ESRD patients and their caregivers. We propose to enhance the usual care team for ESRD patients by providing a primary care doctor in the context of regularly scheduled dialysis sessions and by adding health promoters to help support patients and their caregivers. Patient and family stakeholders and care team members will assist in the design and refinement of the PCMH model.

Method: We plan to implement this model at the University of Illinois Hospital and Health Sciences System (UIHS) dialysis center and a local Fresenius Medical Care dialysis center. Patients receiving dialysis at participating centers will receive an initial comprehensive care visit followed by ongoing care from a multispecialty provider team during the patients' regularly scheduled dialysis visits. Each patient's care team will include a kidney doctor, a primary care doctor, an advanced practice nurse, a dialysis nurse, a dietician, a pharmacist, a social worker, and a health promoter. The primary care doctor will be available in the dialysis clinic to provide general and preventive care to the patient before or after dialysis sessions. This doctor would also coordinate care with other specialists/clinicians on the patient's care team. The trained, bilingual (English/Spanish) health promoter will assist with making and

rescheduling appointments, obtaining transportation, and reinforcing education components. Outcomes: We expect that this approach will increase patient access to care for other conditions and will increase care coordination and communication among members of the patient's care team. These improvements could potentially increase the likelihood of preventing complications or identifying problems earlier and allow for a more successful treatment. We expect that this will reduce emergency room visits and hospitalizations for dialysis patients. In addition, we anticipate that the addition of health promoters to the clinical team will help support and educate patients and their caregivers and, as a result, patient quality of life will improve and caregiver burden may be reduced.

**Link:** <http://www.pcori.org/research-results/2013/bringing-care-patients-patient-centered-medical-home-kidney-disease>

**Project Title:** Comparative Effectiveness of Peer-Led Supplemental O2 Infoline for Patients and Caregivers (PELICAN)

**Principal Investigator:** Jerry A. Krishnan, MD, PhD

**Year(s) Funded:** 2013

**Project Summary:** Background: About 1 million individuals in the United States have a prescription for supplemental oxygen (O2). Using O2 can prolong life and increase quality of life. Patients often do not use their oxygen as prescribed, which means that they are not benefiting as much as they could be from this therapy. In focus groups, patients with chronic obstructive pulmonary disease (COPD) and their caregivers emphasized their need for reliable information about O2, including information about O2 delivery systems, social aspects of O2 use such as embarrassment about using O2 in public, and concerns such as fear of becoming addicted to O2. They expressed a strong interest in getting help from peers who can coach them through the process of adjusting to O2. Data from studies in other populations suggest that peer coaching by phone can help patients improve self-management skills and outcomes. However, the effectiveness of peer coaching in helping patients with COPD use O2 is unknown. We expect that a Peer- Led O2 Infoline for Patients and Caregivers (PELICAN) will increase adherence and improve health. We have developed a broad-based team that includes patients and caregivers, the COPD Foundation, a national O2 supplier, and others to test whether PELICAN leads to increased O2 use and outcomes important to patients.

**Objectives:** Using input from COPD patients and their caregivers, we will develop patient-centered educational and support materials tailored to their needs, to be used in PELICAN. We will study whether PELICAN is effective and results in increased use of O2 as prescribed, more positive attitudes and beliefs about O2 use (such as confidence in the ability to use O2 despite barriers such as social discomfort), and other outcomes. The long-term goal is to help patients use their O2 as prescribed so they can be as healthy as possible.

**Methods:** We will meet with groups of patients with COPD who use O2 and their caregivers to help develop the materials to be used in PELICAN. We will pilot test the materials with a small number of patients, and will modify the materials based on results and feedback from participants. We will then test the effectiveness of the intervention with 450 patients with COPD. We will compare a proactive version of the intervention (peer coaches will contact patients by telephone to deliver the intervention) to a reactive version of the intervention (patients have the option of calling the peer coaches to get information about O2) and to usual care (written self-help materials).

**Projected patient outcomes:** PELICAN will address patients' attitudes and beliefs about O2, including confidence in their ability to use O2 and their understanding of the benefits of using O2 as prescribed. PELICAN has the potential to greatly improve appropriate O2 use and quality of life of COPD patients, by using a non-invasive strategy tailored to their needs.

**Link:** <http://www.pcori.org/research-results/2013/comparative-effectiveness-peer-led-supplemental-o2-infoline-patients-and>

**Project Title:** Developing Quality Metrics from Patient-Reported Outcomes for Medical Rehabilitation

**Principal Investigator:** Allen Heinemann, PhD

**Year(s) Funded:** 2013

**Project Summary:** Healthcare quality in the United States varies widely; this variation has created calls for performance improvement and provider accountability to improve care quality. The only way to know if healthcare quality is improving is to document performance using standard quality measures. Quality measures permit comparisons of how well hospitals deliver care. Quality measures are used for public reporting, quality improvement, and hospital payments. Patient-reported outcome measures (PROMs) provide a valuable information source in describing health changes during rehabilitation hospitalization. However, inpatient rehabilitation facilities rely primarily on clinician-rated outcomes, such as functional status and goal attainment- the patient's voice is not a part of hospital evaluations. However, there are major challenges to using PROMs for accountability and performance improvement, including limited use in clinical practice and uncertainty about how to aggregate PROMs for performance improvement. This proposal addresses this lack of information by identifying issues that are important to the quality of care for rehabilitation patients that could be collected as patient-reported outcomes. We will evaluate the feasibility of collecting PROMs and specify the questions that are required for quality measure development. An advisory committee of stakeholders will help guide the project; it consists of consumer advocacy organizations, patients, clinicians, and policy makers. They will provide input on valued outcomes of medical rehabilitation and patient-reported outcomes that reflect these values. The project's design includes focus groups of patients with stroke, spinal cord injury, traumatic brain injury, Parkinson's disease, multiple sclerosis, and other neurological disorders. We will administer advisory committee-selected PROMs to 300 rehabilitation inpatients and evaluate the feasibility of PROM administration, considering patient and organizational issues. This proposal fulfills PCORI's patient and stakeholder involvement, transparency, and inclusiveness goals. The project engages clinicians, patients, and caregivers; we will be prepared to disseminate results to rehabilitation stakeholders including clinicians, patients and caregivers, payers, and policy makers so as to maximize opportunities for implementation.

**Link:** <http://www.pcori.org/research-results/2013/developing-quality-metrics-patient-reported-outcomes-medical-rehabilitation>

**Project Title:** Facilitating Patient Reported Outcome Measurement for Key Conditions

**Principal Investigator:** Elliott S. Fisher, MD, MPH

**Year(s) Funded:** 2013

**Project Summary:** Background: Researchers have built many different surveys for patients to complete to show what a person's health status is, in general (e.g, physical abilities, mental health, social activities), and have also developed many different surveys to show how specific diseases impact their health (e.g, knee pain). But no one has shown how to efficiently combine patient's answers to generic and disease-specific questions to give whole-person measures of health.

**Objectives:**

**Overall goal:** To use a new model for expanding generic health surveys (in this case, PROMIS) to include condition-specific questions important to patients, in order to develop tailored surveys that work well for people with two important health problems: osteoarthritis of the knee and heart failure. **Specific**

**Aims:**

1. Collect patient and clinician views on the importance of existing and new survey questions to develop brief PROMIS Condition-Specific Impact Assessments (PROMIS-CSIA) for people with osteoarthritis of the knee and heart failure;
2. test PROMIS-CSIA with people with these conditions to learn if the survey does a good job of measuring a person's generic and condition-specific health; and
3. produce "crosswalks" from PROMIS-CSIA to commonly used condition-specific surveys for osteoarthritis of the knee and heart failure to make it possible to link the scores from one to the other.

This is like translating a measure made in inches and feet to a measure made in centimeters and meters. This is done to make sure that the PROMIS-CSIA surveys are seen as relevant and useful by patients who have these health problems. Methods: Study Population: Patients with osteoarthritis of knee and heart failure. Sample Sizes: Focus groups and interviews with about 96 patients and 24 providers and about 1,200 patients completing surveys for measurement testing and calibration.

Methods: Focus groups and interviews will be used to identify condition-specific health impacts important to patients but not covered by existing generic PROMIS questions, and to make expanded PROMIS-CSIA surveys for people with osteoarthritis of the knee and heart failure. Established techniques will be used to test whether or not the PROMIS-CSIA surveys are accurate and useful. Crosswalks will be built to link popular condition-specific survey results to PROMIS-CSIA results.

Projected Patient Outcomes:

Study Results: We will

1. demonstrate the value of using a general model to unify generic and condition-specific surveys using easy to understand scales that can be applied to many other diseases and
2. provide accurate PROMIS-CSIA surveys for osteoarthritis of the knee and heart failure to measure disease burden from the patient's viewpoint.

Importance to Patients: Accurate whole-person assessments for osteoarthritis of the knee and heart failure patients will be available to measure impact of disease, impact of treatments, and changes in health outcomes that matter to patients, over time.

**Link:** <http://www.pcori.org/research-results/2013/facilitating-patient-reported-outcome-measurement-key-conditions>

**Project Title:** Patient Priorities and Community Context: Navigation for Disadvantaged Women with Depression

**Principal Investigator:** Ellen Poleshuck, PhD

**Year(s) Funded:** 2013

**Project Summary:** Background: Socioeconomically disadvantaged (SD) women are at elevated risk for depression and poor treatment engagement and outcomes. Many use obstetric/gynecology (OB/GYN) practices as their primary resource for physical and mental health care. Yet their depression most often goes unrecognized and unaddressed within OB/GYN, and, when addressed, engagement and outcomes are poor. Patients at the greatest risk include those with multiple biomedical and psychosocial problems, trauma exposure, healthcare barriers, and experiencing a lack of empowerment over one's own health. Through our preliminary research and work with our community advisory board (CAB) consisting of patient and provider partners, we concluded many SD patients do not feel conventional depression treatments meet their needs. SD patients require interventions with outreach and support that address the problems of most concern to them.

**Objectives:** This comparative effectiveness study responds to the PCORI Addressing Disparities Funding by comparing Personalized Support for Progress (PSP) to Enhanced Screening and Referral (ESR), both recommended by our CAB. Specifically we will:

- Aim 1. Determine satisfaction among patients receiving PSP and ESR.
- Aim 2. Compare outcomes of PSP to ESR for depression and quality of life (QOL).
- Aim 3. Identify which patients are particularly likely to benefit from PSP compared to ESR.

**Methods:** We will target 200 OB/GYN patients in a practice consisting primarily of SD patients. To be included, patients must: have current depression, be an active OB/GYN patient at the identified practice, be 18 years of age or older, and not currently receiving navigation or case management. Clinic patients will be screened for behavioral health and social needs while waiting for their appointments. Patients who are eligible and agree will be assigned to ESR or PSP. In ESR, patients will receive a list of the concerns they identified and offered referrals as needed. In PSP, patients will meet with a navigator to prioritize their concerns, develop a personalized care plan based on these concerns, and execute the plan over four months. PSP navigators are lay people trained in outreach, care planning, advocacy, and support from the same neighborhoods as the patients. Patients will be evaluated for change before starting the trial, immediately following the intervention, and at three and six months follow-up. Statistical analyses will determine if there are significant differences in satisfaction and in how much patients change between the two intervention groups. Interviews will also be used to assess patient satisfaction.

**Patient Outcomes (Projected):** Depression and QOL are the outcomes identified as critical by patient partners. Our long-term objective is to establish patient-centered, effective interventions that can be used in multiple contexts to improve QOL and depression for SD patients.

**Link:** <http://www.pcori.org/research-results/2013/patient-priorities-and-community-context-navigation-disadvantaged-women>

**Project Title:** Quality of Life in Allogeneic Hematopoietic Stem Cell Transplant Patients Is Improved When Their Caregiver's Distress Is Reduced

**Principal Investigator:** Mark L. Laudenslager, BA, PhD

**Year(s) Funded:** 2013

**Project Summary:** Hematopoietic stem cell transplants (HSCT) are a treatment option for diseases of the blood such as leukemia. The patient is conditioned by removing (ablating) their blood cells, either in whole or in part by radiation and/or chemotherapy. Their cancerous blood cells are replaced (transplanted) with either some of their own blood cells that were "cleaned" and preserved (autologous HSCT) or those from a closely matched donor (allogeneic HSCT). An allogeneic transplant is an extraordinarily challenging experience for both the patient and the caregiver, who must be available 24/7 for at least the first 100 days following transplant. Not surprisingly, quality of life (QOL) of the patient is significantly reduced during this process. Caregivers also report increased stress, depression, and anxiety. Patients and caregivers represent a team in cancer survivorship with tightly woven influences. The challenges, moods, and health of one impact the other. It is our contention that if caregivers are given training that helps them build coping skills, they can better attend to patient needs and consequently patients will have improved QOL. We found that allogeneic HSCT caregivers randomly assigned to a behavioral intervention that taught coping and stress management skills were significantly less distressed (reduced stress, anxiety, and depression) compared to treatment as usual (TAU). Caregivers who refused to participate or dropped out reported feeling overwhelmed by caregiving challenges. These caregivers may actually be in greater need of support services (e.g., high distress or living in a remote area). Over 40% of the patients and caregivers lived outside of the immediate vicinity of the transplant program. The impact on the patient of the caregiver's intervention was not assessed in the initial study. We propose that patient quality of life will be enhanced by providing the caregivers with an intervention that also incorporates greater flexibility, accessibility, and ease of use. We propose to test patient outcomes associated with our caregiver intervention, which incorporates state-of-the-art

smartphone technologies and video chat meetings with the interventionist when face-to-face meetings cannot be arranged. This is a randomized controlled trial of 225 patient/caregiver dyads recruited from the only two regional sites using multiple interventionists to demonstrate overall program feasibility in preparation for wide dissemination. By enhancing the reach of this intervention with the use of state-of-the-art smartphone approaches, the QOL of more patients will be enhanced significantly because their caregivers can provide improved care that is reflected in their loved one's QOL. This relatively simple use of technology, if shown effective in reducing distress and enhancing quality of life for both the patient and caregiver, can be disseminated to other patient-caregiver dyads with other illnesses.

**Link:** <http://www.pcori.org/research-results/2013/quality-life-allogeneic-hematopoietic-stem-cell-transplant-patients-improved>

**Project Title:** Treatment Preference and Patient Centered Prostate Cancer

**Principal Investigator:** Ravishankar Jayadevappa, PhD

**Year(s) Funded:** 2013

**Project Summary:** Prostate cancer is a slow progressing and debilitating disorder that substantially limits the quality and quantity of life for millions of Americans. Due to uncertainties in outcomes, it is important that patients engage in informed decision making to choose the "optimal treatment." Patient-centered care that encompasses informed decision making can improve treatment choice and quality of care. Thus, assessing patient treatment preferences is critical for developing an effective decision support system.

**Objectives:** To test the comparative effectiveness of a conjoint analysis intervention compared to usual care and identify preferred attributes of alternative prostate cancer treatments (including active surveillance) that will aid in designing ways to help patients weigh treatment attributes. We employ values markers, to represent clusters of values for particular aspects of treatments that are valued most by individual patients. We will test if the concordance between values markers and treatment received is predictive of objective outcomes (cancer recurrence and complications) and subjective outcomes (health-related quality of life, psychological well-being, satisfaction with decision, and satisfaction with care). Study hypothesis is that a conjoint task may have an effect on treatment choice, and prostate cancer patients whose treatment is more concordant with their values markers will have improved outcomes.

**Study Design:** We propose a two-phase study design. In Phase 1, to identify the attributes, we will conduct six focus groups of prostate cancer patients and two focus groups with physicians who treat prostate cancer. Next, we will develop a conjoint task instrument using the attributes identified in focus groups and pilot test it. This task requires the patients to trade off various treatments by assessing relative importance of particular treatment attributes. Results of Phase 1 will yield a conjoint analysis instrument to identify profiles of treatment values markers and will be used in Phase 2 to determine common values markers, or profiles of treatment attributes prostate cancer patients value most. Phase 2 consists of a stratified (UPHS, Fox Chase, and PVAMC) randomized controlled trial study of 720 men with localized prostate cancer, aged = 45 and randomized to either the conjoint task intervention group or usual care control group, and followed for up to 24 months for objective and subjective outcomes. We will analyze the effect of conjoint task intervention, association between preferences (developed using the values markers obtained at baseline, pretreatment), treatment, and objective and subjective outcomes. The conjoint task we develop and test here can lead to a values-based patient-centered decision aid and help tailor treatment decision making to the values of prostate cancer patients. This will ultimately improve clinical decision making, improve clinical policy process, enhance patient-centered care, and improve prostate cancer outcomes.

**Link:** <http://www.pcori.org/research-results/2013/treatment-preference-and-patient-centered-prostate-cancer>

**Project Title:** Decision Support for Symptom and Quality of Life Management

**Principal Investigator:** Mary E. Cooley, PhD, CRNP, MSN

**Year(s) Funded:** 2012

**Project Summary:** Integration of patient values, goals and preferences for care during decisions surrounding therapy optimizes patient decision-making, especially in the context of cancer treatment. The weights placed on patient preferences for symptom and quality of life (SQL) and length of survival represent important values that must be thoroughly explored. Research shows that communication surrounding these critical values is not routinely integrated into care. While 95% of patients with cancer reported that they valued quality of life as much as length of survival, only 28% reported that changes in quality of life during treatment for cancer were discussed with their clinicians. This lack of attention to an area surrounding important patient values presents a significant target for intervention. The use of decision support for SQL assessment and management may be an innovative way to enhance patient-engagement, facilitate communication and improve patient-desired outcomes. As these types of interventions are developed and implemented, gathering input from patients and clinicians is essential to ensure that the decision support tools are optimized to enhance the process of care and influence outcomes. The proposed project builds on the past work conducted by our team related to implementing decision support for SQL assessment and management into clinical care. We have conducted the first large-scale randomized trial to examine the impact of SQL assessment with feedback and patient coaching on patient-clinician communication and the first study to develop complex decision support for simultaneous management of pain, depression, anxiety, fatigue and dyspnea. In the proposed project, we seek to adapt our approaches to new environments, which include community settings, and to optimize the delivery of SQL information. We have engaged a team composed of clinicians, patient advocates, nurse scientists, informatics and clinical decision support experts. We will engage patients and clinicians through focus groups to identify their preferences for the types of SQL information and the mechanisms for information delivery that would be generally applicable to decision support tools to improve management and outcomes of care in year 1. Based on this information, we will develop and test prototypes for SQL data provision and processing plus decision support strategies that can be used to enhance communication and management of SQL information through usability testing in year 2.

**RELEVANCE** While investigators have developed questionnaires and electronic applications for patient-report of symptoms and quality of life (SQL) concerns, no group has comprehensively studied the preferences of patients with cancer as they share SQL experiences with clinicians nor the resultant processing and management of that information on the part of clinicians. Our project addresses the PCORI area of interest related to developing, refining, testing and evaluating patient-centered approaches, which include decision support tools, for translating evidenced based care into health care settings in ways that account for patient preferences for various outcomes. We will develop and test a structure and process in which the patient's "voice" is heard as related to SQL concerns and priorities. We will systematically gather information from patients and clinicians to understand their preferences for the types of SQL information and processes for gathering it that would enhance care, and for decision support tools that would enhance management and outcomes of care. A prototype will be created to provide the foundation for a larger study to assess the impact of clinical decision support on enhancing patient-provider communication and clinical outcomes such as improved SQL management and decreased hospital and emergency room visits.

