KCQA PATIENT-REPORTED OUTCOMES INITIATIVE IN-PERSON MEETING
May 16, 2017
Washington, DC

MEETING SUMMARY

Steering Committee Members Attending: Allen R. Nissenson, MD (DVA), KCQA Co-Chair; Paul Palevsky, MD (RPA), KCQA Co-Chair; Lorien Dalrymple, MD, MPH (FMC-NA); Mike Guffey (DPC); Raymond Hakim, MD, PhD (ASN); Chris Lovell, RN, MSN (DCI); Jason Spangler, MD (Amgen); Gail Wick, MHSA, BSN, RN (AKF); Jesse Roach, MD, (CMS Liaison Member).

Attendees: Amit Sharma (Akebia); Nancy Pierce (ANNA); Beckie Michael (ASN); Sarah Swartz (ASPN); Diane Wish (CDC); Joel Andress (CMS); Steve Brunelli (DVA); Eduardo Lacson, Jr. (DCI); Klemens Meyer (DCI); Hrant Jamgochian (DPC); Jackson Williams (DPC); Jennifer Holcomb (Greenfield Health); Don Molony (National Forum of ESRD Networks); Tonya Saffer (NKF); Nancy Gallagher (NNCC); Bridget Pfaff(NRAA); Sue Rotura (NRAA); Caprice Vanderkolk (NRAA); Debbie Cote (NRAA); Tosha Whitley (NWK); Amy Beckrich (RPA); Renee Garrick (RPA); Mark Andaya (Rogosin); Brigitte Schiller (Satellite); Karen Walton (US Renal); Bobbie Reed (patient, NKF); Sara Love Rawlings (KCP); Kathy Lester (KCP); Robyn Y. Nishimi (KCQA); Lisa McGonigal (KCQA); Christine Walizer (KCQA).

Co-Chair Welcome and Introductions

Dr. Nissenson and Dr. Palevsky introduced themselves and welcomed participants. After participant introductions, the Co-Chairs noted that there is currently much activity in the patient-reported outcomes (PROs) realm by multiple entities (e.g., NCQA, CMS) and strongly urged coordination across projects. Dr. Nishimi also welcomed participants, and reviewed the meeting agenda, as outlined in Attachment 1 (slide deck).

Dr. Frederic Finkelstein, Yale University: *PROMs and the ESRD Patient—A Time to Rethink Our Approach*

Dr. Finkelstein's presentation provided an overview of his commissioned paper on the clinical uses of patient-reported outcome measures (PROMs), in particular drawing on research in other clinical areas and how it might apply to the dialysis care setting. He also offered insights on the existing PROMs for patients with ESRD (ICH CAHPS and KDQOL), and concluded with four recommendations on advancing the use of PROMs to improve quality of care for patients with ESRD.

Dr. Finkelstein's slides are provided in Attachment 1 and his remarks are summarized below.

- Studies demonstrate an association between PROs and "hard" outcomes, such as mortality and hospitalization.
- Studies demonstrate substantial discordance between provider and patient perceptions of health status, symptoms, quality of life (QOL), general health, and depression.
- Challenges of utilizing existing PROMs (KDQOL and ICH CAHPS) include:
    - Understanding how results can be translated into appropriate/meaningful treatment strategies.
    - Survey fatigue and provider burden.
    - Difficulties incorporating PROMs into routine care.
- Limitations of current approach/existing PROMs for patients with ESRD:

