SUMMARY
Kidney Care Quality Alliance Conference Call #1 (Cycle 2)
September 09, 2015

A conference call of the Kidney Care Quality Alliance (KCQA) was convened on Wednesday, September 9, 2015. Representatives of the following organizations participated: American Kidney Fund, American Society of Nephrology, American Society of Pediatric Nephrology, DaVita Healthcare Partners, Dialysis Patient Citizens, Dialysis Clinic Inc., Fresenius Medical Care Renal Therapies Group, Greenfield Health Systems, Kidney Care Council, Kidney Care Partners, National Forum of ESRD Networks, National Kidney Foundation, National Renal Administrators Association, Nephrology Nursing Certification Commission, Northwest Kidney Centers, NxStage Medical, Renal Physicians Association, Rogosin Institute, U.S. Renal Care.

OPENING REMARKS
Following the roll call, Drs. Ed Jones and Allen Nissenson, KCQA Steering Committee Co-Chairs, welcomed and thanked the group for participating in the call and the Steering Committee for the considerable work done to date for Cycle 2.

KCQA CYCLE 1 UPDATE
Dr. Nishimi reminded call participants that KCQA completed its Cycle 1 work and submitted two fluid management measures to the National Quality Forum's (NQF) 2015 Renal Project: *NQF 2701 – Avoidance of Utilization of High Ultrafiltration Rate (>/= 13 ml/kg/hour)* and *NQF 2702 – Post- Dialysis Weight Above or Below Target Weight* (previously referred to as FM2). Both measures advanced from the NQF Renal Standing Committee to NQF member and public comment, the UFR measure with a full recommendation and the weight measure with the designation "consensus not reached." Following the NQF member and public comment period, the Standing Committee reviewed the comments on the "consensus not reached" measures and decided not to recommend the weight measure for further endorsement consideration.

KCQA's UFR measure and previously endorsed vascular access measure (*NQF 0251 – AVF or AV Graft or Evaluation for Placement)* both passed NQF Member voting and were well-received by NQF's Consensus Standards Approval Committee (CSAC) and will be before the NQF Board of Directors measures for final ratification. If no appeals are filed, the measure will be fully endorsed. (Of note, KCQA's was the only UFR measure on the voting ballot because the competing UFR measure from CMS was not recommended by the Standing Committee.)

KCQA CYCLE 2
Dr. Nishimi informed the group that as KCQA's fluid management and vascular access measures worked their way through the NQF process, the KCQA Steering Committee has discussed how to approach KCQA's Cycle 2 measure development. She noted that the memorandum distributed in advance of the call summarizes the Committee's thoughts on candidate Cycle 2 measure development areas for KCQA members' review and discussion today.

BREADTH OF CYCLE 2 CANDIDATE MEASURE DEVELOPMENT AREAS
Dr. Nishimi noted that when KCQA initially relaunched, members undertook a systematic prioritization of candidate development areas using a modified Delphi approach that was grounded in KCP's *Blueprint*. The top-ranked measure development areas from this process

were: 1) Fluid Management; 2) Rehospitalization; 3) Vascular Access; 4) Nutrition; 5) Healthcare-Associated Infection; 6) Transplant Referral and Access; 7) Care Transitions; 8) Frequency and Duration of Dialysis (patient engagement in these issues); 9) Medication Management; and 10) Modality Options. At the time of prioritization, it was noted that the list was intended only as guidance for future development, since any new activity would need to account for the changing measurement landscape (e.g., development by others) and evolving evidence base.

In considering Cycle 2 work, Dr. Nishimi informed call participants that the Steering Committee reviewed the Cycle 1 priority list against current CMS activities and recent KCP comment letters. For example, CMS has convened ESRD Technical Expert Panels for vascular access, transplantation, and SHR/SMR (in particular the risk adjustment methodology). Based on TEPs in other care settings and/or cross-cutting areas, CMS foci also include safety (including infections), medication management, and functional assessment. Similarly, KCP comment letters identified the possibility of considering risk-standardized hospitalization, readmission, and/or mortality *rates* (as opposed to the current ratios), as well as other infection measures.