**Link:** <http://www.pcori.org/research-results/2012/decision-support-symptom-and-quality-life-management>

**Project Title:** Influence & Evidence: Understanding Consumer Choices in Preventive Care

**Principal Investigator:** Barry G. Saver, MD, MPH

**Year(s) Funded:** 2012

**Project Summary:** This project will study consumers' and Community Health Workers' reactions to the recent United States Preventive Services Task force recommendations which promote a patient-centered discussion and decision regarding mammography for women aged 40-49 and contain a draft recommendation against routine prostate cancer screening using the PSA test. Year 1 of this project will begin with (1) an exploration of consumer experience with and attitudes toward information from multiple sources, including health care providers, nonpartisan, evidence-focused organizations (e.g., the USPSTF), advocacy groups, traditional decision supports, and online and traditional media sources. Perceived credibility and influence of sources will be assessed and these findings will inform (2) development of one or more brief, "informed advocacy"- based interventions to help consumers understand the USPSTF's evidence-based recommendations related to two cancer screening tests - prostate-specific antigen testing for men aged 50-75 and mammography for women aged 40-49 years. Community health workers (CHWs) play an instrumental role in improving access to health care for vulnerable patients including those with limited English proficiency. Although this group has been shown to be effective in advocating for screening, less is known about their potential as facilitators of more nuanced discussions of screening benefits and harms. Year 1 will therefore (3) explore CHWs' attitudes toward providing messages about cancer screening tests that deviate from a purely promotional approach. Building on this work, Year 2 of the project will evaluate the interventions developed in Year 1 by: (1) assessing changes in knowledge, attitudes, and behavioral intentions, plus subsequent screening test utilization, among a sample of consumers receiving the brief interventions as compared to those receiving a more traditional, evidence-focused decision aid and (2) evaluating how community health workers deliver messages that either encourage careful consideration of a testing decision (mammography) or recommend against testing (PSA screening). We propose a project whose emphasis is understanding and supporting the ability of a patient population to engage in complex decision-making. We seek to translate evidence-based cancer screening guidelines into a comprehensible, patient-centered message with guidance from community health workers already engaged with in our communities. This is a central question for Patient-Centered Outcomes Research.

**RELEVANCE** This project addresses the mission of PCORI to help inform patient-centered choices, using as case studies two recent recommendations from the US Preventive Services Task Force whose messages deviate from the standard screening promotion and require informed discussion of potential benefits and harms. The project is based on the large body of cognitive research demonstrating that human decision-making goes beyond a careful consideration of pros and cons and is often influenced by factors that are subtle but of critical importance to the decision-maker. Our project seeks to help Americans understand why screening choices that are consistent with the best available evidence can also be consistent with their own beliefs and priorities, and we will develop and test interventions to assist this process. As an integral part of this effort, we will seek to engage community health workers, studying whether they are able to use such approaches to transmit more complex messages. By exploring these issues with vulnerable patient groups including exclusively Spanish-speaking patients, this project will provide critical information that is central to the PCORI research agenda.

**Link:** <http://www.pcori.org/research-results/2012/influence-evidence-understanding-consumer-choices-preventive-care>

**Project Title:** Patient Experience Recommender System for Persuasive Communication Tailoring

**Principal Investigator:** Thomas K. Houston, MD, MPH

**Year(s) Funded:** 2012

**Project Summary:** To maximize patient perspective and effectively support lifestyle choices, we will develop the "Patient Experience Recommender System for Persuasive Communication Tailoring." PERSPeCT is an adaptive computer system that will assess a patient's individual perspective, understand the patient's preferences for health messages, and provide personalized, persuasive health communication relevant to the individual patient. To improve the effectiveness of computer tailored health communication, we will adapt recommender systems frameworks that are widely used by innovative businesses outside of healthcare. This project is designed around three specific aims.

We propose to:

1. Collect data for the PERSPeCT machine learning recommender system;
2. Design, implement, train and validate the PERSPeCT system; and then
3. Conduct a pilot randomized trial comparing the impact of PERSPeCT versus a traditional rule-based system.

In order to provide detailed predictions and best represent individual perspectives and preferences, recommender systems make use of data from multiple, complimentary sources. Our initial concept of PERSPeCT includes information about the patients, user feedback (implicit and explicit) and information about the messages themselves.

RELEVANCE PERSPeCT addresses areas of interest for PCORI, namely:

1. Identifying, testing, and/or evaluating methods that can be used to assess the patient perspective when researching behaviors, lifestyles, and choices within the patient's control; and
2. Developing, refining, testing, and/or evaluating patient-centered approaches, including decision support tools.

The successful completion of the PERSPeCT study will move the field of computer tailored health communications forward and open the door to a variety of exciting future directions of direct relevance to the PCORI program.

**Link:** <http://www.pcori.org/research-results/2012/patient-experience-recommender-system-persuasive-communication-tailoring>

**Project Title:** Presenting Patient-Reported Outcomes Data to Improve Patient and Clinician Understanding and Use

**Principal Investigator:** Claire Snyder, PhD

**Year(s) Funded:** 2012

**Project Summary:** Background: Patient-reported outcomes (PROs), such as symptoms and quality of life, assess the impact of a health condition and its treatment from the patient perspective and are commonly included in research studies. PROs can also be used to help manage an individual patient's care. However, there are many different questionnaires that have been developed to measure PROs, and there is no standard way to score and present PRO results. Higher scores may represent better or worse outcomes depending on the measure or depending on the domain within a measure. This variation makes it difficult for patients and clinicians to understand and use the PRO results. Given PROs' potential to help clinicians and patients tailor care to a particular patient's needs, there is a critical need for research on how to present PRO data so that the results are meaningful and useful for patients and clinicians.

Objective: The study aims to:

1. Learn how current ways of presenting PRO results limit patient and clinician understanding
2. Develop new approaches for presenting PRO results to improve patients' and clinicians' ability

to use the findings

3. Evaluate how well the new approaches work in improving patient and clinician understanding and use of PRO data.

The long-term objective is to develop best practices for presenting PRO data to patients and clinicians, thereby improving the ability of patients and clinicians to make treatment decisions to meet a particular patient's needs. Methods: We propose a three-year, three-part study to test different ways of scoring and presenting PRO data. The research will be conducted through the Johns Hopkins Clinical Research Network (a collaboration of teaching hospitals and community practices), supplemented with an Internet survey of key stakeholder groups. The study will include patients who have different amounts of education to make sure the results make sense to patients across education levels. Because cancer has been a major PRO research focus, this study will be conducted in cancer patients and clinicians, though we expect the results to apply across different kinds of diseases.

In Part 1, we will interview 70 clinicians and 200 patients to (a) see how well they understand PRO data presented using existing approaches and (b) find out what they did and did not like about the existing approaches. In Part 2, we will use the Part 1 results and work with stakeholders to develop new approaches for presenting PRO data to promote understanding and use. Part 3 will be an evaluation of the approaches developed in Part 2 in more than 1,000 patients and more than 250 clinicians, both within the Johns Hopkins Network and through an Internet survey of stakeholder groups. To help us understand these evaluations better, we will also interview a subset of the subjects from Part 3. A stakeholder advisory board of patients/caregivers, clinicians, and PRO developers/researchers will inform study design, conduct, and put the results into practice.

**Link:** <http://www.pcori.org/research-results/2012/presenting-patient-reported-outcomes-data-improve-patient-and-clinician>

**Project Title:** Selection of Peritoneal Dialysis or Hemodialysis for Kidney Failure: Gaining Meaningful Information for Patients and Caregivers

**Principal Investigator:** Francesca Tentori, MD, MS

**Year(s) Funded:** 2012

**Project Summary:** Every year, more than 100,000 patients start dialysis to treat kidney failure in the United States. Two types of dialysis are available: hemodialysis (HD) and peritoneal dialysis (PD). HD is done with a machine in a dialysis clinic. PD can be done at home, if the patient or family is willing to perform his or her dialysis treatments. In general, patients survive as long on HD as they do on PD. Based on specific clinical parameters and a patient's needs, one of the two dialysis types is usually going to be a better fit for a given patient. For example, older patients may not want to be responsible for performing their own treatment, and HD may be a better fit for them. On the other hand, PD may be a better choice for patients who want to be able to travel. The challenge for patients with kidney failure is to identify the dialysis type that best fits their lifestyle. However, there is very little information regarding factors that are important to patients starting dialysis, and often patients choose a dialysis type without fully understanding how it will impact their lives. Patients and their families need more information to be able to make better decisions. PD use is much lower in the United States than in other countries, perhaps reflecting the fact that many patients are not given appropriate information regarding this type of dialysis. Given recent financial pressure on kidney doctors to treat more patients with PD, it is even more important that patients receive better information when making a decision regarding dialysis type. The goal of this study is to identify factors that matter the most to patients with kidney disease and study how they are impacted by different types of dialysis. To understand what is most important to them, we will interview more than 130 patients with kidney disease, some before and some after they start dialysis. We will compare factors reported as important across different types

of patients; for example, among men and women, or among those who work outside of the house and those who do not. Using the infrastructure of an existing study of more than 6,800 dialysis patients, we will compare factors identified during the interviews between patients treated with HD and PD. Based on these results, we will develop a Web site presenting information on kidney disease and questions on personal preferences, which will help patients understand which dialysis type is better for them. Results from our study will provide practical information regarding the choice of dialysis type to patients with kidney disease and their families. Patients who are better informed will be able to identify and choose the best dialysis type for their lifestyle and needs. Providing scientific evidence to help patients in their decision process is of great importance, especially at such a stressful time in their lives.

**Link:** <http://www.pcori.org/research-results/2012/selection-peritoneal-dialysis-or-hemodialysis-kidney-failure-gaining>

**Project Title:** A Research Agenda for Translating Disease Specific Care to Patient Goals-Directed Care for People with Multiple Chronic Conditions

**Principal Investigator:** Caroline Blaum, MD, MS

**Year(s) Funded:** 2016

**Project Summary:** Patients with multiple chronic conditions receive care that is fragmented and inefficient that often does not address what matters to them. A major cause is that the clinicians caring for a patient concentrate on their own sets of disease-specific outcomes and not on the health goals and care preferences of patients. However, very little research has focused on a key issue central to patient goals-centered care: How can clinicians translate disease-specific care into care focused on patients' health outcome goals and preferences? This two-year project will organize patients, caregivers, researchers, clinicians, policymakers and healthcare systems representatives to develop a research agenda, and network to implement it, focused on goals-directed care.

**Link:** <http://www.pcori.org/research-results/2016/research-agenda-translating-disease-specific-care-patient-goals-directed-care>

**Project Title:** Building On a Culturally-Sensitive Network for PCOR/CER Dissemination

**Principal Investigator:** Carol Connell, PhD

**Year(s) Funded:** 2015

**Project Summary:** The rural Mississippi Delta region has unique assets and disadvantages related to its culture and heritage. Favorable health outcomes are compromised by limitations in healthcare access, and economic and social well-being, among others. Delta citizens can contribute as PCORI stakeholders to developing approaches for PCOR/CER participation and dissemination that build on cultural strengths. Among those strengths is a grass-roots network that aims to reduce disparities in cancer mortality through awareness, education, and advocacy. This engagement project builds on work of the Mississippi Network for Cancer Control and Prevention to discover how PCOR is received by stakeholders through the network and other means, how network community health advisors disseminate PCOR, and how research capacity-building activities with Delta stakeholder groups strengthen their capacity for engagement in PCOR.

The projected outputs from this project are determination through focus groups of methods perceived by stakeholder groups in rural, high poverty Mississippi Delta counties to be the most effective for the dissemination and uptake of patient-centered outcomes/comparative effectiveness research findings; and increased capacity, interest in, and trust for PCOR/CER research participation by African-American Delta residents.

Project collaborators include a community health advisor; Mississippi Network for Cancer Control and

Prevention; Fannie Lou Hammer Cancer Foundation; Mississippi Delta community member participants; and the University of Southern Mississippi.

**Link:** <http://www.pcori.org/research-results/2015/building-culturally-sensitive-network-pcorcer-dissemination>

**Project Title:** By Consumers, for Consumers: Building Capacity and Partnerships to Enhance Patient-centeredness

**Principal Investigator:** Kay Dickersin, MA, PhD

**Year(s) Funded:** 2015

**Project Summary:** Patients and consumers must contribute meaningfully to research and help ensure that its results are implemented into concrete recommendations for health systems. The objective of this project is to build capacity among stakeholders for partnering with researchers and health professionals in research implementation to achieve mutual trust and long-term impact. As an experienced coalition of patient and consumer groups, Consumers United for Evidence-based Healthcare (CUE) has established methods for increasing capacity and partnerships needed in research implementation. CUE will contribute to building the patient-centered outcomes research (PCOR) community and continue development of the CUE infrastructure, particularly the engagement matching system for patients/consumers and potential stakeholder partners. With development of new learning materials for patients/consumers serving on research implementation advisory panels, this project will strengthen the groundwork for dissemination and implementation of PCOR findings.

The projected outputs from this project are expanded CUE membership and diversity; development of education and training materials, providing a forum for communication and dissemination among stakeholder groups; and facilitation of partnerships between patients/consumers and health professionals engaging in research implementation.

Project collaborators include the National Committee to Preserve Social Security and Medicare; Consumers United for Evidence-Based Health; Black Women's Health Imperative; and an Advisory Board of consumers and health professionals.

**Link:** <http://www.pcori.org/research-results/2015/consumers-consumers-building-capacity-and-partnerships-enhance-patient>

**Project Title:** Empowering Patients and Their Families to Improve Outcomes That Are Most Important to Them after Surgery and Other Therapies for Lung Cancer - Tier III

**Principal Investigator:** David Tom Cooke, MD, FACS

**Year(s) Funded:** 2013, 2015, and 2016

**Project Summary:** The aims of this Tier III Pipeline to Proposal Award are to 1) continue our Tier II goal to improve the clinical and functional postoperative lung cancer surgery outcomes self-identified as most important to patients and families, and 2) develop a comparative-effectiveness research (CER) multi-institutional study.

The aims will be accomplished through two related efforts. The first is utilizing the University of California - Davis Section of Thoracic Surgery Community Stakeholder Advisory Panel, which includes patients, family members, lung cancer advocacy group representatives, care providers, and researchers, in order to further define the general CER ideas developed during Tier II into one or two study ideas that can be protocolled. The second is using our established social media patient engagement platform #LCSM Chat (Lung Cancer Social Media Chat; lcschat.com) in order to rapidly disseminate CER ideas and preliminary information and to garner opinion, input, and recommendations on CER ideas from the greater multi-stakeholder lung cancer community.

**Link:** <http://www.pcori.org/research-results/2016/empowering-patients-and-their-families-improve-outcomes-are-most-important>

**Project Title:** Patients with Familial Hypercholesterolemia Sharing Goals and Difficult Decisions - Tier II

**Principal Investigator:** Robert C. Block, MD, MPH, FACP, FNLA

**Year(s) Funded:** 2015 and 2016

**Project Summary:** Familial hypercholesterolemia (FH) is a genetic disease of cholesterol metabolism characterized by very high levels of LDL cholesterol leading to highly premature fatal and nonfatal myocardial infarction and stroke. It affects one out of 200–500 individuals and 1.3 million people in the United States, but only 10 percent have been diagnosed. The University of Rochester has preventive cardiology/clinical lipidology programs (directed by Robert Block, MD, MPH) caring for patients with FH. Dr. Block and patients affected by FH have partnered for years with the FH Foundation, a national stakeholder focused on the diagnosis and preventive care of those affected. The University of Rochester also has a Department of Public Health Sciences containing many faculty (including Dr. Block and Scott McIntosh, PhD), students, and other staff whose goal is the conduct of research focused on enhancing population health. Patients with FH, Cat Davis Ahmed (outreach coordinator, FH Foundation), Drs. Block and McIntosh, and others with medical expertise regarding FH have formed a very active and team-based community via a Tier I project. In Tier II, they will recruit more affected patients, their family members, and stakeholders including media and other national organizations, along with those with clinical and research FH expertise. The trajectory will be a team-based, highly patient-, researcher-, and stakeholder-driven approach of generating specific future research project ideas from what was found in Tier I, including peer-supportive environments and communication pathways

**Link:** <http://www.pcori.org/research-results/2016/patients-familial-hypercholesterolemia-sharing-goals-and-difficult-decisions>

**Project Title:** What's the SCOOP? Discovering Quality of Life Outcomes that Matter to Squamous Cell Carcinoma of the Oropharynx Patients and Their Families - Tier II

**Principal Investigator:** Steven Chang, MD

**Year(s) Funded:** 2015 and 2016

**Project Summary:** The occurrence of squamous cell carcinoma of the oropharynx (SCOOP) is rapidly increasing and is predicted to outnumber cervical cancer cases in the United States by 2020. In 2012, 52,000 adults were diagnosed with head and neck cancers, composing 3 percent of all U.S. cancer diagnoses, with the majority being squamous cell carcinomas. In Tier I, we created a patient advisory council of head and neck cancer survivors and their caregivers in Michigan, which we engaged through quality improvement projects throughout the Henry Ford Health System. The council's accomplishments include helping create a post-treatment clinic for all patients so that they have clinical support. Additionally, the council has revamped the previously established new patient resource folder to be more patient centered, complete with words of wisdom and nonclinical tips for newly diagnosed patients.

In Tier II, we plan to engage our national collaborators (both researchers and stakeholders) within the cancer research network. We will recruit national SCOOP patient advisors and together will transform our comparative effectiveness research ideas into questions with the guidance of a multidisciplinary clinical and research team. Our focus will be what matters to our patient advisors and their caregivers as it relates to survivorship and quality of life.

**Link:** <http://www.pcori.org/research-results/2016/whats-scoop-discovering-quality-life-outcomes-matter-squamous-cell-carcinoma>

## Appendix: Instruments Available for Use in Assessment Center (7/10/15)

The Assessment Center Instrument Library includes instruments from PROMIS, Neuro-QoL, NIH Toolbox and Health LiTT. All instruments are available for use in data collection through Assessment Center. Most instruments are also available as PDFs that can be used for paper/pencil data collection or to facilitate data collection in other applications. To access PDFs: 1. Navigate to the Assessment Center homepage ([www.assessmentcenter.net](http://www.assessmentcenter.net)) 2. Click on the Request PDF button for PROMIS or NeuroQOL on the right hand side of the page 3. Complete brief registration to obtain an email with information on how to access PDFs 4. Check box to agree to Terms and Conditions 5. Click on link in email sent from [help@assessmentcenter.net](mailto:help@assessmentcenter.net).