    - Existing measures and approaches not adequate.
    - ICH CAHPS and KDQOL do not provide meaningful information or insight.
    - ICH CAHPS is too long, burdensome, and results cannot be used to improve facility quality or individual patient care.
    - Annual scores nonsensical given rapid fluctuations in patient status—need to be more fluid in approach.
    - Generic tools are not effective in capturing individual patients' unique experiences—PROMs need to be individualized.
    - Limitations in translating/utilizing ICH CAHPS and KDQOL in management of patients: *"What do you with the reports?"*
    - 5-Star system and QIP use of PROMs is detrimental to patient care—shifts provider focus to performing for measures at expense of individualized patient care.
- Lessons from other clinical areas:
    - Neurology: Routine use of electronic generic and clinic-specific PROMs at Cleveland Clinic; high degree of patient satisfaction.
    - Gyne Oncology: Administered web-based reporting system to capture PROs in post-op period weekly x 6 weeks, with alerts sent to nurses with problems; high degree of patient satisfaction.
    - Psychiatry: Computer Adaptive Testing (CAT) effective in diagnosing MDD, anxiety disorder, and BPD in large cohort of patients in psychiatric clinic; high sensitivity and specificity.
    - Oncology: Routine incorporation of PROMs into care enhances patients' and clinicians' experience; positive impact on "hard" outcomes (e.g., emergency department [ED] visits, hospitalization).
- Issues with ESRD care and PROM use:
    - Effort expended on conforming to 5-Star and QIP requirements; annual requirements for PROMs now mandated.
    - Challenges of addressing multiple problems of ESRD patients (e.g., comorbidities, multiple medications).
    - Known problem areas identified by PROs for patients with ESRD may not always be viewed as important by patient (e.g., aspects of HRQOL) nor improve with intervention (randomized trial focusing on pain, erectile dysfunction, depression showed no improvement in scores with intervention).
    - Need to overcome patient and facility barriers in developing patient-centered treatment plans:
        - Rigid adherence to established performance measures in 5-Star and QIP; programs shift focus from the specific, individual needs of each patient.
        - Documentation requirements.
        - Staffing patterns.
        - Lack of flexibility in developing personalized patient-centered care approach, especially for HRQOL.
- Regulatory context for PROMs for dialysis facilities:
    - PROMs that best capture patients' experience not well-defined.
    - Arbitrary, standardized measures not recommended; need flexibility in determining which PROMs are most useful and best modes of administration, and facilities should be able to adapt and modify routine use of PROMs.
    - Ability of facility to impact individual patient problems unrelated to dialysis may be limited.

    - Using "scores" from PROMs to compare dialysis facilities is not appropriate and can be counterproductive.
- Recommendations:
    1. Mandate PROMs be incorporated into routine patient care, addressing some or all issues discussed.
    2. Leave mode, frequency of administration, and choice of instrument to discretion of facility.
    3. Encourage innovative approaches, given lack of clear data on how PROMs should be incorporated into routine care and translated into improved patient experiences.
    4. Require documentation of patient concerns and plan to address those concerns (e.g., address problem using facility resources or referral to other providers/ community resources).

(Although a brief Q&A period followed Dr. Finkelstein's presentation, all discussion has been consolidated and summarized in a separate section, below.)

Dr. Ronald Hays and John Peipert, University of California, Los Angeles: ***Methodological Considerations in Using PROMs in Dialysis Clinics***

Dr. Peipert provided an overview of his and Dr. Hays' commissioned paper, which focused on the methodological consideration of using PROMs for patients with ESRD. He reviewed the current KDQOL and ICH CAHPS instruments. He also reported on the potential application of PROMIS, which uses computer-adapted technology (CAT), for use with patients with ESRD, and noted transplantation-related PROs might be an additional area that should be explored. Dr. Hays and Dr. Peipert made six recommendations on advancing the use of PROMs to improve quality of care for patients with ESRD.

Dr. Hays' and Mr. Peipert's slides are provided in Attachment 1 and are summarized below.

- Patient-reported measures ("PRMs")[1] are major a source of data: Survey reports, attitudes, experiences, perceptions of health.
- PRMs can be assessed along every stage of the patient-provider encounter.
- Successes and challenges administering PROMs have been reported in the literature, including:
    - Patient-reported symptoms associated with fewer ED visits and increased survival.
    - A systematic review of the use of PRMs showed improvements in processes and outcomes 40-50% of the time.
    - Some providers may not change their care plans even when presented with PRM data.
- Current PRM use in the dialysis setting: ICH CAHPS in QIP and KDQOL for internal quality improvement (IQI) and incorporation into care plans.
- Identification of PRMs for use in dialysis (using Fung & Hays framework):
    - Major concepts: Preferences for care, HRQOL, QOL, satisfaction with care.

[1] The Hays/Peipert paper refers to Patient-Reported Measure (PRMs) and does not encompass health behaviors and quality of care because they not outcomes per se. KCQA's scope of PROMs has adopted NQF's broader view that PROMs should include these. The term "PRM" is retained here only for purposes of the commissioned paper.