MEASURE DEVELOPMENT DOMAINS NOT RECOMMENDED

Dr. Nishimi noted that *Fluid Management* emerged as the clear choice for Cycle 1, and KCQA's measure development in this domain proved timely and successful. She advised members that, of the remaining top candidate measure development areas from the modified Delphi, the Steering Committee does not recommend pursuing six at this time: *Rehospitalization* (modified Delphi rank #2), *Vascular Access* (3), *Transplant Referral and Access* (6), *Care Transitions* (7), *Frequency and Duration of Dialysis (patient engagement in these issues)* (8), and *Modality Options (patient engagement in these issues)* (10).

Dr. Nishimi emphasized a recommendation not to pursue a particular area is not an indication of a lack of importance of that domain to kidney care quality. Rather, it merely denotes that KCQA measure development in the area is not recommended at this time, given existing external activities, the evidence base, and/or available resources. She then reviewed the Committee's rationale against pursuing these areas:

- *Rehospitalization* (or *hospitalization* or *mortality*) *rate* measures would require a significant increase in resources to address risk adjustment requirements. Of additional concern is the extent to which CMS is wedded to the existing *ratio* approach, thereby limiting the potential acceptance of new KCQA *rate* measures. Also unknown is the extent to which favorable changes to SHR and SMR will be made in the ongoing TEP.
- *Vascular Access* and *Transplant Referral and Access* also are being addressed through current CMS TEPs, again introducing the potential for a lack of CMS uptake.
- Owing to complexities in definitional issues, data availability and access, potential need for risk adjustment, and the need to avoid "check box" measures for NQF consideration, *Care Transitions* is not recommended at this time.
- Measure development in the areas of patient engagement and education in *Frequency and Duration of Dialysis* or *Modality Options* would be difficult because NQF currently seeks measures in such areas that take a patient comprehension and/or a patient-reported outcome approach. Both are difficult to construct, potentially must be risk adjusted (e.g., for sociodemographic factors), and would involve costly testing. Of note, KCQA had a modality options patient education measure that assessed whether all

modality options (including no treatment) were discussed with individuals. Although fully tested and initially NQF-endorsed, the measure lost endorsement in a later maintenance cycle because it was a "check box" measure. The specific feedback from NQF was that a comprehension measure is sought.

MEASURE DEVELOPMENT DOMAINS FOR DISCUSSION

Dr. Nishimi informed KCQA members that, as with Cycle 1, Cycle 2's scope is development and testing of 1-2 related measures for NQF endorsement consideration. She noted, for example, that a vaccination and a medication management measure would not be related, nor would a pneumococcal vaccination and a Hepatitis vaccination measure, even though they are within the same subdomain; these pairs of measures are based on different evidence and would require different testing. Conversely, two medication reconciliation measures that address the same topic might be considered related, depending on their specifics.

Dr. Nishimi instructed that KCQA members should thus focus on identifying a single domain for Cycle 2. Based on an assessment of the current measure development environment and the availability (or lack thereof) of existing measures, she informed call participants that the Steering Committee recommends three areas for all-KCQA discussion: *Infections*, *Medication Management*, and *Nutrition*. She noted that *Infections* and *Medication Management* are recommended by the Steering Committee, but that while there was some support for *Nutrition*, a clear majority of Committee members did not favor measure development in this domain. In the interests of transparency and inclusion, however, the Steering Committee agreed it should be discussed by all KCQA members on this call.

Dr. Nishimi informed KCQA members that for each of the domains or subdomains discussed in the memo, examples of measures identified through an environmental scan are provided to give an indication of the types of measures that could be pursued. She noted that, in many cases, ESRD-specific measures were not identified, so measures from other care settings or conditions are presented only for illustrative purposes so as to indicate the types of measures KCQA could draw upon. She emphasized that the examples are provided merely for context, not to indicate that KCQA should or would pursue similar measures for ESRD.

Infections

For purposes of the memo and this discussion, Dr. Nishimi noted that the *Infections* domain was defined broadly to encompass both healthcare-associated infections commonly encountered by patients on dialysis and community-acquired infectious diseases to which the ESRD population is highly susceptible. She also noted that the Steering Committee initially considered three categories of infection measures: infection- related outcome measures; infection rate measures; and vaccination measures. Because infection-related outcome measures (e.g., infection-related hospitalization) have the same significant disadvantages of acceptance/uptake and cost as do overall outcome measures (noted above), it was not included in this analysis.