PROMIS has many assessment options available to measure self-reported health for clinical research and practice. PROMIS assessment instruments are drawn primarily from calibrated item banks (sets of well- defined and validated items) measuring concepts such as pain, fatigue, physical function, depression, and social function. These calibrated item banks can be used to derive short forms (typically requiring 4-10 items per concept), or computerized adaptive tests (CAT; typically requiring 4-7 items per concept for more precise measurement). Instruments are available for adult self-report, child self-report, and parent proxy report for his/her child. Tables 1 through 4 list the calibrated PROMIS item banks or scales, item pools, short forms, and profiles. Item banks are calibrated items from which a summary score can be obtained from a subset of items (i.e. via CAT or short form) whereas scales are calibrated items from which a summary score should be obtained only from the complete set of items. Item pools are collections of related items that are not intended to produce a summary score but instead are to be used as single items. Short forms are static subsets of item banks, and profiles are fixed collections of short forms measuring multiple concepts. Table 5 lists PROMIS instruments currently under development.

Table 1: PROMIS Instruments Available in Assessment Center ([www.assessmentcenter.net](http://www.assessmentcenter.net))

Domain	Adult # items		Pediatric # items		Parent Proxy Report for Pediatric Patients # items	
	Bank/ Scale/ Pool	Short Forms	Bank/ Scale	Short Form	Bank/ Scale	Short Form
Emotional Distress – Anger	22	5	5		5	
Emotional Distress – Anxiety	29	4, 6, 7, 8	13	8	13	8
PROMIS-Cancer – Anxiety	22					
Emotional Distress – Depression	28	4, 6, 8a, 8b	13	8	13	6
PROMIS-Cancer – Depression	30					

Domain	Adult # items		Pediatric # items		Parent Proxy Report for Pediatric Patients # items	
	Bank/ Scale/ Pool	Short Forms	Bank/ Scale	Short Form	Bank/ Scale	Short Form
Applied Cognition – Abilities	33	4, 6, 8				
Applied Cognition – General Concerns	34	4, 6, 8				
Psychosocial Illness Impact – Positive	39	4, 8				
Psychosocial Illness Impact – Negative	32	4, 8				
Alcohol – Alcohol Use	37	7				
Alcohol – Positive Consequences	20	7				
Alcohol – Negative Consequences	31	7				
Alcohol – Positive Expectancies	9	7				
Alcohol – Negative Expectancies	11	7				
Fatigue	95	4, 6, 7, 8	23	10	23	10
PROMIS-Cancer – Fatigue	54					
Pain – Behavior	39	7				
Pain – Interference	40	4, 6a, 6b, 8	13	8	13	8
PROMIS-Cancer – Pain Interference	35					
Pain Intensity	3					
Physical Function	121	4, 6, 8, 10, 20				
PROMIS-Cancer – Physical Function	45					
– Mobility	16		23	8	23	8
– Upper Extremity	15		29	8	29	8
Physical Function for Samples with Mobility Aid Users	114	11				
Sleep Disturbance	27	4, 6, 8a, 8b				
Sleep-Related Impairment	16	8				
Sexual Function and Satisfaction: Global	7					

Domain	Adult # items		Pediatric # items		Parent Proxy Report for Pediatric Patients # items	
	Bank/ Scale/ Pool	Short Forms	Bank/ Scale	Short Form	Bank/ Scale	Short Form
Satisfaction with Sex Life						
Sexual Function and Satisfaction: Interest in Sexual Activity	4					
Sexual Function and Satisfaction: Lubrication	8					
Sexual Function and Satisfaction: Vaginal Discomfort	10					
Sexual Function and Satisfaction: Erectile Function	8					
Sexual Function and Satisfaction: Orgasm (uncalibrated item pool)	3					
Sexual Function and Satisfaction: Therapeutic Aids (uncalibrated item pool)	9					
Sexual Function and Satisfaction: Sexual Activities (uncalibrated item pool)	12					
Sexual Function and Satisfaction: Anal Discomfort (uncalibrated item pool)	5					
Sexual Function and Satisfaction: Interfering Factors (uncalibrated item pool)	10					
Sexual Function and Satisfaction Screener Questions (uncalibrated item pool)	3					
Satisfaction with Participation in Discretionary Social Activities (v1.0)	12	7				
Satisfaction with Participation in Social Roles (v1.0)	14	4, 6, 7, 8				
Satisfaction with Social Roles and Activities (v2.0)	44	4, 6, 8				
Ability to Participate in Social Roles and Activities	35	4, 6, 8				
Companionship	6	4				
Informational Support	10	4, 6, 8				
Emotional Support	16	4, 6, 8				
Instrumental Support	11	4, 6, 8				

Domain	Adult # items		Pediatric # items		Parent Proxy Report for Pediatric Patients # items	
	Bank/ Scale/ Pool	Short Forms	Bank/ Scale	Short Form	Bank/ Scale	Short Form
Social Isolation	14	4, 6, 8				
Peer Relationships			15	8	15	7
Asthma Impact			17	8	17	8
Global Health*	10					

\* The Global Health instrument is scored into physical and mental health summary scores.

Instruments in black are only available in English. Instruments in blue are available in English and Spanish.

Table 2: PROMIS Adult Profile Instruments Available on Assessment Center ([www.assessmentcenter.net](http://www.assessmentcenter.net))

Domain	PROMIS-29 v2	PROMIS-43 v2	PROMIS-57 v2
	# Items		
Emotional Distress – Anxiety	4	6	8
Emotional Distress – Depression	4	6	8
Fatigue	4	6	8
Pain – Interference	4	6	8
Pain – Intensity	1	1	1
Physical Function	4	6	8
Sleep Disturbance	4	6	8
Ability to Participate in Social Roles and Activities (v2.0)	4	6	8

Table 3: PROMIS Pediatric Profile Instruments Available on Assessment Center ([www.assessmentcenter.net](http://www.assessmentcenter.net))

Domain	PROMIS Pediatric 25	PROMIS Pediatric 37	PROMIS Pediatric 49
	# Items		
Emotional Distress – Anxiety	4	6	8
Emotional Distress – Depression	4	6	8
Fatigue	4	6	8
Pain – Interference	4	6	8
Pain – Intensity	1	1	1
Physical Function – Mobility	4	6	8
Peer Relationships	4	6	8

Table 4: PROMIS v1.0 Sexual Function Brief Profiles

Domain	Men (8 items)	Women (11 items)	Both Genders (skips inappropriate gender questions)
	# Items		
Interest in Sexual Activity	2	2	2
Orgasm	1	1	1
Global Satisfaction with Sex Life	2	2	2
Erectile Function	3	-	3
Lubrication	-	2	2
Vaginal Discomfort	-	3	3

Table 5: PROMIS Instruments To Be Available in 2015

Domain	Target Population
Cognitive Function v2.0	Adult
Dyspnea (Severity, Functional Limitations)	Adult
Gastro-intestinal Symptoms (Pain, Gas and Bloating, Diarrhea, Constipation, Bowel Incontinence, Gastroesophageal Reflux, Nausea and Vomiting, Disrupted Swallowing)	Adult

Domain	Target Population
Pain Behavior v2.0	Adult
Pain Quality v2.0 (Nociceptive Pain, Neuropathic Pain)	Adult
Self-Efficacy for Managing (Daily Activities, Emotions, Medications and Treatments, Social Interactions, Symptoms)	Adult
Sexual Function & Satisfaction v2.0 (Satisfaction with Sex Life, Orgasm – Ability, Orgasm – Pleasure, Oral Dryness with Sexual Activity, Oral Discomfort with Sexual Activity, Interest in Sexual Activity, Factors Interfering with Sexual Satisfaction, Anal Discomfort with Sexual Activity, Bother Regarding Sexual Function, Vulvar Discomfort with Sexual Activity – Labial, Vulvar Discomfort with Sexual Activity – Clitoral, Vaginal Discomfort with Sexual Activity, Therapeutic Aids for Sexual Activity, Sexual Activities)	Adult
Smoking (Nicotine Dependence, Coping Expectancies of Smoking, Positive Emotional and Sensory Expectancies of Smoking, Social Motivations, Negative Psychosocial Expectancies of Smoking, Negative Health Expectancies of Smoking)	Adult
Substance Use	Adult
Anger v2.0	Pediatric

Appendix: Comments received from the Information Request on End-Stage Renal Disease (ESRD) Patient Reported Outcomes and Patient Centric Measures

**President**

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Castle Rock, CO

**Forum Coordinator**

Dee LeDuc  
Birchwood, WI

June 29, 2016

RE: Information Request on End-Stage Renal Disease (ESRD) Patient Reported Outcomes and Patient Centric Measures

The Forum of ESRD Networks is pleased to offer feedback on two questions investigating the implementation of ESRD patient driven measures as requested by the University of Michigan Kidney Epidemiology and Cost Center. These comments are representative of the patient voice and perspective and were generated by members of the Kidney Patient Advisory Council (KPAC) of the Forum.

1. *What ESRD patient reported outcomes/patient centered outcome measures are meaningful to patients and health care providers?*

While it is understood that all patients are concerned with their quality of care and the clinical setting of their dialysis, there are many areas surrounding the quality of life on dialysis that may not be given adequate attention.

- Adequate, well-trained and consistent staffing availability
- Personalized care and attention
- Being treated with mutual respect and dignity
- Open and non-judgmental communication
- Anticipating patient's needs before they become critical
- Symptoms being effectively addressed
  - Pain
  - Vomiting & nausea
  - Excessive itching
  - Anxiety
  - Fatigue
  - Depression

In addition, currently there are no standards for comfort among dialysis facilities. For example, within the same LDO one dialysis facility in NV has a coffee bar, an ice chip station with flavors to add, heated dialysis chairs, iPads, Wi-Fi, and TVs with DVDs. Yet another in CA has older chairs, older TVs with 8 channels, no ice, and air conditioning/heating that doesn't work consistently. Unfortunately the facilities with lesser amenities tend to be in areas with lower socioeconomic status. We are not saying all facilities should have every amenity listed above, but there should be a minimum standard for comfort.

*2. What data may be available to support future development and testing of these measures?*

We believe that most of the data for several of the items above can be obtained from the ICH-CAHPS survey. Additionally, many of the ESRD Networks have initiated programs on topics surrounding patient centered care.

Sincerely,

*Maggie Carey*

Maggie Carey  
Chair, Kidney Patient Advisory Council  
Forum of ESRD Networks

A handwritten signature in black ink, appearing to read "D. Forfang", is placed on a light yellow rectangular background.

Derek Forfang  
Vice-Chair, Kidney Patient Advisory Council  
Forum of ESRD Networks



# Home Dialyzors United

Home Dialyzors United (HDU) is pleased to offer The University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) comments concerning its upcoming report to CMS which investigates avenues for acquiring the evidence, data and infrastructure necessary to implement ESRD patient-driven measures. We understand that UM-KECC is soliciting comments about patient reported outcomes (PROs) quality of life; patient centered outcomes (PCOs) and experience of care. HDU would like to comment on these and suggest patient driven measures.

HDU, a 501(c)(3) non-profit organization, is the only dialysis patient group dedicated to home dialysis. Our mission is to inspire, inform, and advocate for an extraordinary quality of life for the home dialyzer community. We know from personal experience that, with the right dialysis treatment, patients with ESRD (and their families and care partners) can lead a normal life, enjoying family and friends, and pursuing employment, education, volunteer, and leisure activities. We also know that studies have repeatedly shown that patients who dialyze at home have better treatment outcomes.

Despite these findings, 90% of patients who need dialysis are treated in-center, most spending three to four hours, three times per week, connected to a dialysis machine. The treatment itself can be disabling, stressing the heart and other vital organs and may contribute to premature death. Although some centers offer treatment shifts that start after 5:00 P.M., most patients must undergo their in-center treatments during the day, making it difficult to work or engage in other life activities. Patients are often discouraged from being active partners in their care. With conventional dialysis treatments, many patients live to dialyze, rather than dialyzing to live.

Bearing in mind those ideas, we would like to suggest possible new measures and to comment on several studies which can be used as a basis for implementing those measures that are meaningful to patients and health care providers.

## **Recovery Time after Dialysis**

HDU feels that recovery time after dialysis, sometimes called post-dialysis fatigue (PDF), should be considered as a patient-centered measure. We feel strongly that this measure would drive improvement in many other areas of patients' lives.

A recent study in the American Journal of Kidney Diseases (AJKD), entitled "Patient and Caregiver Priorities for Outcomes in Hemodialysis:



# Home Dialyzors United

An International Nominal Group Technique Study,”<sup>1</sup> aimed to identify and rank outcomes that are important to patients. Whereas investigators tend to choose clinical outcomes that they feel are important to maximizing life expectancy and minimizing morbidity, those priorities are seldom the same as those that patients consider to be important. The study found that while biochemical markers are simple to measure, patients are more concerned with outcomes that have an impact on their day-to-day lives and well-being.

The aforementioned AJKD study ranked the highest patient and caregiver priorities as follows:

- 1) Fatigue/energy
- 2) Resilience/coping
- 3) Travel
- 4) Dialysis free time
- 5) Impact on family
- 6) Ability to work
- 7) Sleep
- 8) Anxiety/stress

When clustered into domains, the main themes elicited are:

- 1) Maximizing the capacity to function
- 2) Being normal

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<sup>1</sup> Urquhart-Secord R, Craig JC, Hemmelgarn B, Tam-Tham H, Manns B, Howell M, Polkinghorne KR, Kerr PG, Harris DC, Thompson S, Schick-Makaroff K, Wheeler DC, van Biesen W, Winkelmayer WC, Johnson DW, Howard K, Evangelidis N, Tong A. Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group Technique Study. *Am J Kidney Dis*. doi:10.1053/j.ajkd.2016.02.037.



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Long PDF is a vivid example of deficiencies in both of these themes. Inability to function (or even stay awake) for multiple hours after each dialysis session is abnormal and clearly prevents persons with ESRD from engaging in activities of daily living at home, at work, and elsewhere. Unfortunately, long PDF is common. One survey of 550 patients found that 40% had not recovered until bedtime.<sup>2</sup> In a larger study of over 6000 patients who participated in the Dialysis Outcomes and Practice Patterns Study (DOPPS), 68% of patients required more than 2 hours to recover after treatment and 27% required more than 6 hours.<sup>3</sup>

Furthermore, PDF is a cross-cutting outcome, because it is associated not only with poor quality of life, but also with poor clinical outcomes. In the aforementioned DOPPS cohort, each additional hour of post-dialysis recovery time was associated with 5% increased risk of death and 3% increased risk of hospitalization. This strengthens the argument that recovery time after dialysis ought to be significant to clinicians, as well. After all, serum phosphorus is universally considered to be clinically significant, but that is primarily because of observational studies that show an association of phosphorus with clinical outcomes.

One of the common misconceptions about persons with ESRD is that their disease is so disabling that they cannot continue working at their current employment, and must either find alternate employment that is less demanding or stop working entirely and rely on disability benefits. However, the Medicare statute contemplates that persons with ESRD may be able to work and should be supported in their efforts to do so. Specifically, the statute says:

*(6) It is the intent of the Congress that . . . the maximum practical number of patients who are suitable candidates for vocational rehabilitation services be given access to such services and encouraged to return to gainful employment. SSA Section 1881(c)(1)(A)(i)(6)*

Although it is true that persons with ESRD *may have disabilities*, it does not follow that they are, in fact, *disabled*. Unfortunately, it is too often the treatment modality that is disabling. First of all, it is difficult to work during normal business hours if the person has to go to in-center treatment

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<sup>2</sup> Caplin B, Kumar S, Davenport A. Patients' perspective of haemodialysis-associated symptoms. *Nephrol Dial Transplant Off Publ Eur Dial Transpl Assoc - Eur Ren Assoc.* 2011;26(8):2656-2663. doi:10.1093/ndt/gfq763.

<sup>3</sup> Rayner HC, Zepel L, Fuller DS, et al. Recovery time, quality of life, and mortality in hemodialysis patients: the Dialysis Outcomes and Practice Patterns Study (DOPPS). *Am J Kidney Dis Off J Natl Kidney Found.* 2014;64(1):86-94. doi:10.1053/j.ajkd.2014.01.014.



# Home Dialyzors United

three times a week. As delineated above, often the traditional treatment is sufficiently intense that the post-treatment recovery may take hours. In fact, the Social Security Administration recognizes ESRD requiring frequent dialysis as a possible qualifying condition for Social Security Disability Insurance (SSDI).

HDU would argue forcefully that initiating a measure of recovery time after dialysis/post dialysis fatigue would address not only employment and sleep but also the other top patient priorities. Patients who are not fatigued following treatment are able to travel, interact with family and work and are less anxious and depressed. In addition, the dialysis-free time is available for patients to lead a normal life, rather than spending that free time simply recuperating from dialysis. “Post Dialysis Fatigue: A Frequent and Debilitating Symptom,” a recent review in by Maurizio Bossola and Luigi Tazza in *Seminars in Dialysis*, also addressed the decreased quality of life in the vast number of patients who experience PDF. The review concluded that PDF is one of the most common and most debilitating problems associated with short thrice-weekly dialysis.

Measuring recovery time after dialysis would also be simple and take relatively little effort thereby minimizing staff burden. DOPPS has demonstrated that a very simple question can generate answers that correlate strongly with clinical outcomes and QOL. “How long does it take you to recover from dialysis?” has been shown to be easily interpreted, to elicit clear and simple answers, and to have stability?

## **Recommendations and Conclusion**

HDU recognizes that the addition of too many quality measures may dilute the intent of the QIP. Therefore, we recommend that any measures that are topped out or ones that are no longer effective be replaced by measures that truly matter to patients.

HDU supports the proposals in the QIP to continue including pain assessment and depression screening as reporting measures. However, we continue to believe that these measures need to be further developed, to ensure that the assessment looks at the psychosocial and quality of life issues that may contribute to the patient’s depression or pain, and that appropriate follow-up steps are taken to help relieve the depression and pain. Because home dialysis has been shown to improve patient scores in these areas, it is critical that follow-up include an assessment of the patient’s interest in home dialysis and assistance with moving to home dialysis if that is the patient’s wish. Presently, the QIP is still a long way from ensuring that patients get high quality care that provides them with an optimal quality of life, based on their values.



# Home Dialyzors United

In conclusion, HDU would make a recommendation to investigate the use of the following patient centered outcome:

Adoption of a recovery time after dialysis measure would hopefully encourage centers to offer lifestyle friendly modalities that allow patients and their families to live normal lives.

Home Dialyzors United is available at any time to offer further input to the UM-KECC and thanks the Center for the opportunity to provide these comments.

Sincerely,

Home Dialyzors United

Denise Eilers, BSN, RN (& former HHD care partner)

President, HDU Board of Directors

## References

- [1] Urquhart-Secord R, Craig JC, Hemmelgarn B, Tam-Tham H, Manns B, Howell M, Polkinghorne KR, Kerr PG, Harris DC, Thompson S, Schick-Makaroff K, Wheeler DC, van Biesen W, Winkelmayer WC, Johnson DW, Howard K, Evangelidis N, Tong A. Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group Technique Study. *Am J Kidney Dis*. doi: 10.1053/j.ajkd.2016.02.037.
- [2] Caplin B, Kumar S, Davenport A. Patients' perspective of haemodialysis-associated symptoms. *Nephrol Dial Transplant Off Publ Eur Dial Transpl Assoc - Eur Ren Assoc*. 2011;26(8):2656-2663. doi:10.1093/ndt/gfq763.
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- [4] Bossola M, Tazza L. Postdialysis Fatigue: A Frequent and Debilitating Symptom. *Semin Dial*. 2016;29(3):222-227. doi:10.1111/sdi.12468.