    - Direct indicators: Patient characteristics, technical QOL, needs assessment, patient reports about care, health behaviors.
    - HRQOL is an outcome influenced by other concepts/indicators, including health behaviors and quality of care, which are not outcomes and thus are not PROs (in their paper's lexicon).
- HRQOL PRMs:
    - PROMIS database is state-of-science system for generic HRQOL measurement.
        - General domains: global, physical, mental, and social health.
        - Assessed through static "short forms" or CAT.
        - Scored on T-score metric.
        - Adult and pediatric measures.
        - PROMIS-29 is a multi-domain profile measure: Physical function, anxiety, depression, fatigue, sleep disturbance, ability to participate in social roles/activities, pain interference, pain intensity.
    - KDQOL-36
        - Derived from KDQOL-SF; encompasses SF-12, Burden of Kidney Disease, Symptoms/Problems with Kidney Disease, Effects of Kidney Disease.
        - Pros: Developed with patient input, brief, contains generic and targeted HRQOL scales, evidence of reliability and validity, used with 1000's of dialysis patients, norms available for comparison.
        - Recommend continued use of KDQOL-36 for dialysis center IQI, but improve by replacing SF-12 PCS & MCS with PROMIS items.
- Patient Experience with Care PRM:
    - ICH CAHPS
        - Three multi-item scales (Nephrologists Communication and Caring, Providing Information to Patients, Quality of Dialysis Center Care & Operations) and three global items.
        - Included in QIP and Dialysis Facility Compare.
        - Pros: Developed with patient input; evidence of reliability and validity; administered to 1000's of dialysis patients; norms available for comparison.
        - Recommend continued use of ICH CAHPS for CMS's dialysis center performance monitoring, but improve parsimony by reducing number of items in scales.
- Suggested additional PRMs:
    - CMS requires that all dialysis patients be informed of the option for transplant, but unclear that patients are being appropriately informed.
    - Recommend development of a PRM of whether patients have been informed about their options for transplant be adopted.
- Web-based electronic PRM administration:
    - Pros: Allows for efficient data capture with simultaneous data entry, flexible timing for data collection, and is convenient for patients.
    - Cons: Difficult to ensure privacy, upfront costs for PRO system/maintenance, potential software problems, would require additional testing for equivalence and updates to instructions and formatting for surveys designed for paper/pencil.
    - Recommend equivalence between electronic and paper versions of PRMs be evaluated prior to widespread use of electronic administration.
- Support for PRM use in dialysis:

    - Cost of administration is burdensome for providers and patients, material costs, data entry.
    - Recommend explorations to identify mechanisms for CMS to reimburse these costs.
- Training for PRM administration:
    - Skills required for interview administration: Understanding standardized survey administration techniques; ways to elicit unbiased, accurate responses; trouble shooting; interview skills; data entry protocols.
    - Recommend continued development of effective, low-cost training programs to help providers administer PRMs, including e-learning programs.
- Conclusions:
    - Many successes in use of PRMs in dialysis.
    - Good measures available.
    - Room to grow and improve: Measures, administration methods, support of staff administering PRMs.
- Recommendations:
    1. Continue use of KDQOL-36 for dialysis center IQI, but improve current iteration by replacing SF-12 PCS & MCS with PROMIS items.
    2. Continue use of ICH CAHPS for CMS's dialysis center performance monitoring, but improve parsimony by reducing number of items in scales.
    3. Develop a PROM focused on whether patients have been informed about their options for transplant.
    4. Evaluate equivalence between electronic and paper versions of PRMs prior to widespread use of electronic administration.
    5. Explore mechanisms for CMS to reimburse costs of administration/data entry and material costs.
    6. Develop effective, low-cost training programs to help providers administer PRMs, including e-learning programs.

Discussion of Commissioned Papers

The discussion on the commissioned papers was wide-ranging, with the following main points:

- General patient and provider considerations:
    - Patient concerns about retaliation from facility personnel for expressing dissatisfaction must be addressed.
    - Focus of surveys should be on aspects important to patients.
    - Assumption is that all patients can comprehend the questions and respond coherently, which is not always true. Should there be some assessment to establish a minimum level of cognition for PROMs? Should "teach-back" be considered?
    - Burden on patients of PROMs must be addressed.
    - Providers need to make sure patients understand the importance of participating—why something is being asked—but must also demonstrate tangible results to improve care based on the burden of patient participation.
    - Providers should provide feedback to patients and information about the actions taken as a result of the survey.
    - For HRQOL or symptom burden, in particular, patients should be asked whether they are comfortable being asked about x or whether they are concerned about x.
- Methodological considerations:
    - Who interviews (if in-person) is important.