Infection Rate Measures

Dr. Nishimi reminded KCQA members that currently *NQF 1460 – NHSN Bloodstream Infection Rate in Hemodialysis (HD) Outpatients* has been incorporated into the QIP, but that it is a general bloodstream infection measure and limited to HD patients. She noted that other measures could be pursued to broaden the domain, such as venous catheter-associated infection rate, peritoneal dialysis-related infection rate, and other infection rate (e.g., blood-born viral infection rate or multi-drug resistant organism infection rate). Dr. Nishimi reviewed the identified pros

and cons of pursuing measure development in this area.

- **Advantages:** The topic is of high impact, patient-centered, and of great interest to CMS. A peritoneal dialysis-related infection rate measure, while affecting a subpopulation, would also round out the infection portfolio and complement the current hemodialysis measure.
- **Disadvantages:** Depending on the measure, some risk adjustment might need to be considered; consequently, the cost of testing could be a barrier. Additionally, small numbers could be an issue, depending on the measure. Testing and data sources could be complicated—i.e., definitional issues, data availability, and/or data capture could be problematic (e.g., exposure calculus may be difficult to obtain, may need to rely on hospitalization data depending on the measure chosen, etc.).

During KCQA members' discussion of this domain, one issue was raised:

- For the NHSN bloodstream infection rate measure, dialysis facilities are required to identify data from different sources, and it could be even more complex and laborious for facilities to gather data for a new infection measure, depending on what is pursued—for example, the feasibility of collecting data for a peritoneal dialysis measure, depending on the specifications and focus, could be challenging.

Vaccination Measures

Dr. Nishimi informed KCQA members that while illustrative examples were identified for other (sub)domains, two patient vaccination measures are specifically presented because of existing guidelines and availability in other care settings of NQF-endorsed measures: Pneumococcal vaccination (hospital-, home health agency-, health plan-, and nursing home-related measures have been endorsed by NQF) and Hepatitis B vaccination (hepatitis vaccination measures for certain populations have been endorsed by NQF).

- **Advantages:** A potentially high impact and patient-centered topic area that is broadly applicable. Pneumococcal vaccination is of interest to CMS, which developed a candidate measure through its Prevention TEP (which did not advance at NQF/MAP because of lack of testing data). KCQA has experience with developing a vaccination measure (i.e., influenza). Would not require risk adjustment.
- **Disadvantages:** Potential data granularity issue, in particular in light of recent (2014) guidelines for pneumococcal vaccination (PCV13 and PPSV23). Lower ranking in KCQA's modified Delphi process.

The following comments were made by KCQA members during the ensuing discussion:

- Distinguishing between the Prevnar and Pneumovax will be difficult with existing data sources. Tracking Prevnar will be difficult for dialysis facilities because CMS does not reimburse dialysis facilities for its administration.
- Hepatitis B vaccinations are covered and tracking is much simpler because the information is received from the primary care physician or the vaccine is administered at the dialysis facility.
- A question was raised as to why influenza vaccination was not included, but it was noted that KCQA is currently the measure steward of an NQF-endorsed, facility-level influenza vaccination measure. It was noted, then, that if this area is pursued,

consideration should be given to bundling any vaccination measure(s) that might be developed in Cycle 2.

Medication Management
Dr. Nishimi noted that medication management is of significant and ongoing interest to CMS across the spectrum of care settings. Currently, two measures are part of the Comprehensive ESRD Care measure set: *NQF 0419 – Documentation of Current Medications in the Medical Record* (CMS; clinician-level) and *NQF 0097 – Medication Reconciliation* (NCQA; clinician/group), and CMS has in the recent past convened TEPs that included medication management measure development for other care settings.

As with the other areas, Dr. Nishimi again reminded the group that examples of measures were presented for context, only. She noted that, overall, four categories of medication management measures were identified: therapeutic appropriateness; medication reconciliation/documentation; medication adherence measures; and medication safety.

Therapeutic Appropriateness Measures
Dr. Nishimi noted that identified *Therapeutic Appropriateness* measures were largely of similar construct—i.e., the percentage of patients with a given clinical condition who were prescribed a particular, clinically appropriate medication. For example, *NQF 1525 – Atrial Fibrillation and Flutter – Chronic Anticoagulation Therapy* (ACC, clinician office/clinic level) and *ACE Inhibitor or ARB Use and Persistence Among Members with CAD at High Risk for Coronary Events* (Health Benchmarks-IMS Health, clinician/group/facility/health plan/integrated delivery system levels).