June 30, 2016

Joseph Messina, MD  
Director  
The University of Michigan Kidney Epidemiology and Cost Center  
1415 Washington Heights, Suite 3645 SPHI  
Ann Arbor, MI 48109-2029

RE: Information Request on End-Stage Renal Disease (ESRD) Patient Reported Outcomes and Patient Centric Measures

Dear Dr. Messina:

The Renal Physicians Association (RPA) is the professional organization of nephrologists whose goals are to ensure optimal care under the highest standards of medical practice for patients with kidney disease and related disorders. RPA acts as the national representative for physicians engaged in the study and management of patients with kidney disease. Additionally, RPA has served as a lead physician-level measure developer for the past decade. We are writing to provide responses to the questions on the Information Request on End-Stage Renal Disease (ESRD) Patient Reported Outcomes and Patient Centric Measures posed by KECC.

**1. What ESRD patient reported outcomes/patient centered outcome measures are meaningful to patients and health care providers?**

RPA recognizes the paucity of existing kidney-disease specific patient reported or patient centered outcome measures. Among existing measurement systems, there may be measures that could be adapted for kidney patients, as outlined below. However, RPA believes that there must be a dialogue with patients to determine what issues pertaining to measures are important to them. For example, patients should be queried about the burden of the continual focus on illness rather than on health and asked how their ability to maintain economic stability is compromised by their health problems (i.e., Is the workplace accommodating? Are they feeling too ill to work fulltime or part time? Do they feel better or worse after visiting with the doctor? Does the doctor calm their fears?) After engaging in this collaborative dialogue measure developers can then determine what areas of patient concerns have enough evidence to support performance measures and what concerns need further study or can be measured using evidence based surrogates.

## *PROMIS*

In the Patient Reported Outcomes Measurement Information System (PROMIS), the following areas are of particular relevance to kidney patients:

1. Overall symptom burden
2. CKD uncertainty
3. Fatigue
4. Depression
5. Anxiety
6. Mobility
7. Peer relationships
8. Specific symptoms for CKD patients
  - a. Pain
  - b. Itching
  - c. Skin changes
  - d. Loss of appetite
  - e. GI symptoms (nausea, vomiting)
  - f. Shortness of breath
  - g. sleep disorders
  - h. restless legs and
  - i. sexual dysfunction

In addition, it is appropriate to include questions related to the patient's ability to do usual daily activities (e.g., dressing, eating, undressing, etc.).

## *McGill*

Another option is for patients to self-report of quality of life using the single-item question from the McGill<sup>1,2</sup> quality of life scale.

*Considering all parts of my life-physical, emotional, social, spiritual, and financial-over the past two days the quality of my life has been: 10 point Likert scale with 0 being very bad and 10 being excellent.*

## *Manns*

RPA recommends KECC review the 10 questions for research priorities of patients in Table 3 in the attached article by B. Manns et al<sup>3</sup> for additional ideas on high priority patient-driven measures.

- 2. What data may be available to support future development and testing of these measures?**

Patients are concerned about issues at a different level than nephrologists, as a specialty, appreciate. RPA believes that it is time that we encourage, support and/or facilitate kidney patients' ability to select their own measures based on their own priorities; in other words, true patient-engagement and empowerment. Developing robust measures based on patient-reported outcomes will require asking a broad population of patients what is most important to them and not relying on the opinions of "experts".

RPA also believes that its Kidney Quality Improvement Registry, a CMS-approved qualified clinical data registry (QCDR) may provide a means for supporting and testing patient reported/patient centered outcome measures.

As always, RPA welcomes the opportunity to work collaboratively with KECC in its efforts to improve the quality of care provided to the nation's kidney patients, and we stand ready as a resource to KECC in its future endeavors. Any questions or comments regarding this correspondence should be directed to RPA's Director of Public Policy, Rob Blaser, at 301-468-3515, or by email at [rblaser@renalmd.org](mailto:rblaser@renalmd.org).

Sincerely,



Rebecca Schmidt, DO  
President

**References:**

1. Cohen SR, Mount BM, Strobel MG, Bui F: The McGill Quality of Life Questionnaire: A quality of life measure appropriate for people with advanced disease. A preliminary study of validity and acceptability. Palliat Med 9:207-219, 1995.
2. Kimmel PL, Emont SL, Newman JM, Danko H, Moss AH. ESRD Patient Quality of Life: Symptoms, Spiritual Beliefs, Psychosocial Factors, and Ethnicity. Am J Kidney Dis 42(4): 713-721, 2003.
3. Manns B, Hemmelgarn B, Lillie E, Dip SC, Cyr A, Gladish M, Large C, Silverman H, Toth B, Wolfs W, Laupacis A: Setting research priorities for patients on or nearing dialysis. Clin J Am Soc Nephrol 9: 1813–1821, 2014.

To: Joel Andress, PhD  
Centers for Medicare & Medicaid Services  
University of Michigan Epidemiology and Cost Center

Date: June 30, 2016

RE: CMS Technical Expert Panel (TEP) Request for Information on ESRD Patient-Reported Outcomes Quality of Life, Patient Centered Outcomes, and Experience of Care Measures

The National Renal Administrators Association (NRAA) is a voluntary organization representing dialysis providers throughout the United States. Our membership primarily includes small for-profit and not-for-profit providers serving patients in urban, rural, and suburban areas in both free-standing and hospital-based facilities. We strongly support CMS efforts to improve quality of care and patient outcomes for Medicare beneficiaries with End-Stage Renal Disease (ESRD) and appreciate the ongoing recognition by CMS of the unique challenges posed to small and medium facilities providing high quality care to this vulnerable patient population.

The NRAA welcomes the opportunity to comment on the Technical Expert Panel request for information on patient-reported outcomes (PROs) quality of life, patient centered outcomes (PCOs), and experience of care measures for ESRD patients. Our comments below suggest potential measures for assessing improvement in quality of life and patient outcomes, as well as describe important principles that any measure in these areas must follow.

**Potential Measures:** We recommend that the TEP consider measures that show clear and demonstrable changes in improvement in patient quality of life and patient-reported outcomes.

1. **Return to work:** An adult measure for the non-retirement age population could assess whether the individual is able to return to work. Such a measure clearly would demonstrate increased patient function in ability to perform meaningful daily tasks, representing an improved quality of life and health outcome for the patient.
2. **Return to school:** A pediatric measure could evaluate whether the patient is able to return to school. Similar to the proposed adult measure, this measure would represent a discernible improvement in patient function and ability to perform meaningful daily tasks.
3. **Kidney transplant:** A measure for both patient populations could assess the percentage of patient eligible for a kidney transplant compared with the percentage of eligible patients that actually received such transplant. Eligible patients on dialysis clearly would achieve a meaningful improvement in quality of life and an improved patient-reported outcome if they received kidney transplants.

**Principles:** The NRAA recommends the following key principles for any measures assessing PROs, PCOs, and experience of care measures for ESRD patients.

1. **Small improvements are meaningful in the ESRD patient population:** We strenuously urge the TEP to recognize in the measurement development process that even slight changes in patient function and ability to perform limited tasks can represent significant improvement in quality of life and patient outcomes for this very sick and vulnerable patient population. Hence, we strongly urge that the TEP recognize small, incremental changes in improvement on these measures as sufficiently meaningful to achieve an acceptable level of performance on these measures.

2. **All measures should meet reliability and validity tests:** Patient-reported outcome, quality of life and experience measures in certain instances have not met standard reliability and validity tests. Such criteria are necessary to ensure that CMS assesses facilities appropriately and fairly on the quality of care they provide to patients. Without reliable and valid data, CMS cannot reasonably determine whether a facility satisfies any PRO, PCO or patient experience measure criteria.
3. **Risk adjustment should apply to all patient outcome and quality of life measures:** Lack of appropriate risk adjustment could encourage facilities to “cherry pick” the healthiest patients and discourage facilities from accepting the sickest patients who require the most care. Hence, the NRAA strongly urges that CMS risk adjust these measures to ensure all patients continue to have access to and benefit from high quality care.
4. **Measures should be based on data currently accessible and not require additional surveying of patients:** We strongly urge the TEP only to consider measures for which data are currently available, for example through CROWNWeb, Medicare administrative claims data, or the CMS ESRD Medicare entitlement and registration form (the CMS 2728 Form). ESRD patients already experience frequent surveys through individual facility quality assessment surveys and the In-Center Hemodialysis Consumer Assessment of Healthcare Providers and Systems (ICH CAHPS) survey. Patients anecdotally have reported survey fatigue. Moreover, administering surveys frequently poses challenges for facilities and providers, particularly for small facilities. Hence, we strongly recommend that patient-reported outcome and quality of life measures derive from data already collected and available.
5. **All proposed PRO, PCO, and experience measures should go through the National Quality Forum (NQF) endorsement process:** The NQF uses its Consensus Development Process to evaluate and endorse consensus standards on performance measures. The process asks for valuable stakeholder input and carefully considers stakeholder interests across the healthcare community. PRO and PCO measures for the ESRD population would benefit from stakeholder feedback and, consequently, the NRAA strongly urges that any measures developed go through the NQF endorsement process.

In conclusion, the NRAA appreciates the opportunity to comment on the development of quality of life and patient outcome measures for the ESRD population. We strongly support CMS’s goal of seeking to improve quality of care and health outcomes for these very vulnerable patients. We look forward to continuing work with the Agency in achieving this very important work. If you have any questions, please do not hesitate to contact Marc Chow at [mchow@nraa.org](mailto:mchow@nraa.org) or 215.564.3484 (ext. 2294).

Sincerely,



Helen Currier  
President



June 30, 2016

Joseph Messana, M.D.  
UM-KECC  
1415 Washington Heights  
Suite 3645 SPHI  
Ann Arbor, MI 48109-2029

Dear Dr. Messana,

On behalf of Kidney Care Partners (KCP), I want to thank you for the opportunity to respond to questions that UM-KECC has posed related to patient-reported outcomes measures (PROMs). As we discussed this morning, we look forward to working with you and your team as UM-KECC prepares the white paper requested by CMS. This letter sets forth our written answers to the questions on which you requested comments.

## **I. Adoption of Guiding Principles**

Since the creation of the Kidney Care Quality Alliance (KCQA), KCP has supported the development of quality measures and linking payment to performance. In our work, we identified a set of [guiding principles](#) that should be followed when developing any type of measure. In particular for PROMs we highlight the following principles:

- Be patient-centered.
- Reflect patient values and needs.
- Allow for appropriate variations in individual patient care regimens.
- Be equitable and ensure that sicker patients continue to receive high quality care.
- Be consistent with the patient-physician relationship, as well as the relationship between patients, providers, facilities, and other health care professionals.
- Reflect an array of aspects of care.
- Encourage improved quality and effective practices.
- Focus on improving the safety, effectiveness, and efficiency of care.
- Be public to ensure integrity and allow for understanding of reported data by patients and their families.
- Produce consistent and credible results.
- Be reliable, valid, precise, based on sound scientific evidence, and predictive of overall quality performance.
- Be standardized, transparent, explicit, and measurable.

- Be based on standardized definitions, technical specifications, and methodologies.
- Allow for mastering benchmarks and demonstrating improvement.
- Facilitate meaningful comparisons at the facility-level and be risk adjusted or risk stratified when appropriate.
- Be based on KCQA's prioritization of the Blueprint's domains/subdomains.
- Be based on a strong consensus.

These principles are consistent with those the National Quality Forum (NQF) has set forth in its report on PROMs.

- Conceptual and measurement model documented
- Reliability
- Validity
- Interpretability of Scores
- Burden
- Alternative modes and methods of administration
- Cultural and language adaptations
- Electronic health record capability

## II. Response to UM-KECC Questions

### ***1. What patient reported outcomes/patient centered outcome measures are meaningful to patients and health care providers?***

There are very few validated PROMs in the ESRD space. The ICH-CAHPS for ESRD and the KDQOL instruments are two examples of PROMs that are in use today.

**ICH CAHPS:** KCP believes that it is critically important to evaluate patients' experiences when receiving dialysis. The current ICH CAHPS survey is one tool that if adjusted could be considered for a PROM, but as currently designed and implemented in the ESRD Quality Incentive Program (QIP) it is burdensome for the patients and the dialysis facilities.

The complete survey contains 56 questions and requires the patients to answer all of the questions in a single setting. The length can be very taxing on patients who are battle kidney failure and trying to maintain as normal a life as possible. The Agency for Healthcare Research and Quality (AHRQ) also understood this concern and conducted validity and reliability testing for the survey in total, as well as in three independent sections, to allow providers to divide the survey among different patients and reduce the burden.

In addition to the burden on patients, there is also the administrative burden

on facilities, as the measure is currently implemented in the ESRD QIP. In this program, facilities must administer the survey twice each year, rather than once a year as others have recommended. The American Institutes for Research/RAND *et al* have described in detail the difficulties in translating the results from ICH CAHPS into interventions resulting in meaningful improvement when administered more frequently than once a year.<sup>1</sup>

**KDQOL:** PROMs may also focus on quality of life (QOL) and functional status. These patient-reported outcomes can be measured for individual patients through standardized instruments, such as the Kidney Disease Quality of Life Survey (KDQOL) or the Short Form Health Survey (SF-36). We also note that KDQOL was originally validated on 165 patients in 1997.<sup>2</sup> As dialysis patients are known to have a different disease burden today than 17 years ago, we believe the instrument should be validated and modified as necessary just as other clinical measures are, in a larger, more contemporary dialysis population. Moreover, while the KDQOL is useful as a tool to assess individual patients, it does not adequately identify patients' underlying goals and values that would permit a truly patient-centered approach to improving QOL; additional research and development in this area could improve care plans, QOL, and patient satisfaction and experience with care.

It is also important to recognize the distinctions among satisfaction, functional status/QOL, and patient engagement in the context of PROMs. Engagement in a patient's own care is still a very difficult thing to measure despite concepts like the Patient Activation Measure.

## ***2. What data may be available to support development and testing of these measures***

As noted above, we believe that additional research needs with regard to the KDQOL to identify patients' goals and values to make sure the instrument is patient-centered, as well as to validate the measure.

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<sup>1</sup> See, American Institutes for Research, RAND, Harvard Medical School, Westat, Network 15. Using the CAHPS® In-center Hemodialysis Survey to Improve Quality: Lessons Learned from a Demonstration Project. Rockville, MD: Agency for Healthcare Research and Quality. December 2006.

<sup>2</sup> Mayne T, Dunn D, Marlowe G, Schatell D. Revalidation of the Kidney Disease Quality of Life Questionnaire (KDQOL). Davita, Inc. Denver, CO; MEI, Madison, WI. Abstract presented at ASN's 2010 Renal Week. <https://www.asn-online.org/>. Last accessed January 16, 2014.

### III. Conclusion

Again, KCP appreciates the opportunity to provide comments in response to the questions UM-KECC has raised. We also look forward to finding a way to collaborate as KCP pursues its work on PROMs as well. If you have further questions, please do not hesitate to contact Kathy Lester at [klester@lesterhealthlaw.com](mailto:klester@lesterhealthlaw.com) or (202) 534-1773.

Sincerely,



Frank Maddux, M.D.  
Chairman  
Kidney Care Partners

cc: Claudia Dahlerus, Ph.D., M.A.  
Jordan Affholter  
Elena Balovlenkov, R.N.  
Joel Andress, Ph.D.

July 7, 2016

Joseph Messina, MD  
Director  
The University of Michigan Kidney Epidemiology and Cost Center  
1415 Washington Heights, Suite 3645 SPHI  
Ann Arbor, MI 48109-2029

RE: Information Request on End-Stage Renal Disease (ESRD) Patient Reported Outcomes and Patient Centric Measures

Dear Dr. Messina:

On behalf of the American Society of Nephrology (ASN), thank you for the opportunity to input regarding End-Stage Renal Disease (ESRD) patient-reported outcomes and patient-centric measures. ASN represents nearly 16,000 physicians, scientists, nurses, and other health professionals dedicated to treating and studying kidney diseases to improve the lives of people with kidney diseases. ASN is a not-for-profit organization dedicated to promoting excellence in kidney care. Foremost among the society's concerns is the preservation of equitable patient access to optimal quality chronic kidney disease (CKD) and end-stage renal disease (ESRD) care and the integrity of the patient-physician relationship.

ASN appreciates UM-KECC and the Centers for Medicare and Medicaid Services (CMS) interest in investigating avenues for acquiring the evidence, data, and infrastructure necessary to implement ESRD patient-driven measures. The society believes that developing patient-reported outcomes (PROs) quality of life, patient-centered outcomes (PCOs) and experience of care, and other measures that are patient driven are all particularly important areas of focus for CMS to prioritize.

While ASN sincerely appreciates the opportunity to provide comment on this effort, and hopes its input is helpful, the society also urges UM-KECC and CMS to solicit direct input from patients with kidney disease on dialysis as well as who have received a transplant at this and other stages of this important initiative.

Currently, metrics in the nephrology space—including many of the metrics in the ESRD Quality Incentive Program (QIP)—are, for the most part, not patient-focused. From the patient's perspective the most important thing is quality of life and reaching their goals related to health and quality of life. For the provider, measures that facilitate or uncover opportunities for important quality improvement efforts to impact patient-centered/important outcomes are the most useful.

Limiting the number of metrics in any quality assessment program to a manageable size and focusing on high-level, outcome metrics that are meaningful from a patient perspective will lessen the burden on providers and healthcare delivery systems. This focus permits concentration on caring for the patient, understanding the needs of individual patients and

improving care—not concentrating efforts on succeeding within the boundaries of the system—thus having a greater effect on overall patient-centered outcomes.

As health care delivery transforms into a more patient centered model, outcomes that impact the patient experience with kidney disease and an individual's quality of life will assume more importance in clinical practice. Here, ASN presents concrete examples of specific areas the evidence suggests are highly valued by patients. Again, the society reiterates that engagement of patients and their families to identify and prioritize the areas of greatest need for patient-centric metrics will be imperative.

Presently, research on this topic is in its infancy. Most of the data collected thus far have focused on "hard" clinical outcomes: cardiovascular events, time to dialysis, and death. These outcomes are of course important to patients. However, emerging palliative care literature in nephrology suggests that patients also care about other outcomes, particularly in symptom control. However, the early evidence base provides several suggestions of clinical outcomes that are valued by patients. ASN encourages UM-KECC and CMS to consider and explore the evidence base and evaluate opportunities to develop measures in these areas:

- Experience of care/engagement: Experience of care metrics should focus on the ultimate goal of enabling patients to be successful in managing the burden of their chronic disease the added burden of the other co-morbidities that often accompany CKD/ESRD. Patients have told us they have essential needs that must be addressed in order for them to be successful managing their disease. Meeting these needs, particularly during transitions of care or transitions throughout the trajectory of chronic disease is essential to success. An important element is facilitating the patients' understanding that they are truly equal partners in the multidisciplinary team, and have meaningful input into decisions that affect them.