    - Patients should have a choice of where to complete surveys, since some of the questions are sensitive and personal and might not be answered truthfully in front of others.
    - Interviews/surveys must be voluntary, with an option to quit.
    - Although choice and options for administration are important, for performance measurement for accountability, standardized ground rules must be deployed.
- Existing PROMs:
    - ICH CAHPS is viewed as burdensome, but disagreement with conclusion that ICH CAHPS is not useful for aspects of facility/unit-level improvement.
    - The purpose of ICH CAHPS, as currently deployed, is to report to consumers about relative performance, *in aggregate*. Need to ask if this is the right paradigm.
    - Important to differentiate between HRQOL, IQI, and patient-llevel care planning. KDQOL is a tool for individual patient assessment and the impact on his/her health over time. KDQOL is not appropriate for facility-level quality improvement or facility accountability.
- Proposed modifications to existing PROMs:
    - Proposed that ICH CAHPS: 1) be updated to improve parsimony by reducing the number of items; 2) be expanded to include patients on home therapies; and 3) be separated into versions for incident and prevalent patients, given the two populations are profoundly different with different experiences, risks, and outcomes.
    - KDQOL is an "ossified" patient assessment tool (30 years old) that needs to be updated to reflect current patient input and current survey methodologies (e.g., CAT). Assessment of HRQOL has advanced considerably since KDQOL development.
    - Differential responses by race and ethnicity exist for KDQOL and must be examined and accounted for if used beyond individual assessment.
    - Time on dialysis (i.e., incident vs. prevalent) likely impacts patients' responses. In the near-term, consider examining ICH CAHPS results by vintage.
- Suggested new PROMs:
    - 3-item questionnaire: 1. What are the 3 most important issues/problems you are experiencing right now? 2. What do you think could be done to alleviate those issues/problems? 3. What can your healthcare provider do to help you alleviate those issues/problems?
    - For HRQOL, it's important to understand that patients can be satisfied without complete resolution of a given issue, and that there are issues they do not want addressed. Patients should be asked about x and whether the matter is even of concern to them. Only if it is, should they be queried as to whether the concern has been addressed.
    - For HRQOL, it's important to assess what patients think when starting dialysis and then whether their goals are met; withdrawal from dialysis (and why) is important to understand.
        - Physician-level PROM looking at whether end-of-life care directives—including a discussion of the option to cease dialysis—were addressed by the nephrologist.
        - Physician-level PROM asking patients if and how their nephrologist informed them of their treatment options when first starting dialysis—including a discussion of the option not to commence dialysis.

        - Facility-level PROM asking patients whether they have been informed/educated about their options for transplant.
    - Overall, stimulate PROM development and thinking beyond the mandated instruments—innovation is needed.

KCQA Survey/Interview Results and Discussion

Dr. Nissenson and Dr. Palevsky reviewed the work undertaken to date by KCQA, including the environmental scan, identification of a PRO framework for measurement, KCQA member interviews, and KCQA member and supplemental patient prioritization of areas for PROMs for patients with ESRD.

Their presentation is provided at Attachment 1, and the main points from their presentations and the discussion were:

- KCQA PROs Initiative Project consists the following steps:
    - Environmental scan
    - Development of draft framework outline
        - 4 high-level categories: *HRQOL*, *Symptoms/Symptom Burden*, *Patient Experience with Care*, *Health Behaviors*.
        - Used environmental scan to build out subcategories/domains for each high-level category.
        - Used to guide semi-structured interviews and survey prioritization.
        - Minor adjustments recommended following survey analysis.
    - Commissioned papers
    - Semi-structured interviews
        - 52 interviews of KCQA members, patients, KCQA Steering Committee members, other experts.
        - Focused on completeness/appropriateness of draft framework outline, priorities for PRO measurement for ESRD, feedback on ICH CAHPS and KDQOL, and perceived challenges and potential solutions to PRO measurement for ESRD.
    - Prioritization survey
        - 50 completed surveys from KCQA members, patients, and Steering Committee members.
            - KCQA member response was excellent (> 75%).
            - Included enhanced outreach to patients facilitated by AKF, DPC, NKF, Forum of ESRD Networks.
        - Focused on prioritizing high-level PRO categories and domains.
        - Results analyzed by two cohorts: KCQA members and patients.
    - In-person meeting
    - Report
- Interview and survey results
    - Draft framework outline was considered comprehensive and appropriate by interviewees and survey respondents; minor suggestions recommended (see Breakout Summaries).
    - Priorities for ESRD PRO measurement
        - Top priority for both patients and KCQA members changed from Patient Experience in the interviews to HRQOL in the survey; change likely due to preliminary nature of interview and slight variation in composition of the 2 populations (~81% overlap).