- **Advantages:** Ensuring individuals receive appropriate medications is patient-centered.
- **Disadvantages:** Potential evidence issues, and some measures may require risk adjustment. By definition, the measure will apply only to a subset of patients.

No issues were raised for discussion.

Medication Reconciliation/Documentation Measures
Dr. Nishimi informed KCQA members that *Medication Reconciliation/Documentation* measures identified through the environmental scan address receipt and review of transition records with patients; reconciliation of pre-admission, admission, and/or discharge records; medication therapy management services with a pharmacist following discharge; and review/documentation of current medications by providers. Examples of reconciliation/documentation measures include *NQF 0419 – Documentation of Current Medications in the Medical Record* (CMS clinician/population levels [ESCO measure]) and *NQF 0554 – Medication Reconciliation Post-Discharge* (NCQA, clinician/group/facility/health plan levels).

- **Advantages:** High impact area of interest to CMS, patient-centered, and potentially applicable to all patients. Does not require risk adjustment.
- **Disadvantages:** Potential data standardization and availability issues; the need to avoid a "check box" approach will probably exacerbate those issues. Locus of control issues are likely.

The following topics were raised by KCQA members during the ensuing discussion:

- Since CMS is already implementing medication management measures in other settings,

it is likely that a dialysis facility measure will eventually be sought as well. Given this, it would be advantageous to be proactive and develop a meaningful measure with input from the renal care community.

- There is generally a correlation between medication reconciliation and mortality; a measure in this area could have a substantial positive impact on care and outcomes for patients.
- There should be ways to develop measure specifications that are not a "check box" measure.

Medication Adherence Measures

Dr. Nishimi noted that *Medication Adherence* measures identified through the environment scan generally assess medication possession ratios or the proportion of days a patient is "covered" by a prescription. For example, *NQF 0545 – Adherence to Statins for Individuals with Diabetes Mellitus* (CMS, group/health plan/integrated delivery system/population levels) and *NQF 1799 – Medication Management for People with Asthma* (NCQA, health plan/integrated delivery system levels).

- **Advantages:** Ensuring individuals are in possession of appropriate medications is patient-centered. May be of interest to CMS, depending on measure identified.
- **Disadvantages:** Potential data source and collection issues. May apply only to a subpopulation. Possession does not equate to patient use.

No issues were raised for discussion.

Medication Safety Measures

Dr. Nishimi indicated that *Medication Safety* measures include adverse events, monitoring, and use of high-risk medications, and that the environmental scan identified (non-ESRD) measures such as *Use of Benzodiazepine Sedative Hypnotic Medications in the Elderly* (PQA, level of analysis not indicated, not endorsed) and *NQF 2456: Medication Reconciliation – Number of Unintentional [Admission and Discharge] Medication Discrepancies Per Patient* (Brigham and Women's, facility level).

- **Advantages:** Patient-centered. Likely to be of high interest to CMS. Other than the existing NHSN infection measure, which CMS classifies under safety, the current portfolio lacks safety measures.
- **Disadvantages:** Potential data definition and collection issues. Small-numbers issue likely to be a significant challenge for testing. Potential attribution issues, depending on the specific topic.

The following issues were raised by KCQA members during the ensuing discussion:

- There are a number of existing pharmacy data programs that can look at drug-drug interactions; picking just one could lead to problems.
- Tracking adverse events is problematic because many aren't ever reported to the dialysis facility. Medication changes are discovered after the fact in most instances.
- Medications changes are frequent and, consequently, difficult to track.

- Drs. Nissenson and Nishimi clarified that the goal for today is to discuss the three candidate areas broadly in the context of the background material provided and so KCQA members should not dwell on specific measures or medication management subdomains. Dr. Nishimi noted that Lead Representatives will vote to decide which area is pursued and decisions related to measure specifics will then fall to a technical Workgroup (not yet appointed), as occurred during Cycle 1.