Currently the communication and care coordination measures reflect documentation that a discussion or decision regarding aspects of care was made, but the measures do not reliably reflect patient-focused communication or patient engagement in decisions. A measure should be developed to better reflect shared decision-making and effective communication between the patient and the care team. Aspects such a measure would ideally help to reflect include:

- Open and Honest Communication (transparency)
  - Shared Decision Making (Non-paternalistic discussion between the patient and the care team around goals within the community.)
  - Collaboration & Empowerment (Effectively exchanging information to set up mutual understanding and success for the entire community.)
  - Improved Education Intervals and Interpretation (Real-time information that has a tighter feedback loop translated on the patient level to gain maximum usability of information.)
- Symptom management: Pain, fatigue, insomnia: Many patients with advanced kidney disease experience untreated pain. Providers are often afraid to provide proper pain management, or not educated on the topic. Pain level has obvious impact on quality of life. Patients also often have disrupted sleep cycles and suffer from poor sleep quality or insomnia. This insomnia has a direct influence on ability to function in day to day activities. Besides pain management, symptom management also includes aspects

such as pain control and mild uremia symptoms like poor appetite, poor energy, nausea, and itching

- Emotional Support/Symptoms: Anxiety/depression/caregiver support: Anxiety and depression are highly prevalent in this patient population and should be appropriately managed with both pharmacological and non-pharmacological treatment. Caring for a multi-morbid patient often is an extreme burden on caregivers and these individuals can use support.

The psychiatric morbidity that occurs with kidney disease, for some patients, also includes depression and suicide. Patients may also experience social difficulties, including the financial burden that kidney disease exerts on them.

- Prognostic information: Dialysis patients report wanting to know their prognosis, but in studies on this topic, very few have had such conversations with their providers. Such a conversation could allow for planning and for upstream conversations about advance care planning.
- Proper end of life care planning: The gold standard of End-of-life care is hospice enrollment and access to palliative care. Every patient with serious illness, including advanced kidney disease, deserves access to palliative care. Despite these standards, very few patients receive this care.
- Intensity of care at the end of life: Many dialysis patients experience aggressive procedures during the month before death. This would be optimal time to introduce hospice services and allow for more peaceful and natural deaths, if this is in keeping with the patient's values.
- Prevention of CKD progression: Many patients highly prioritize avoiding dialysis.
- More access to transplant: Greater access to transplantation would also eliminate going on dialysis or remaining on dialysis, providing greater quality of life and hope.
- Location of residence and whether a patient can live at home (versus an institutional setting such as a nursing home)
- Functional Status: This category would include the ability to ambulate, exercise capacity, ability to perform ADLs, etc.
- 

There are many QIP metrics that assess *risk* of death and need for hospitalization, but the ultimate measures of importance for many patients' are mortality and hospitalization—and thus far those measures have not yet been implemented. Such metrics may enable providers/healthcare delivery systems to dig deeper to uncover the most impactful care processes to improve. ASN recognizes that work is underway to develop, refine, and implement measures in these arenas. As the society has addressed in previous comments to UM-KECC and CMs, finalizing the following measure types would be an important step towards reflecting the ultimate goal of survival for patients:

1. Appropriately risk adjusted hospitalization ratio
2. Appropriately risk adjusted 30 day readmission ratio
3. Appropriately risk adjusted mortality ratio

Importantly, ASN encourages excluding from the mortality ratio patients who die due to withdrawal from dialysis or death in hospice as these are often patient-centered decisions.

In terms of the data being collected, ASN encourages UM-KECC to consider the following resources and data sources:

- Shilipak, et al. Observational Research Databases in Renal Disease, JASN December 1, 2005 vol. 16 no. 12 3477-3484  
(<http://jasn.asnjournals.org/content/16/12/3477/T1.expansion.html>)
- MDS: Minimal dataset, CMS administrative data on Skilled Nursing Facilities)
- In-Center Hemodialysis-CAHPS

Again, thank you for the opportunity to comment on this important area of focus. ASN appreciates UM-KECC and CMS's commitment to exploring the best opportunities to develop patient-focused measures and your to engage the society and other stakeholders. ASN would be pleased to discuss these comments if it would be helpful and stands ready to assist in any way; please contact ASN Associate Director of Policy and Government Affairs Rachel Meyer at (202) 640-4659 or at [rmeyer@asn-online.org](mailto:rmeyer@asn-online.org).

Sincerely,

John R. Sedor, MD, FASN  
Chair, Public Policy Board  
ASN Secretary-Treasurer

Comment from kidneyhelp@uarts.com:

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

I am writing in response to your request for feedback on the following patient-centered issues:

1. What ESRD patient reported outcomes/patient centered outcome measures are meaningful to patients and health care providers? 2. What data may be available to support future development and testing of these measures?

For the past year I have been involved with an unique, international consortium of medical researchers, nephrologists, kidney patients and their caregivers to develop universal criteria for standardizing research outcomes in nephrology trials; It's know by the acronym SONG (standardized outcomes in nephrology).

The first of four planned studies focused on hemodialysis. It's based on the precept that patient-centered care involves shared decision making, which takes into account patients' priorities and values as well as the biomedical goals of the clinician. SONG-HD is a five-phase, multi-method project that includes systematic reviews, focus groups, semi-structured interviews, Delphi surveys with best-worst/choice experiments, and a consensus workshop.

The alarming number of new patients who begin dialysis annually has led to a plethora of studies. The Cochrane Renal Group Specialised Register shows that from 2004 to 2014, there were 1,500 randomized, controlled trials in hemodialysis. Yet there has been very limited improvement in clinical, quality-of-life and mortality outcomes for dialysis patients. In 2014, the Lancet reported that 85% of the \$240 billion expended on health research in 2010 was wasted because of problems in the design, conduct, analysis and reporting of research, much of which ignored patients non-medical needs.

Most findings from these studies aren't meaningful for patients, because patients were not included in their planning. Researchers from academia and industry typically define the outcomes, largely in biomedical values. Patients, on the other hand, have different priorities, to which the SONG-HD (hemodialysis) Initiative gives equal consideration. Patient-desired outcomes can include empowerment, independence, social acceptance, concerns for family and care partners, normality, free time from dialysis, and freedom to travel.

The SONG Initiative takes its cue from the success of the Outcome Measures in Rheumatology (OMERACT) initiative which began in 1992. OMERACT outcomes have improved the reporting and relevance of outcomes in rheumatology trials and its methodology has been applied successfully in cancer, middle ear infection, eczema, and chronic pain. Both the World Health Organization and the U.S. Food and Drug Administration have endorsed OMERACT outcomes. And in 2010, the international Core Outcome Measures in Effectiveness Trials (COMET) organization was launched to facilitate the development and application of core outcome sets.

Core outcome sets represent the minimum that should be measured and reported in all clinical trials for a specific condition; however, they are not meant to be definitive. The intention is that the core outcomes be collected and reported to allow the results of trials and other studies to be compared, contrasted, and combined as appropriate; researchers are at liberty to collect and explore other outcomes. A core outcome set does not exist for CKD.

Approximately 200+ patients and caregivers and 1,000 health professionals (nephrologists, surgeons, nurses, allied healthcare professionals, researchers, policy makers and people from industry), took part in the three rounds of the SONG-HD Delphi survey. There was a similar proportion of males and females, and a wide range of ages (18 years to over 81 years). Round 1 participants were from 73 countries and began by ranking 34 desired HD outcomes on a scale of 1 (least important) to 9 (critical). In Round 2, five outcomes with medians <7 were excluded, leaving 29 to rank. In Round 3, nine outcomes with a median <7 were excluded, leaving 20 to rank. Outcomes that were removed are still important—but not of critical importance to both patients and health professionals.

The published results (see footnotes) showed a wide gap between patient/care partner preferences and those of the healthcare professionals. While dialysis adequacy, ability to travel and vascular access problems, fatigue, and dialysis-free time topped the patient list, healthcare professionals rated vascular access problems, death/mortality, cardiovascular disease, drop in blood pressure and ability to work as their top five. Only vascular access problems were common to both top five rankings. Ability to travel, #2 on the patient/care partner ranking, was at the bottom of the healthcare pro's ranking; Death/mortality was on top of their list, but ranked only 11th on the patient list. Hospitalization was 6th on the healthcare ranking, yet second to last (19th) on the patient list.

I can't say I was surprised by the overall rankings of the healthcare professionals. Nephrology practice in the U.S. has been guided largely by biomedical markers for decades, as doctors have less and less daily contact with their patients, and rarely see them when they are on dialysis. Patients too often tend to become numbers on a monthly lab chart.

However, I was very pleasantly surprised by the deference the healthcare professionals showed toward the patients in the consensus workshop I attended in November, 2015 in San Diego, CA, which followed the three-phased Delphi study. They were genuinely interested in our opinions and eager to learn from us. Many doctors indicated in personal conversations afterward that they were tired of repeatedly poor patient outcomes in their practices and were looking for a better approach with the patient as a full member of the healthcare team.

I feel strongly that the SONG-HD Initiative has broken through an invisible barrier which for too long has relegated patients to victim status, rather than consumers of healthcare. Or, put more correctly, people who have kidney failure, with the emphasis on "people." When we change that mindset—and SONG-HD does—we have a fighting chance of saving more lives and taking dialysis practice from adequate to rehabilitative.

Thank you for the opportunity to comment on this most important project.

David L. Rosenbloom

1 Tong, A. et. al. "Standardised outcomes in nephrology – Haemodialysis (SONG-HD): study protocol for establishing a core outcome set in haemodialysis," BioMed Central, Trials 201516:364, DOI: 10.1186/s13063-015-0895-7,19 August 2015.

2 Craig,J., et. al., "Patient and Caregiver Priorities for Outcomes in Hemodialysis: An International Nominal Group Technique Study," IJ KD, DOI: <http://dx.doi.org/10.1053/j;ajkd;2016;02;037>, March 8, 2016.

David L. Rosenbloom

Patient Advocate/Educator - Kidney Dialysis & Transplantation

ESRD Network 18 - Board of Directors, Medical Review Board  
& Chairman, Patient Advisory Committee  
Steering Group, SONG-Tx Initiative  
Patient Advisory Board, NxStage Medical Inc.,  
Kidney Advocacy Committee, National Kidney Foundation

Email: [kidneyhelp@uarts.com](mailto:kidneyhelp@uarts.com)

Twitter: @allseasonsman & @hdunews

Tel: 323-354-4594

Mobile: 323-810-7819

Comment from bfletcher@usrenalcare.com:

Good Day,

Just one suggestion: dialysis units should not have a low fistula rate held against them. This is a small unit, with a current census of 20 patients. Because we have a large portion of patients whom the surgeons decided did not have the vascular sufficiency to support an AVF, we have a large percentage of patients with AVGs. This is something we have absolutely no control over.

We have a consistently good CVC rate however, as this is an area where we can be proactive. We get our CVC patients in to see access surgeons asap, so we can get permanent accesses placed quickly.

Bricker (Chip) Fletcher  
Facility Administrator  
USRC Tillamook Dialysis Center  
1000 3rd St., Tillamook, OR 97141  
503-842-0444

Comment from julie.hills@davita.com:

My suggestion is to delete the 13ml/kg per hour due to the fact that this is going to increase our hospitalization rates. We cannot control what the patient drinks at home, and due to the fact that they are drinking more that we can remove during the treatment because of the max removal rate is 13ml/kg/hour, you are going to see increase hospitalizations for fluid overload. Sorry, but it will take you a year of gathering information to realize that this is NOT a good patient oriented measure.

Julie Hills RN CNN

Facility Administrator

Davita Wenatchee Valley Dialysis #05778

Davita East Wenatchee Dialysis #02423

Office Phone: 509-662-0385

Fax: 509-662-0656

Cell 509-741-0742

Comment from farmer6116@gmail.com:

Hello,

I received the abovementioned request from ESRD Network 5. I am a former in-center hemo, nocturnal hemo, and PD patient who received a kidney transplant from a deceased donor a year ago. My replies are as follows:

General measures/outcomes:

Adequacy of dialysis

Pain

Depression

Cramping

Hypotension

Facility-specific measures/outcomes:

Cleanliness

Safety

Staff attentiveness

Temperature/noise/comfort

Access to social services

Wait time before put-on

Some of the above might be captured through telesurveys similar to the ones that hospitals offer to patients after they are released.

I hope this helps!

--

Dave White

301-433-5054

davidmwhite@aya.yale.edu

\*This commenter sent a follow-up response that included these examples as part of social services:

Having social worker on the premises

Availability of a dietician

Ease of transportation and travel

Comment from tap@renalcareassoc.com

Sirs,

I am responding to your request for possible useful patient reported quality measures on behalf of the American Society of Diagnostic and Interventional Nephrology. Working with the Renal Physicians Association, we developed a number of measures related to the care ESRD patients receive related to their dialysis vascular access and that is often provided in access centers (see attached file). CMS approved a number of those measures for PQRS reporting within the RPA Qualified Clinical Data Registry. The first measure on the list - Pain control as reported by patient - was not accepted by CMS but we believe that it would be a useful measure as this is a quite important issue to patients who often must endure multiple procedures in the creation and maintenance of their dialysis access. We would recommend it to you for consideration and thank you for asking our input.

Best regards,

Tim Pfloderer

Chair, ASDIN public policy committee

Timothy A. Pfloderer, MD, FASN, FASDIN

President

Illinois Kidney Disease and Hypertension Center

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## **Appendix: Patient Experience of Treatment Measure Mock-Up**

**Thinking about your last dialysis session, to what extent you bothered by each of the following?** [this is KDQOL wording, potentially I would like to replace “extent” with how much, but that would limit our direct comparisons to the CMS-required instrument]

### **Access Problems**

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

### **Cold**

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

### **Cramps**

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

### **Dizziness** [KDQOL-36 combines Faintness and Dizziness]

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

### **Dry Mouth**

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

### **Headache**

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

### **Itchy skin**

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

**Low Blood Pressure**

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

**Nausea** [KDQOL-36 combines Nausea or Upset stomach]

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

**Restless Legs**

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

## Appendix: Dialysis Patient Citizens (DPC) Comment Letters to CMS

February 18, 2015

Elena Balovlenkov, R.N.  
Technical Lead for Dialysis Facility Compare  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Mail Stop S3-02-01  
Baltimore, MD 21224

Dear Elena:

To meet your timeline for raising issues to be brought before the DFC Star Rating TEP, DPC recently conducted a survey of our active patient volunteers asking them to identify priority items for quality measures to be included in both DFC star ratings and the QIP. Per the advice of the Kidney Care Quality Alliance (KCQA) consultant on quality measures, we developed a lengthy list of subjects for measures, and asked patients to choose five that they felt were most important to them and matters for which dialysis facilities should be held accountable. The list included current QIP and DFC measures, items on the dialysis CAHPS questionnaire, patient-reported outcomes on the KDQOL questionnaire and other subjects identified by KCQA.

Following the survey, we convened a focus group call with 24 participants who were provided the results beforehand. That conference call, as well as a call with our Board of Directors the following day, confirmed this list of patient priorities:

Top Five:

- Staff respect/listening
- Patient Education
- Dialysis Adequacy
- Infection Control
- Transplantation Referral/Access

Tied for 6<sup>th</sup>:

- Quality of life – cramping
- Quality of life- washed out feeling
- Healthy Days at Home
- Anemia management

We are proposing several items for consideration by CMS, the TEP and CMS' contractor for inclusion in DFC. These priorities may be subject to change or re-ordering if we learn that some items are impracticable, or if our larger annual member survey reaches significantly different results. But in keeping with your timetable, we request that groundwork be prepared on these items by your contractor before and during the TEP process. Below we discuss the implications of our survey for DFC.

1. Staff Respect/Listening: This topic compresses two questions on the CAHPS questionnaire that received the most votes. During the focus group, it was apparent that patients are riled by encounters with facility staff who are dismissive of their concerns. While our volunteers may not be representative of all ESRD patients—most are longtime veterans of dialysis who are exceptionally engaged in their care—they feel strongly that they know a lot about their treatment, often more than facility techs, and demand that staff be responsive to their unique concerns. We ask you to consider breaking out these questions currently on the CAHPS questionnaire (#10 and #12) for separate scoring and reporting, and significant weighting in determining QIP and star-rating scores.
2. Patient Education: Our survey respondents felt that sometimes education is cursory, such as distributing numerous handouts and asking for receipt signatures, rather than the in-depth conversations that convey the information that patients need to put them in control of their health. There is also concern that education is front-loaded upon incident patients who are too overwhelmed to absorb it, and not reinforced afterward when the patient may be better equipped to act upon it. We understand that in the past there have been unsuccessful attempts to formulate a measure capturing this dimension. We ask CMS to prioritize another run at this. One step, perhaps temporary, might be to compile education-related responses to CAHPS (e.g., #26, #27, #30). We realize it may be necessary for HHS to support researchers with grant funding to further develop this area.
3. Dialysis Adequacy, Anemia Management and Infection Control: Since these measures are already being scored and reported, we ask simply for their inclusion in the star rating. CMS should perhaps consider expanding the infection measure to encompass patient reporting (e.g. “In the last 3 months how many dialysis related infections did you have?” which was asked in the Acumen survey).
4. Transplantation Referral/Access: As this measure is already in development, we have no requests of you at this time, other than to support its inclusion in DFC.
5. Quality of life – Cramping/Washed out feeling: We ask you to consider supporting development of a patient-reported outcome measure assessing fluid management using answers to these questions from the KDQOL survey. Currently KCQA is testing a facility-reported fluid management measure, which we expect to support if validated; however, it would be wonderful if DFC star ratings could spur pioneering activity on a patient-reported outcome measure that assesses a dimension of care that is so important to our population.

6. Healthy Days at Home: Again, there is strong interest generally among our leadership in a patient-reported outcome measure. As you may know, last month MedPAC discussed such a measure for Medicare beneficiaries and specifically discussed its applicability to ESRD patients. There are numerous possible variations on this and we ask you to give this serious consideration going forward.
  
7. Other items for reporting on Dialysis Facility Compare “dialysis facility information” page: During the most recent Open Door Forum, several additional candidates for DFC were mentioned by Elena and by Celeste Lee. These came too late for inclusion on our survey, but one of the items, whether there is a Peer Mentor or Support Group program based at the facility, was mentioned by several respondents in an open-ended question. We listed all of these items for our focus group. There was interest expressed in the Mentor/Support Group item as well as information on Staff Turnover and Staff to Patient Ratio. These items may merit inclusion on the page reporting “characteristics and services,” and we ask that options be developed for the TEP’s consideration;

During our upcoming Board Meeting on March 3, we expect that some of the patients who participated in this process will briefly present on these items and we encourage you to bring any questions you might have to be addressed by them directly.