        - Both patients and KCQA member survey respondents ranked HRQOL #1 most frequently, but HRQOL was favored to a higher degree by patients; patients also most frequently ranked Patient Experience #2 and ranked Symptoms as #2 significantly less frequently than KCQA members.
        - Rationales provided for rankings:
            - HRQOL:
                - Overall well-being and good health most important thing to patients and are good to guide patient care.
                - HRQOL is a complex concept difficult to effectively measure and measurably impact.
                - Noted that inverse correlation between HRQOL and patient's decline as disease progresses compromises potential value as performance metric.
            - Symptoms:
                - Gaining better sense of symptoms might provide insight into how to more directly improve QOL.
            - Patient Experience with Care:
                - Believed to be more actionable than other categories.
                - More positive interaction between patients and providers—especially communication—would improve other three PRO categories.
                - Providers intervening to put patients at ease during care experience would improve other aspects of care.
            - Health Behaviors:
                - Least likely to reflect facility's quality.
                - Patient behavior difficult to influence.
    - Barriers to collecting PRO information
        - Patients and members nearly universally cited survey fatigue.
        - Other barriers cited by patients: More pressing concerns, feel too ill to participate, belief that nothing will/does change, mistrust and reluctance to be honest due to fears of retribution.
        - KCQA members cited: Patient literacy, burden of administration, subjective nature makes responding difficult.
        - Solutions to barriers:
            - No easy answers, and recommendations often contradictory: Some recommended electronic, some said face-to-face preferable; some feel anonymization key, while others feel identification important to permit facility to address issues; limiting survey length and options would improve, yet some patients recommend more opportunity for open-ended responses.
    - Perspectives on CAHPS and KDQOL
        - Nearly all interviewees with prior experience view ICH CAHPS and KDQOL as not effective, not providing meaningful information on patients' experiences and/or QOL.
        - ICH CAHPS:
            - Burdensome, gaps in content, low response rate raises concern about validity of scoring, patients feel categorical responses limit their ability to provide meaningful information.
        - KDQOL:

        - Pros: More interviewees were favorable (n=13) compared to CAHPS—asks more meaningful questions, provides more actionable information.
        - Cons: Concerns about validity in modern populations, no validation as a performance measure (vs. patient-specific assessment), more effective instruments exist (e.g., SF-36, PROMIS), significant concern about use as performance measure.
    - Care aspect that could be most improved through PROs:
        - No single (or even a few) areas emerged as prominent—areas cited ranged across the PRO framework categories.
        - Patient experience with care: Short-term, immediate issues (chair comfort, temperature, etc.), longer-term issues (patient-provider communication, making patient feel respected, safe, heard).
        - Symptoms: Identification and reduction of symptoms.
        - HRQOL: Effective detection of patients with depression, cognitive dysfunction, low functional status.
        - Health Behaviors: Identification of individuals who need more intensive education to improve health behaviors.
    - Other issues:
        - PRO evaluation of healthcare professionals should be specific, not general.
        - Important to address home dialysis.
        - Family and caregiver outcomes should be assessed.
        - Questions should focus on transactions, "What did X do to address your problem?"
        - Focusing on how a patient feels immediately after treatment (time to recovery) would improve QOL.
        - Validation of any HRQOL metric requires knowing prior patients' QOL and health behaviors.
        - Patients feel not heard, not respected, not included in care decisions.
- Survey fatigue with ICH CAHPS and KDQOL is substantial:
    - Significant push-back on twice per year ICH CAHPS administration, as well as isssues with scheduling KDQOL and CAHPS (in particular when ESCOs are involved); response rates are low and decreasing.
    - Patients also are asked to complete other (non-dialysis-related) surveys, further increasing burden—e.g., HCAHPS with every hospitalization, outpatient clinic surveys.
    - Salience to patients of all the surveys is the key issue; it is not clear that patients are getting anything out of completing the surveys, despite the high burden.
    - Dialysis facilities have no empiric guidance during the 8 months per year of "black out" for ICH CAHPS (i.e., there can be no changes implemented in a facility for 4 months around each survey administration, twice a year).
    - A CMS representative noted there are methodological reasons why ICH CAHPS has to be administered twice a year, and that since PROs currently are not sufficiently comprehensive, there will be more in the future.
- Key messages voiced by participants from KCQA's findings were:
    - Patients value QOL, patient experience, communication; dialysis environment is at the bottom of the list.
    - Patients' perception differs from providers'.