While we continue to have significant concerns over the current DFC Star Rating Program, we very much want to work with you to ensure that it ultimately achieves its goal of being both “useful and meaningful” to patients. As a result, I hope that you will work to incorporate the feedback of our patient advocates and dedicate resources to collecting such information when it is not available but is ascertainable.

Sincerely,

A handwritten signature in black ink, appearing to read "Hrant Jamgochian". The signature is fluid and cursive, with the first name "Hrant" being more prominent and the last name "Jamgochian" following in a similar style.

Hrant Jamgochian, J.D., LL.M.  
Executive Director

cc: Joel Andress, Ph.D., Center for Quality Measurement in the Health Assessment Group  
Kate Goodrich, M.D., Director of the Quality Measurement and Health Assessment Group

December 1, 2015

Elena Balovlenkov, R.N.  
Technical Lead for Dialysis Facility Compare  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Mail Stop S3-02-01  
Baltimore, MD 21224

Re: Addition of New Measures to Dialysis Facility Compare

Dear Ms. Balovlenkov:

DPC appreciates the opportunity to comment on the four measures CMS is considering adding to DFC in 2016. We support the reporting of measures on bloodstream infection, patient experience, fluid management, and pediatric peritoneal dialysis adequacy. We applaud the agency for expanding this transparency tool. We would like to comment further on the subject of the CAHPS measures.

We are happy to see that ICH CAHPS scores are in line to be reported on DFC. These surveys give patients the opportunity to offer feedback on the experience of receiving care. However, we do have two matters to bring to your attention.

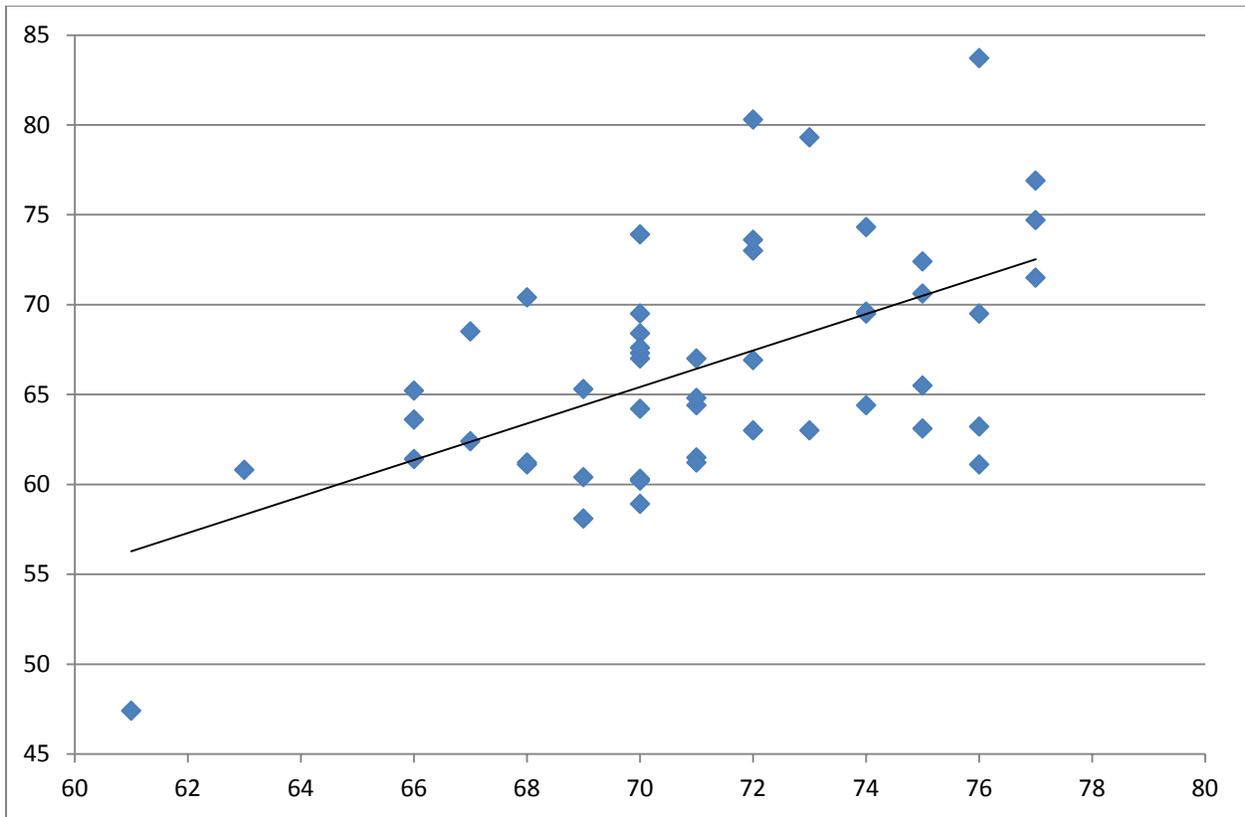
We are concerned that the composite measures approved by NQF may aggregate too many factors. ICH CAHPS measure #5 includes answers to 17 questions and #6 includes answers to 9 questions, and both encompass a wide range of topics. For instance, #5 covers such diverse issues as physical comfort, staff listening/respect, privacy, pain management, timely start, cleanliness, dietary advice, and explaining blood tests. Measure #6 also includes answers to questions on privacy and patient education in addition to information on treatment modalities.

We wonder if the composites are granular enough to, from the consumer perspective, give specific enough information about the dimensions an individual patient might care about and, from the provider perspective, give specific enough information to spur improvement. We note that Hospital Compare reports 11 CAHPS measures culled from 25 questions, while dialysis CAHPS reports just 6 measures from 44 questions. For Hospital Compare, information from CAHPS about facility cleanliness and pain management is broken out separately, not lumped into a larger composite.

Comparing measure testing submissions to NQF from the developers of the ICH CAHPS composites and the H-CAHPS composites did not turn up enough information to clarify why H-CAHPS yielded .44 measures per survey question while ICH CAHPS yielded just .14 measures per survey question. Two possibilities are worth investigating: Did ICH CAHPS developers hold their composites to a higher reliability standard than H-CAHPS developers did? Or were the ICH CAHPS developers insufficiently creative in exploring possible iterations of measure structures?

We would request that CMS ask the ICH CAHPS team to take another run at creating an expanded measure set; and further, that a panel of patients be involved in articulating what types of measures are important to them. We realize that it will take a long time to develop and gain approval for new measures and hope that such a project can begin forthwith. May we suggest, as a first step, that CMS facilitate a meeting between stakeholders and the ICH CAHPS team to help us understand how ICH CAHPS and H-CAHPS yielded different measure structures?

In October CMS released the first state-by-state compilation of dialysis CAHPS scores. As indicated in the scatterplot below, plotting these scores against hospital CAHPS scores at the state level found that about 32% of the variation in one care setting can be explained by the variation in the other care setting—meaning that the scores differentiate patient satisfaction, but about 1/3 of the variation simply measures people’s general attitudes in a particular state. (Hospital scores are on the horizontal axis, dialysis facilities on the vertical.) Previous research on geographic variations in H-CAHPS scores found variability correlated with population density, and that pattern seems to hold true with ICH CAHPS as well. The pattern disfavors places with higher population density, such as DC, NY, NJ and MD which are clustered at the bottom left of the scattergram.



At the risk of sounding like a broken record, we must caution that it is not valid to compare satisfaction scores at the national level. Hospital Compare first shows a hospital's ratings compared to the statewide average, which is helpful, but hospital star ratings and value-based purchasing adjustments will be regionally biased. Of greater concern is that the pattern is somewhat similar to ESRD outcome measures meaning that western, upper Midwest and New England states generally have higher satisfaction rates. As such, if CAHPS scores are added to outcome measures in nationwide tournaments in DFC star ratings and the QIP, the existing geographic skewing will be reinforced.

Respectfully submitted,

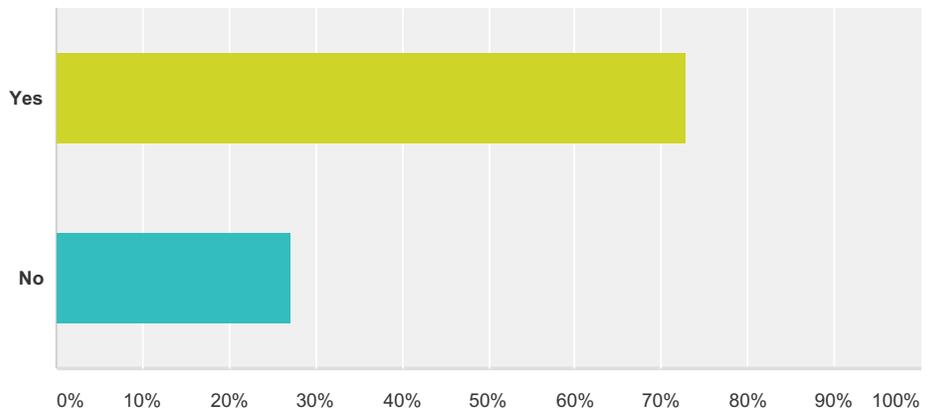
Hrant Jamgochian, J.D., LL.M.  
Executive Director

cc: Joel Address, Ph.D., Center for Quality Measurement in the Health Assessment Group  
Kate Goodrich, M.D., Director of the Quality Measurement and Health Assessment Group

## Appendix: Results from the National Kidney Foundation 2016 Survey on Patient Centered Quality Measures

### Q1 Are you or a family member currently on dialysis?

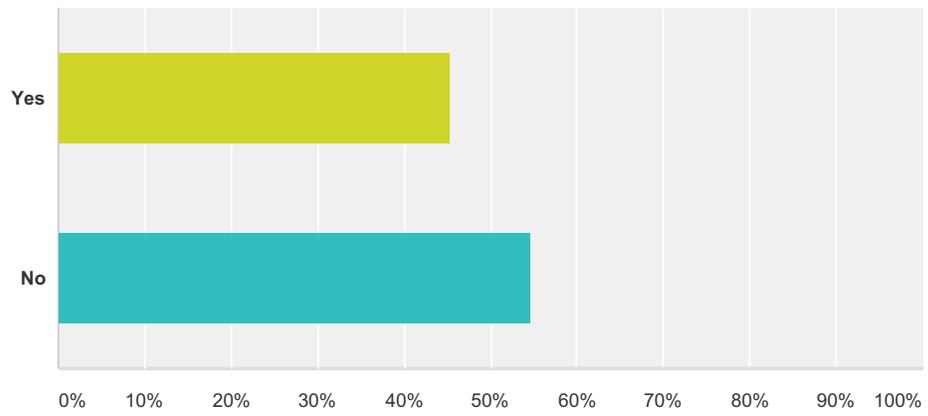
Answered: 821 Skipped: 0



Answer Choices	Responses	
Yes	72.84%	598
No	27.16%	223
<b>Total</b>		<b>821</b>

## Q2 Are you or a family member a transplant recipient?

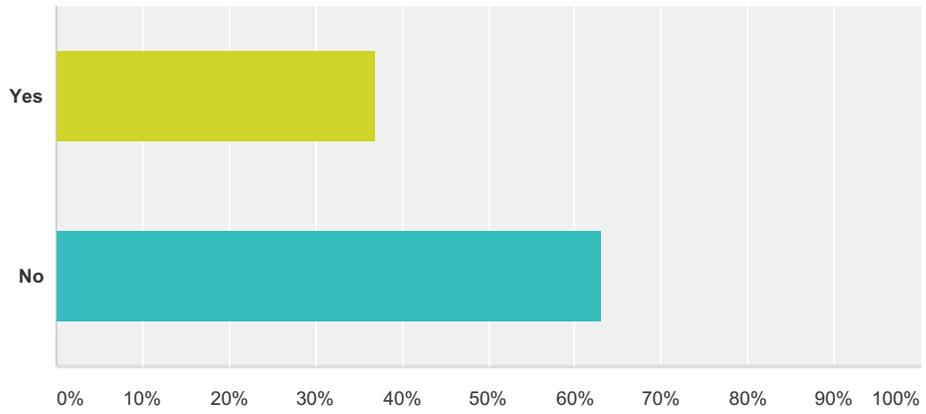
Answered: 221 Skipped: 600



Answer Choices	Responses
Yes	45.25% 100
No	54.75% 121
<b>Total</b>	<b>221</b>

### Q3 Do you or a family member currently have chronic kidney disease?

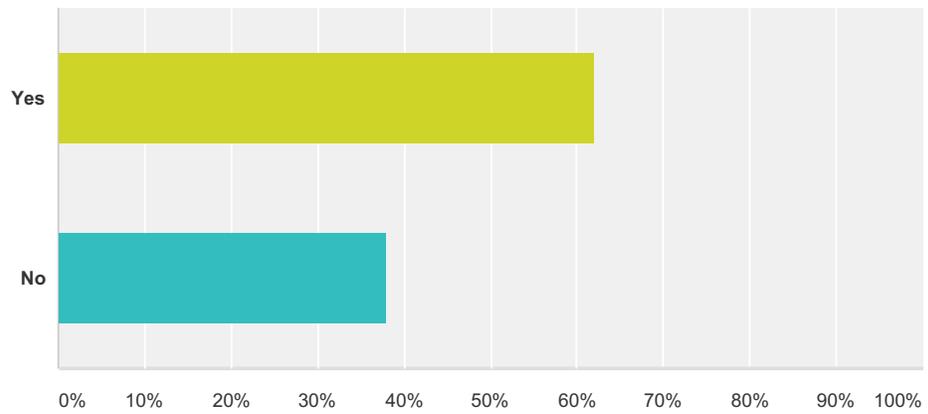
Answered: 122 Skipped: 699



Answer Choices	Responses	
Yes	36.89%	45
No	63.11%	77
<b>Total</b>		<b>122</b>

### Q4 Have you considered dialysis as a future treatment option?

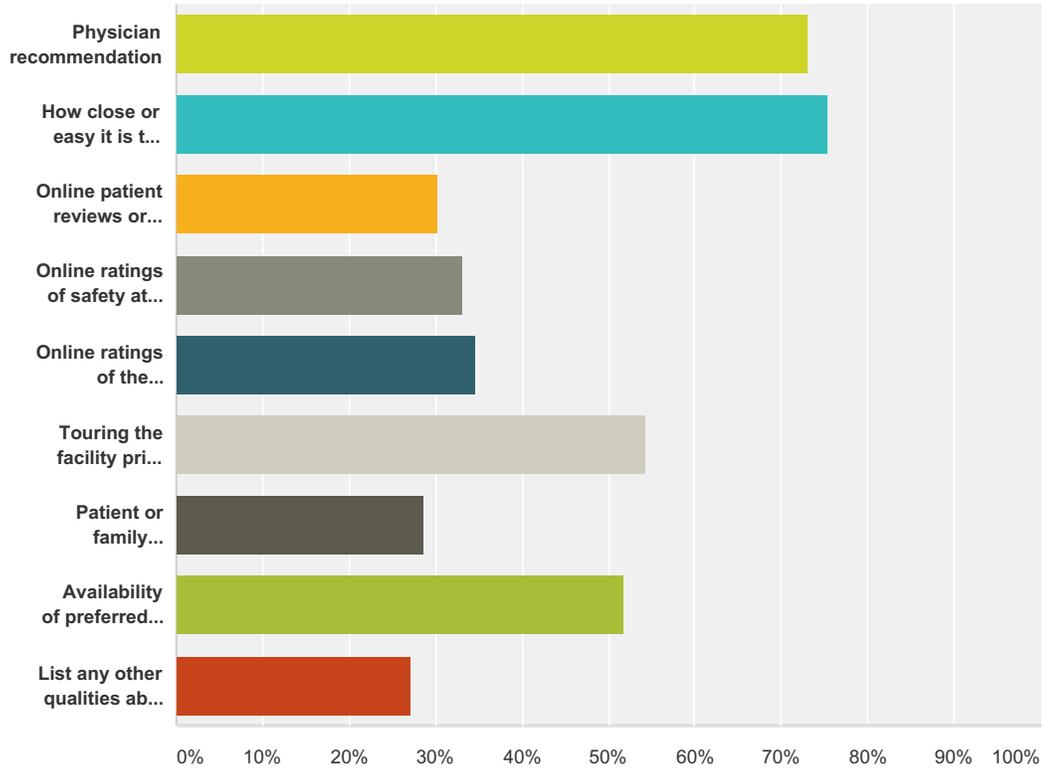
Answered: 142 Skipped: 679



Answer Choices	Responses	
Yes	61.97%	88
No	38.03%	54
<b>Total</b>		<b>142</b>

**Q5 In evaluating which dialysis facility you or a family member would want to receive care from how would you choose the facility (check all that apply)?**

Answered: 655 Skipped: 166

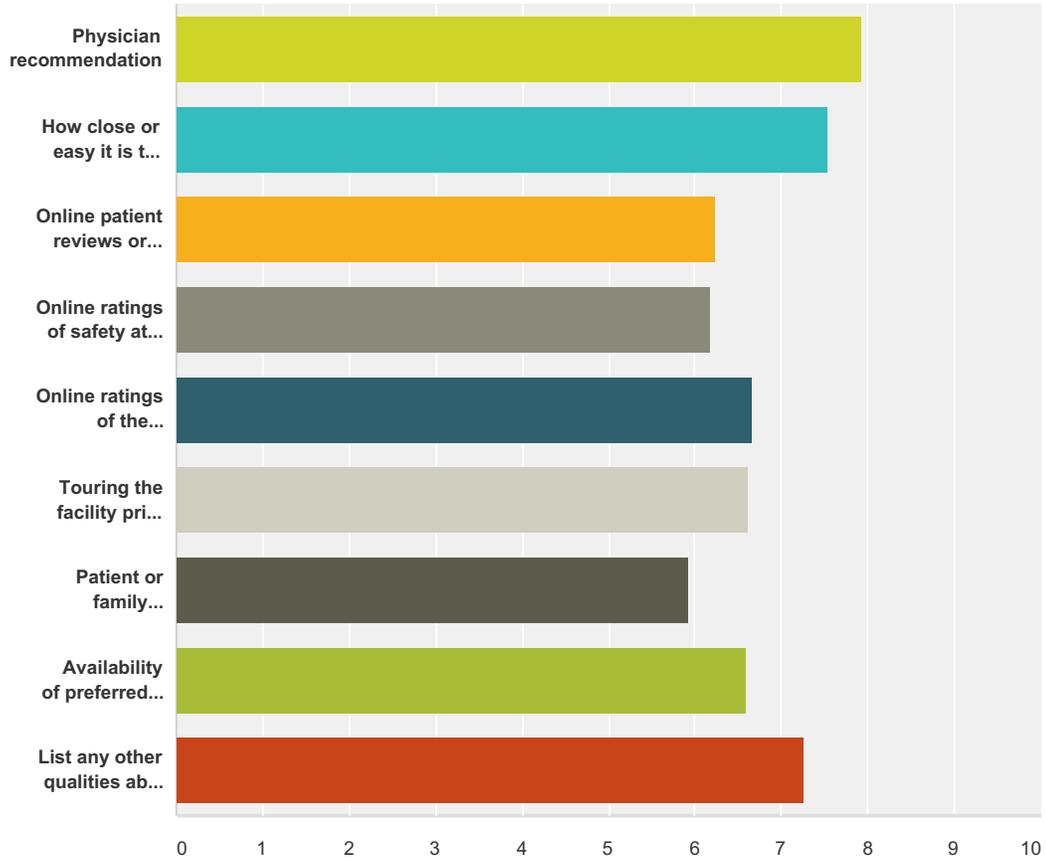


Answer Choices	Responses
Physician recommendation	72.98% 478
How close or easy it is to get to from your home or work	75.27% 493
Online patient reviews or patients' experience ratings	30.23% 198
Online ratings of safety at the facility	33.13% 217
Online ratings of the facility's performance on clinical measures of care (for example, rate of patient hospitalization, rate of patient survival)	34.66% 227
Touring the facility prior to starting dialysis and meeting with the staff	54.35% 356
Patient or family caregiver word of mouth	28.55% 187
Availability of preferred treatment times	51.76% 339
List any other qualities about the facility that you think are important to know about:	27.18% 178
<b>Total Respondents: 655</b>	

## Patient Centered Quality Measures

### Q6 Of the previous selections that you checked, what is/are the most important to you? What is/are the least important? #1 being the MOST important.