    - Must address whether multitude of surveys in current format is stifling ability to address patients' concerns in effort to achieve high ratings.
    - Patients' fear of retaliation must be addressed.
    - Interviewed patients largely feel they're not heard and not involved in their day-to-day care; they believe that surveys are administered only to "check a box", that responses are not routinely reviewed, and that there is minimal effort expended to respond to issues identified in the surveys.
- Attendees suggested that KCQA survey be fanned out for additional input.

Breakout Context and Goals

Breakouts discussed in greater depth:

- Commissioned paper recommendations, KCQA prioritization findings, and recommended changes to framework outline.
- Points of consensus and disagreement.
- Whether:
    - the current KCQA Principles are salient/applicable to PROMs;
    - consensus exists on a single priority (*Patient Experience with Care* or *HRQOL*) or if both of equal priority for PROM development; and
    - consensus exists `on one or a few subcategories for either *Patient Experience* or *HRQOL*) that merit exploration for measure development (by KCQA or other parties) in the near-term.

Breakout Reports

Meeting participants were split into two groups. Dr. McGonigal and Dr. Nishimi summarized the small-group break-out discussions, as follows:

Breakout 1

- Supported consideration of use of PROMIS measures, and in particular the CAT mode of administration, but recognized the need to validate PROMIS measures in the ESRD population. Members were cognizant that elderly and low SDS patients might not have access to electronic devices.
- Agreed that patients' fear of retribution should inform the best way to capture PRO data in order to receive honest responses, but also noted that anonymized surveys can't inform individualized care; suggested that allowing patients flexibility in choosing survey mode and place of administration might help address this issue.
- Identified two distinct goals/approaches to PROM development: Population-level metrics for accountability purposes and individualized patient-level metrics for quality and care improvement. Since two population-level metrics (ICH CAHPS and KDQOL) are already being used by CMS, the group suggested that KCQA support and work with Hays/Peipert on their current work to modify and improve ICH CAHPS, permitting KCQA to possibly focus on identifying/developing a patient-level measure to improve and individualize care. Results of such a measure could eventually be aggregated to determine if it could ultimately be used as a population-level metric. Specifically, development of the following individualized patient-level PROMs should be considered:

- 1) What is the most important issue/problem you are experiencing today? 2) Did the dialysis facility respond to your concern? 3) Are you satisfied with the dialysis facility's response?
- PROM assessing whether patients have been appropriately educated on their options for transplant. Suggestions ranged from asking patients if they received the existing standardized transplant information form to developing a measure using the teach-back approach to determine patient comprehension of what was taught.

Breakout 2

- Offered several suggestions to update the KCQA Guiding Principles, which will be redlined in and circulated to KCQA members.
- Discussed at length the locus of measurement and implications for impact based on the level of analysis. What is the most effective leverage point for PROMs?
  - Reached consensus, but not unanimity, that KCQA's focus should be on facility PRO-PMs.
  - Acknowledged the impact of some PRO PMs could be greater if "pushed down" to other levels—e.g., clinician level.
- Agreed that KDQOL is not appropriate for facility-level accountability; it is a patient-level assessment tool. It also needs to be updated.
- While recognizing the importance of HRQOL, consensus existed that measuring HRQOL with the goal of facility-level accountability has the potential to be problematic because of limits to facility control of many aspects, complexity of individual assessments being attributed as group characteristics, case mix, and potential for cherry-picking of patients.
- Concurred that transplants are an important focus for PROMs, but felt any PROM should include all other modality options, including no treatment.
  - Discussed whether patient comprehension was feasible and desirable, but no consensus on whether the complexities of such a measure were so significant that this approach should not be pursued.
  - Discussed a more administrative approach to address the issue—i.e., documentation of occurrence—recognizing this is not patient-reported; suggested perhaps such a measure combined with a process measure of intervention could be useful.
  - Agreed an approach that should be explored is asking the patient (hence a PRO) whether he/she feels adequately informed and then look for improvement over time.
- Agreed that results stratified by incident vs. prevalent patients was an important approach to pursue for PRO-PMs (existing and potentially new ones).

Next Steps

- Meeting summary will be prepared and distributed.
- A draft report encompassing the full project (environmental scan, framework, principles, survey, in-person meeting) will first be reviewed by the Steering Committee, then will be reviewed for approval by KCQA members; target for a final report is August 2017l
- No commitment to fund measures; funding decisions TBD by KCP.