Answered: 560 Skipped: 261



	1	2	3	4	5	6	7	8	9	Total	Score
Physician recommendation	52.36% 211	19.60% 79	13.40% 54	6.95% 28	3.47% 14	1.99% 8	1.24% 5	0.74% 3	0.25% 1	403	7.94
How close or easy it is to get to from your home or work	30.79% 129	29.12% 122	21.00% 88	8.83% 37	6.21% 26	1.43% 6	1.67% 7	0.95% 4	0.00% 0	419	7.54
Online patient reviews or patients' experience ratings	8.07% 13	20.50% 33	19.25% 31	20.50% 33	14.91% 24	9.32% 15	4.35% 7	2.48% 4	0.62% 1	161	6.25
Online ratings of safety at the facility	13.29% 23	16.76% 29	13.87% 24	19.65% 34	16.76% 29	10.98% 19	5.20% 9	1.73% 3	1.73% 3	173	6.17
Online ratings of the facility's performance on clinical measures of care (for example, rate of patient hospitalization, rate of patient survival)	18.39% 32	17.24% 30	21.26% 37	18.39% 32	13.79% 24	5.17% 9	4.02% 7	1.15% 2	0.57% 1	174	6.67
Touring the facility prior to starting dialysis and meeting with the staff	18.27% 55	17.61% 53	22.59% 68	17.61% 53	8.97% 27	7.31% 22	4.65% 14	2.33% 7	0.66% 2	301	6.62
Patient or family caregiver word of mouth	11.18% 17	13.82% 21	15.79% 24	21.71% 33	13.16% 20	9.21% 14	7.89% 12	6.58% 10	0.66% 1	152	5.92

## Patient Centered Quality Measures

Availability of preferred treatment times	<b>10.36%</b> 29	<b>29.64%</b> 83	<b>20.36%</b> 57	<b>15.00%</b> 42	<b>10.71%</b> 30	<b>5.71%</b> 16	<b>3.57%</b> 10	<b>4.29%</b> 12	<b>0.36%</b> 1	280	6.59
List any other qualities about the facility that you think are important to know about:	<b>35.42%</b> 51	<b>21.53%</b> 31	<b>14.58%</b> 21	<b>9.72%</b> 14	<b>9.72%</b> 14	<b>4.17%</b> 6	<b>1.39%</b> 2	<b>1.39%</b> 2	<b>2.08%</b> 3	144	7.26

**Q7 Thinking through a positive healthcare experience you have had what was good about the care you received?**

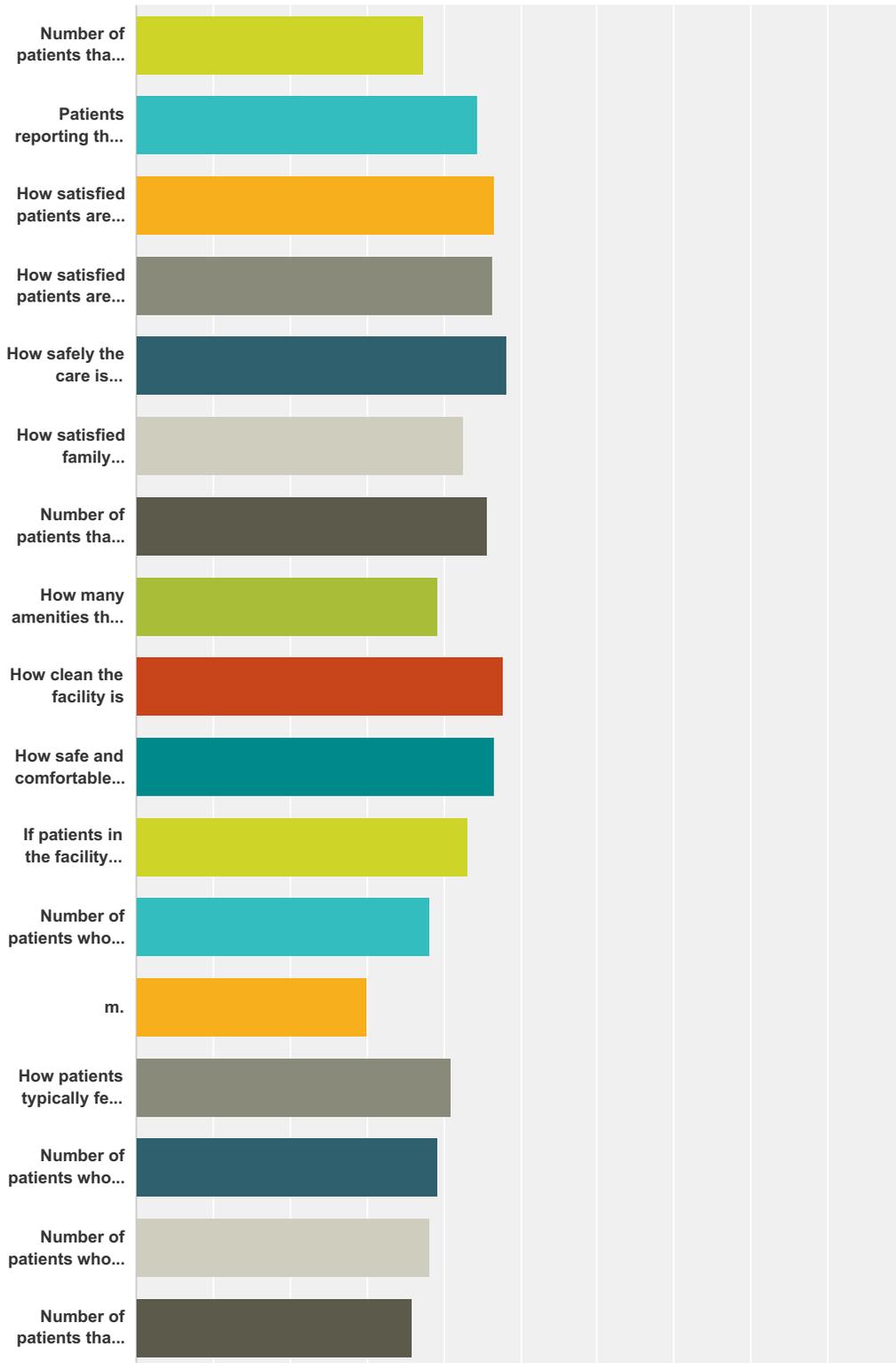
Answered: 479 Skipped: 342

**Q8 Thinking through a negative healthcare experience what was bad about the care you received?**

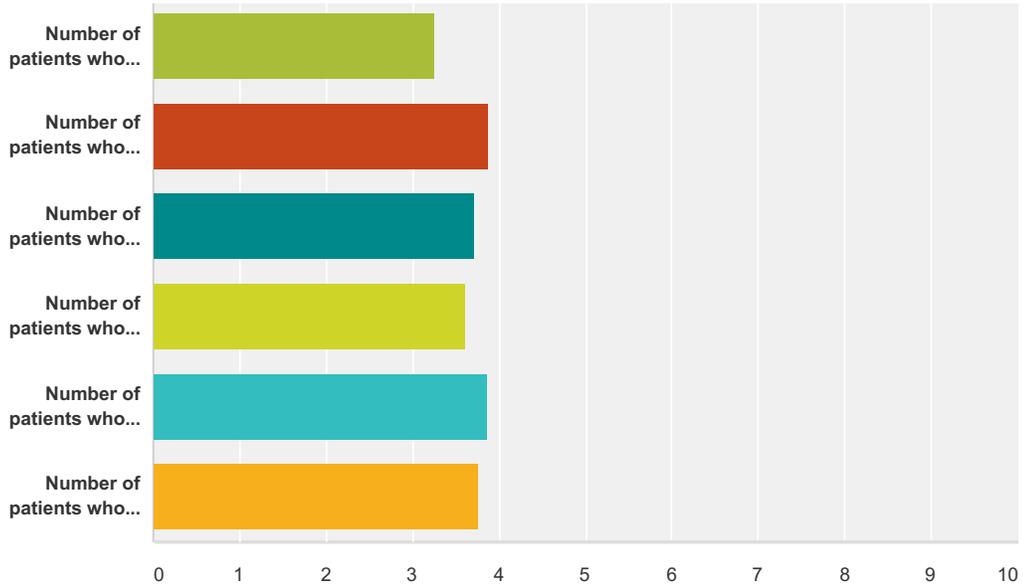
Answered: 477 Skipped: 344

**Q9 Please rate how important it is that you have the following information about a dialysis facility before choosing to receive care there for you or a family member (please rate each item):**

Answered: 471 Skipped: 350



## Patient Centered Quality Measures



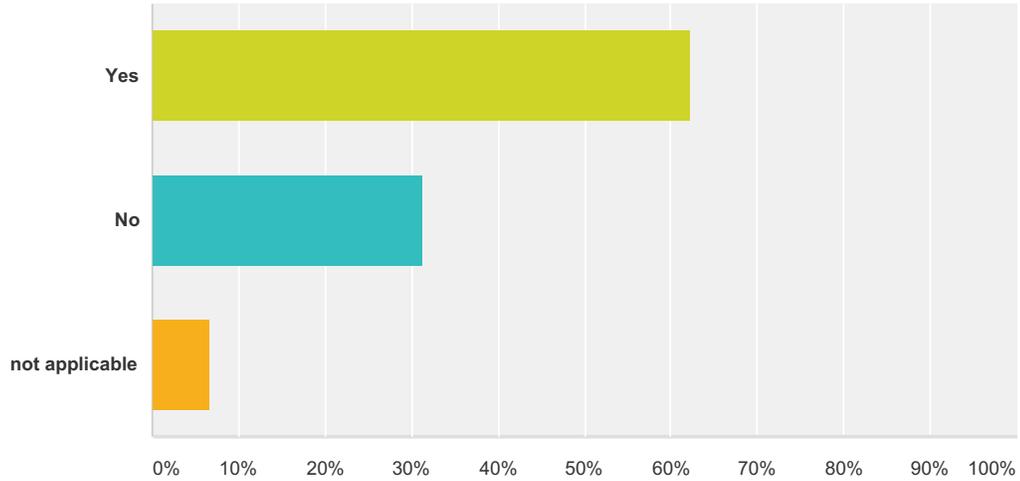
	Not important at all	Slightly important	Neutral	Somewhat important	Very important	Total	Weighted Average
Number of patients that have a care plan based on their personal goals, values and healthcare needs.	10.19% 48	7.86% 37	19.11% 90	24.63% 116	38.22% 180	471	3.73
Patients reporting they feel like they are part of the decision process about their treatment plans	3.18% 15	4.88% 23	5.10% 24	18.05% 85	68.79% 324	471	4.44
How satisfied patients are with the care they receive	1.27% 6	2.12% 10	2.76% 13	16.77% 79	77.07% 363	471	4.66
How satisfied patients are with the attention the staff gives them at the facility	1.70% 8	2.34% 11	2.34% 11	17.41% 82	76.22% 359	471	4.64
How safely the care is delivered (free from medical errors, proper infection control precautions, protection of vascular access)	1.49% 7	0.85% 4	1.06% 5	7.43% 35	89.17% 420	471	4.82
How satisfied family members/caregivers are with the care their loved ones receive	1.49% 7	4.46% 21	12.53% 59	29.51% 139	52.02% 245	471	4.26
Number of patients that feel they are respected and listened to by the dialysis facility staff	1.27% 6	2.12% 10	4.88% 23	20.59% 97	71.13% 335	471	4.58
How many amenities the facility has (ice machine, Wi-Fi, television, comfortable chairs)	4.03% 19	7.22% 34	16.14% 76	36.52% 172	36.09% 170	471	3.93
How clean the facility is	1.49% 7	0.64% 3	1.49% 7	9.98% 47	86.41% 407	471	4.79
How safe and comfortable patients feel to voice concerns about their care to dialysis facility staff (no fear of retribution for issuing complaints)	2.12% 10	1.49% 7	3.40% 16	14.23% 67	78.77% 371	471	4.66
If patients in the facility report they have a good quality of life and able to do their day to day activities	3.61% 17	3.40% 16	8.92% 42	24.20% 114	59.87% 282	471	4.33
Number of patients who report they are able to maintain their employment or stay in school/college	8.28% 39	4.03% 19	22.93% 108	26.54% 125	38.22% 180	471	3.82
m.	22.29% 105	1.49% 7	49.47% 233	7.86% 37	18.90% 89	471	3.00
How patients typically feel after their dialysis treatment (e.g., tired, nauseous/sick, or, generally okay)	3.82% 18	4.67% 22	16.35% 77	29.09% 137	46.07% 217	471	4.09

## Patient Centered Quality Measures

Number of patients who report experiencing reoccurring or ongoing pain	<b>4.25%</b> 20	<b>6.16%</b> 29	<b>21.02%</b> 99	<b>29.72%</b> 140	<b>38.85%</b> 183	471	3.93
Number of patients who experienced ongoing signs or symptoms of depression or anxiety	<b>6.37%</b> 30	<b>6.79%</b> 32	<b>22.08%</b> 104	<b>28.24%</b> 133	<b>36.52%</b> 172	471	3.82
Number of patients that report sleep problems	<b>8.28%</b> 39	<b>7.43%</b> 35	<b>27.60%</b> 130	<b>30.15%</b> 142	<b>26.54%</b> 125	471	3.59
Number of patients who do their dialysis at home	<b>18.90%</b> 89	<b>6.79%</b> 32	<b>32.27%</b> 152	<b>14.65%</b> 69	<b>27.39%</b> 129	471	3.25
Number of patients who understand transplant as an option and the process to get a transplant	<b>8.92%</b> 42	<b>5.10%</b> 24	<b>19.32%</b> 91	<b>21.44%</b> 101	<b>45.22%</b> 213	471	3.89
Number of patients who have been referred for a transplant	<b>10.19%</b> 48	<b>5.10%</b> 24	<b>24.63%</b> 116	<b>22.51%</b> 106	<b>37.58%</b> 177	471	3.72
Number of patients who understand home dialysis as options	<b>11.46%</b> 54	<b>6.16%</b> 29	<b>25.05%</b> 118	<b>23.35%</b> 110	<b>33.97%</b> 160	471	3.62
Number of patients who feel their health is no worse than it was one year ago	<b>7.43%</b> 35	<b>4.88%</b> 23	<b>19.96%</b> 94	<b>28.45%</b> 134	<b>39.28%</b> 185	471	3.87
Number of patients who report feeling tired or fatigued most days	<b>7.64%</b> 36	<b>6.16%</b> 29	<b>23.35%</b> 110	<b>29.30%</b> 138	<b>33.55%</b> 158	471	3.75

**Q10 For patients currently or previously on dialysis: Have you ever completed a quality of life survey asking you about your symptoms or burden of your kidney disease?**

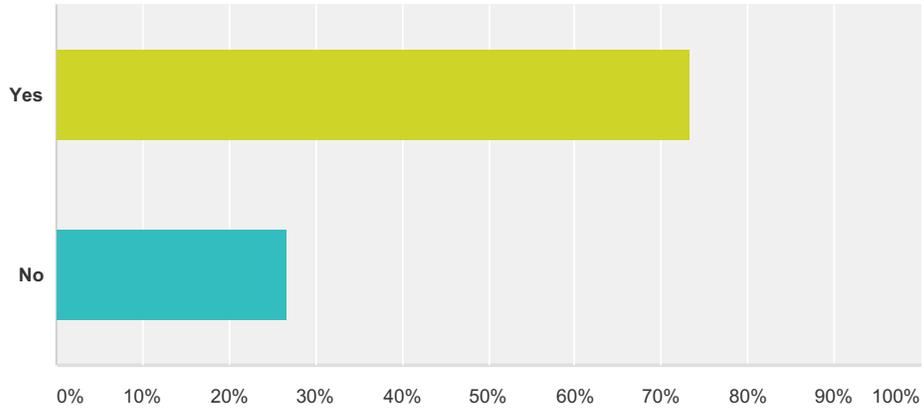
Answered: 470 Skipped: 351



Answer Choices	Responses
Yes	62.13% 292
No	31.28% 147
not applicable	6.60% 31
<b>Total</b>	<b>470</b>

### Q11 Did you someone on your dialysis care team review your answers to the quality of life survey with you?

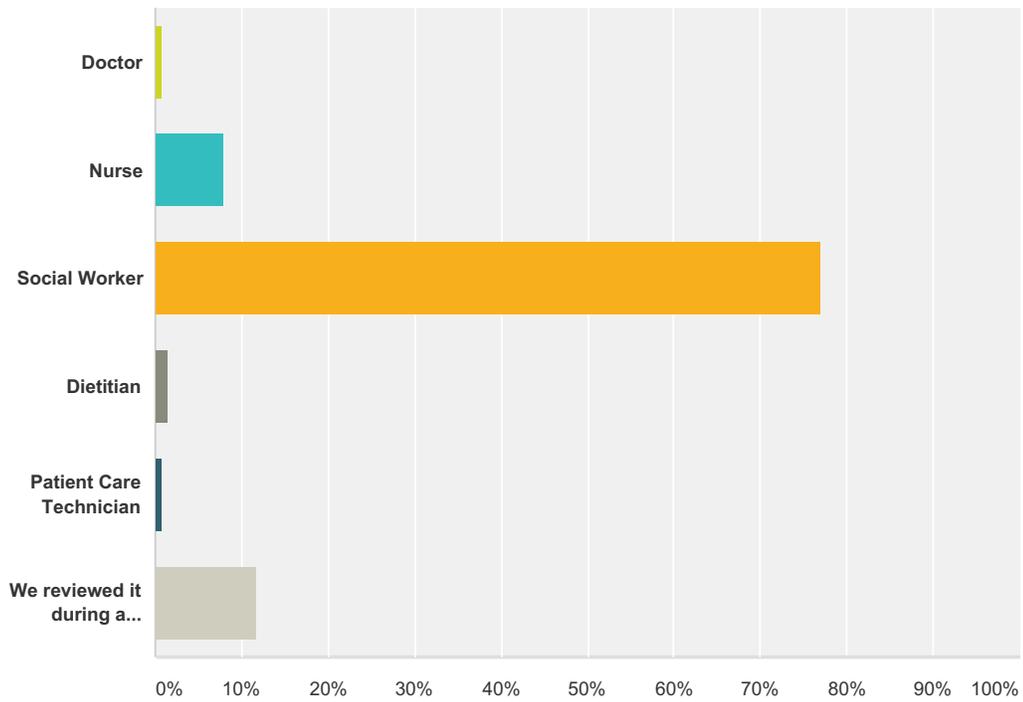
Answered: 285 Skipped: 536



Answer Choices	Responses	
Yes	73.33%	209
No	26.67%	76
<b>Total</b>		<b>285</b>

### Q12 Who reviewed your quality of life survey answers with you?

Answered: 214 Skipped: 607

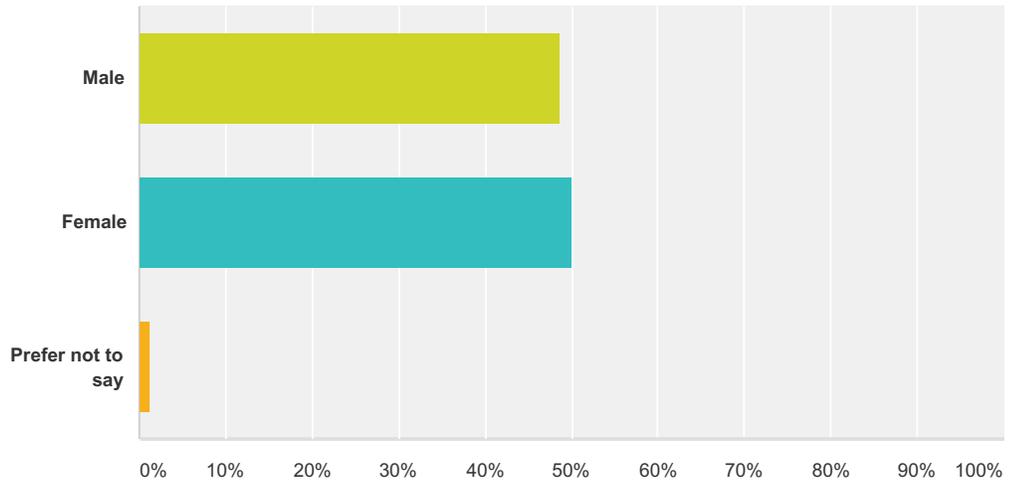


Answer Choices	Responses
Doctor	0.93% 2
Nurse	7.94% 17
Social Worker	77.10% 165
Dietitian	1.40% 3
Patient Care Technician	0.93% 2
We reviewed it during a meeting with my entire dialysis care team	11.68% 25
<b>Total</b>	<b>214</b>

# Patient Centered Quality Measures

## Q13 Gender:

Answered: 467 Skipped: 354

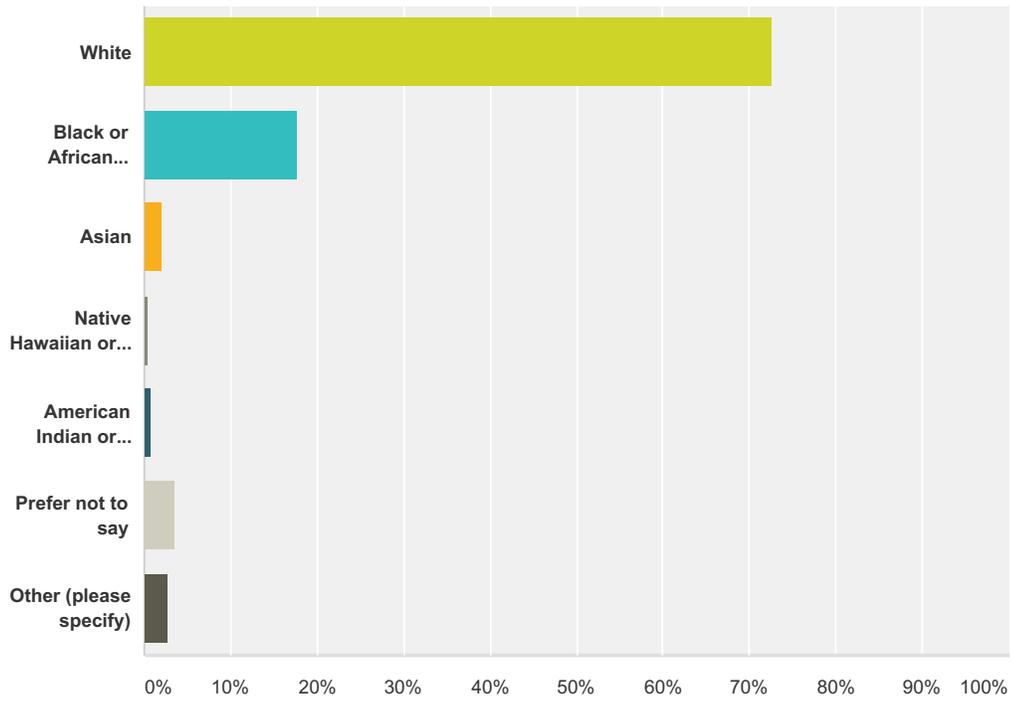


Answer Choices	Responses	
Male	48.61%	227
Female	50.11%	234
Prefer not to say	1.28%	6
<b>Total</b>		<b>467</b>

Patient Centered Quality Measures

**Q14 Race:**

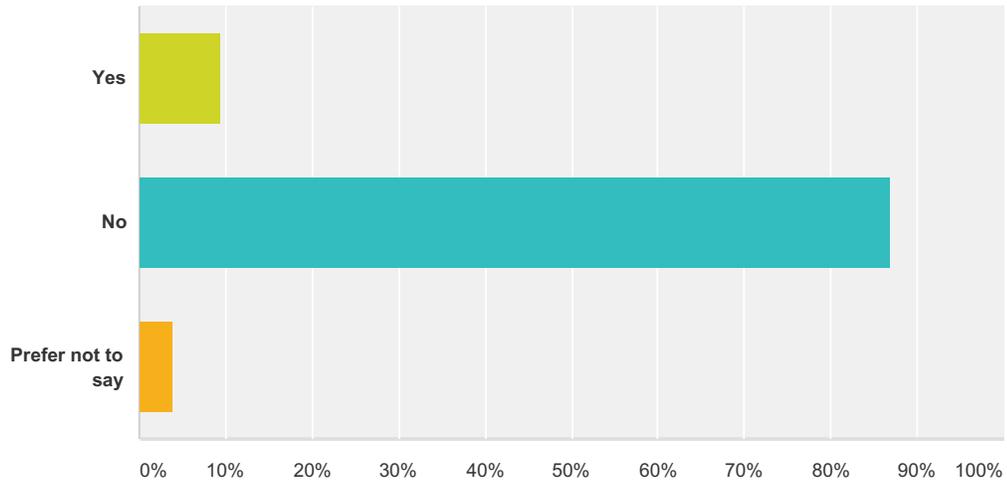
Answered: 464 Skipped: 357



Answer Choices	Responses
White	72.63% 337
Black or African American	17.67% 82
Asian	2.16% 10
Native Hawaiian or Other Pacific Islander	0.43% 2
American Indian or Alaska Native	0.86% 4
Prefer not to say	3.45% 16
Other (please specify)	2.80% 13
<b>Total</b>	<b>464</b>

### Q15 Are you Hispanic or Latino?

Answered: 461 Skipped: 360

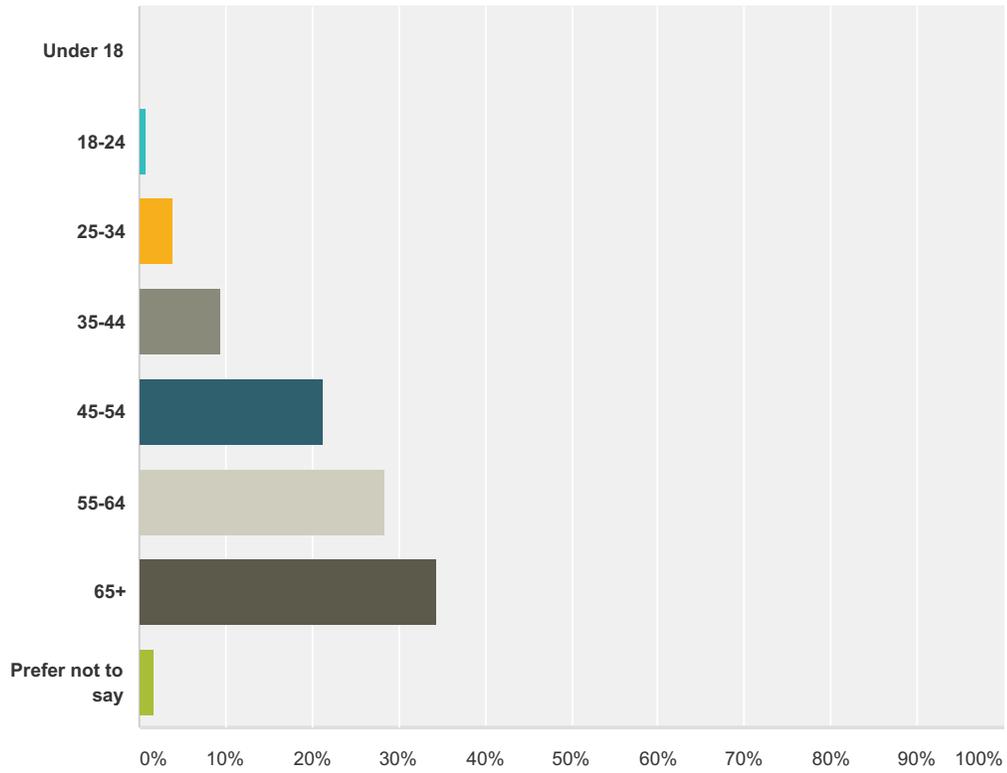


Answer Choices	Responses	
Yes	9.33%	43
No	86.77%	400
Prefer not to say	3.90%	18
<b>Total</b>		<b>461</b>

Patient Centered Quality Measures

**Q16 Age:**

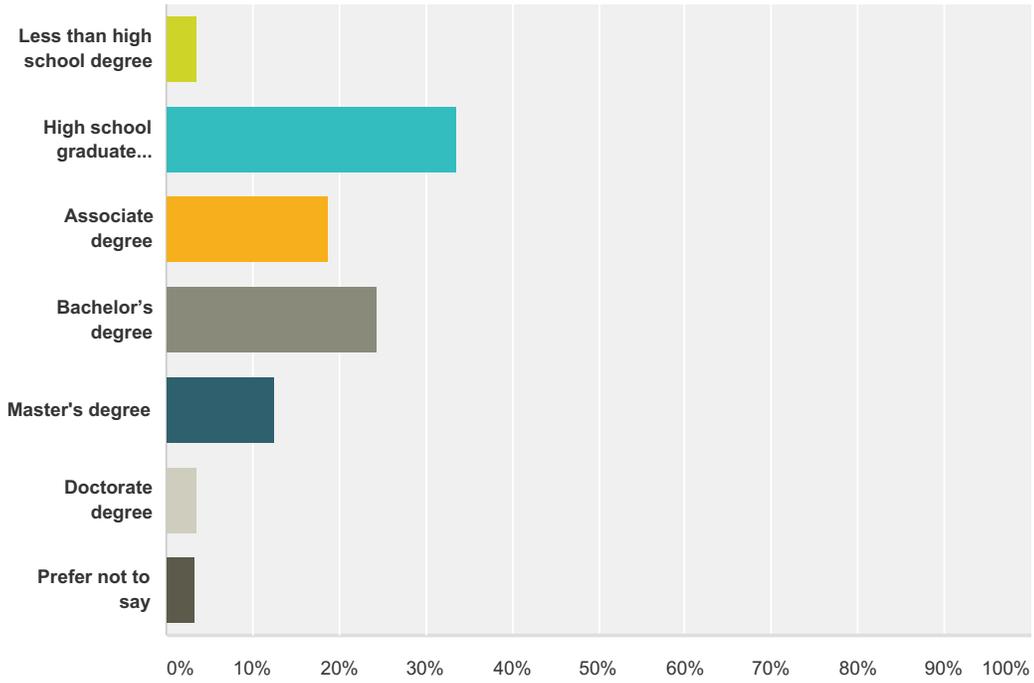
Answered: 465 Skipped: 356



Answer Choices	Responses
Under 18	0.00% 0
18-24	0.86% 4
25-34	3.87% 18
35-44	9.46% 44
45-54	21.29% 99
55-64	28.39% 132
65+	34.41% 160
Prefer not to say	1.72% 8
<b>Total</b>	<b>465</b>

### Q17 Education

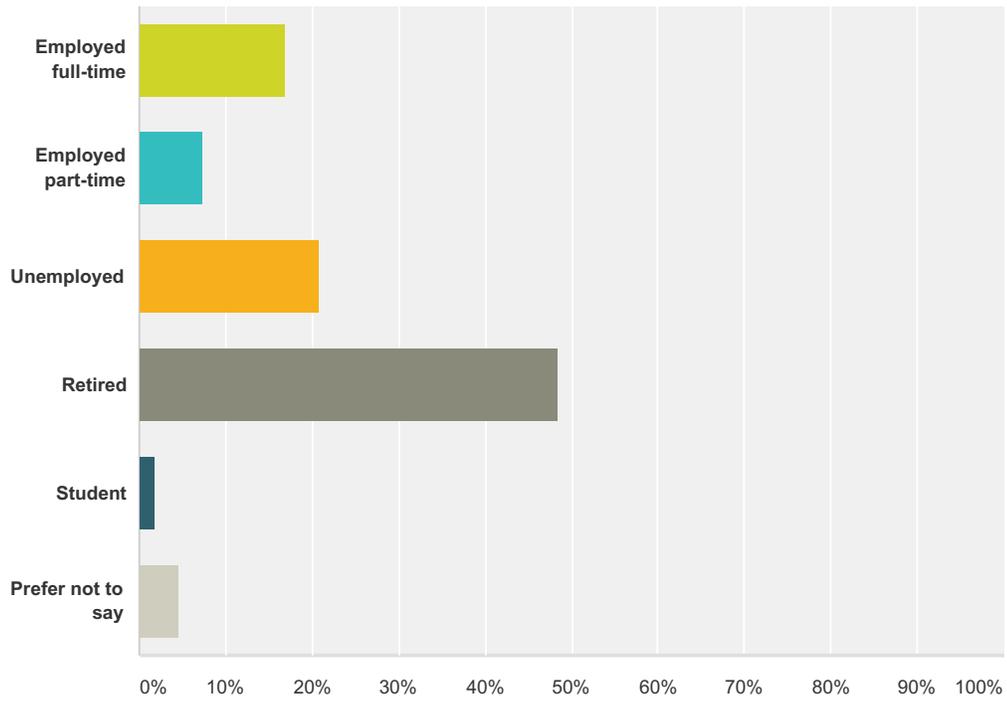
Answered: 468 Skipped: 353



Answer Choices	Responses
Less than high school degree	3.63% 17
High school graduate (diploma or GED)	33.55% 157
Associate degree	18.80% 88
Bachelor's degree	24.36% 114
Master's degree	12.61% 59
Doctorate degree	3.63% 17
Prefer not to say	3.42% 16
<b>Total</b>	<b>468</b>

### Q18 Employment Status:

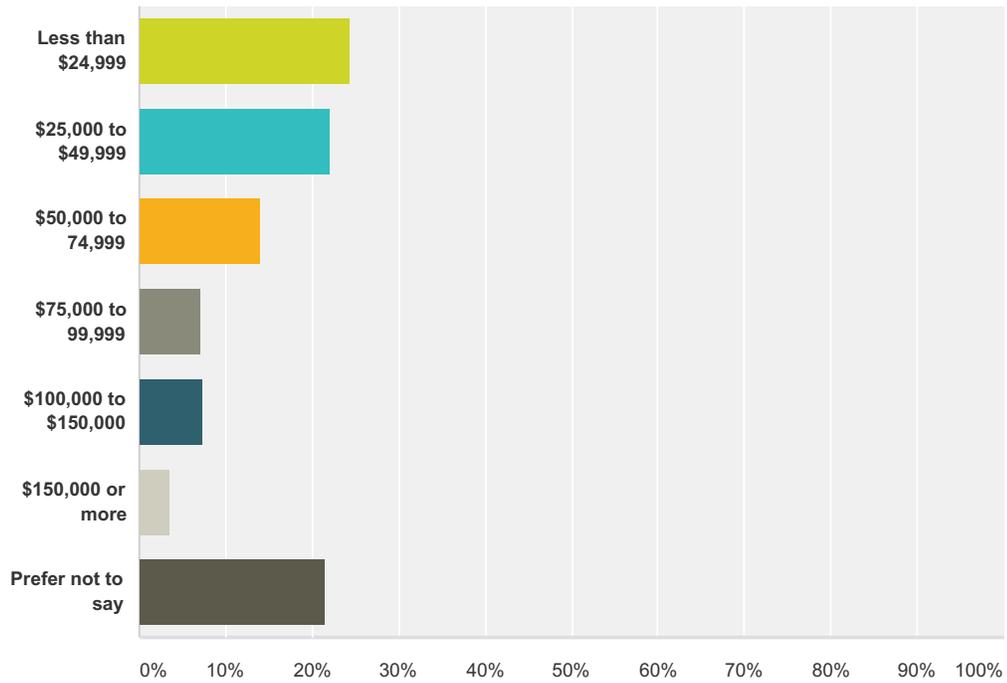
Answered: 464 Skipped: 357



Answer Choices	Responses	Count
Employed full-time	16.81%	78
Employed part-time	7.33%	34
Unemployed	20.91%	97
Retired	48.49%	225
Student	1.94%	9
Prefer not to say	4.53%	21
<b>Total</b>		<b>464</b>

### Q19 Household Income

Answered: 468 Skipped: 353



Answer Choices	Responses	
Less than \$24,999	24.36%	114
\$25,000 to \$49,999	22.22%	104
\$50,000 to \$74,999	13.89%	65
\$75,000 to \$99,999	7.05%	33
\$100,000 to \$150,000	7.26%	34
\$150,000 or more	3.63%	17
Prefer not to say	21.58%	101
<b>Total</b>		<b>468</b>

**Q20 Please provide your contact information below if you would like to be entered for a chance to win a \$40 American Express Gift Card. NKF will protect your privacy and keep your responses anonymous. Your information will not be shared with Medicare or anyone else outside of the National Kidney Foundation.**

Answered: 348 Skipped: 473

Answer Choices	Responses	
Name	99.71%	347
Company	16.95%	59
Address	98.28%	342
Address 2	15.52%	54
City/Town	98.28%	342
State/Province	97.41%	339
ZIP/Postal Code	98.28%	342
Country	90.52%	315
Email Address	97.13%	338
Phone Number	87.64%	305