Nutrition

Dr. Nishimi again noted that whether to advance *Nutrition* as a candidate development area was discussed at length by the Steering Committee, with a clear majority not favoring development at this time. Those advocating for it as a priority cited research linking its import to hospitalization and mortality and its ranking in the modified Delphi. Others did not dispute the importance of nutrition as a clinical area, but noted the evidence to support a performance measure per se was not strong and that interventions to improve performance are not clear-cut. Ultimately, however, the Committee agreed that, in the interests of transparency and inclusion, it should be reviewed. Illustrative examples provided were *NQF 1423: Measurement of nPCR for Pediatric Hemodialysis Patients* (CMS, dialysis-facility level) and *Advanced CKD: Percent of Patients with Qualified Nutritional Counseling* (RPA, clinician- level, not endorsed).

- **Advantages:** Patient-centered; potentially applicable to pediatric and adult populations.
- **Disadvantages:** Controversy on strength of evidence to support NQF endorsement of any measure developed.

The following points were raised by KCQA members during the ensuing discussion:

- Given that the two other candidate areas have more significance and are less controversial, nutrition should be set aside for now.
- Nutrition is a very important clinical topic, but it is important to remain cognizant of the fact that the measure will be submitted to NQF for endorsement consideration. Given the existing evidence, it will be extremely difficult to develop a measure that will pass NQF's criteria. Some wonderful clinical measures have not been endorsed for this reason. It is important to focus on measure development rather than clinical practice.
- Just because measure development in this area will be challenging does not mean that it's not the right thing to do. The topic should at least remain on the list for further consideration.
- Albumin as a measure of nutrition is the second most important modifiable parameter that can impact outcomes, and has been shown to decrease mortality, hospitalization, and rehospitalization in two large studies.
- A 2014 interventional study by one member LDO demonstrated that each year about 80% of patients receive supplements.
- While nutrition is a critical topic for health, it is unclear what the intervention would be from dialysis providers.
- Oral nutritional supplements are not reimbursed, nor are they allowable costs for dialysis facilities. To put facilities in a position where they will be financially penalized under these circumstances in unreasonable.

- Dialysis patients residing in nursing homes and skilled facilities typically have albumin levels below 4, despite appropriate interventions that are effective in other treatment settings. While the topic is extremely important, implementing a nutrition measure across the country in a pay-for-performance setting is problematic, given that such intractable cases are not uncommon. Pursuit of measure development in this area would be premature with the existing lack of controlled data.
- The vast majority of dialysis patients are not in nursing home or skilled care settings and could benefit from a nutrition measure, and there is a lack of controlled data for many performance measure topics.
- A CJASN paper by Frank Maddux published two days ago indicates that the use of serum albumin as a nutritional marker is problematic and needs to be assessed in prospective trials. The paper proposed an entirely alternative index of nutritional status that still needs to be evaluated. The paper further pointed out that prospective interventional trials are still needed to document the value of nutritional supplements. The NQF panel will read this and will recognize that because we're still in the learning phase with nutrition, we cannot develop a sufficiently rigorous metric.
- Comparing data from home patients vs. peritoneal patients vs. the in-center population is very difficult, especially when penalties are involved.
- The measure is intended only for hemodialysis patients.
- The fact that there are no prospective RCTs is not a good argument. Many good experiments have demonstrated that nutritional supplementation does reduce mortality; in the meantime, patients are dying because of low albumin levels.

Dr. Nishimi reminded participants that we're not looking at measure specifics such as which populations are to be measured, but rather are only asking if *Nutrition* should be included for voting. Dr. Nishimi asked Dr. McGonigal to call the roll by organizations, reminding individuals that only one person per organization should vote. Results were 3 no, 10 yes, and 1 abstention. Dr. Nishimi confirmed that because the KCQA healthy majority threshold is defined as 75%, *Nutrition* will be included in the survey monkey vote.

Next Steps
Dr. Nishimi outlined next steps:

- The surveymonkey link to will be emailed to all KCQA Lead Representatives on or before Monday, September 14 and be open for 10 days to 2 weeks. Dr. Nishimi also noted that the Steering Committee would review the results and decide whether a second "run-off" vote was indicated; that voting period would likely be shorter.
- *Infection Rates* and *Vaccinations* will be separated into two distinct topic areas in the survey, given their significantly different foci.
- Lead Representatives will rank each of the candidate areas, with "1" representing the highest preference and "4" the lowest.

Dr. Jones reminded KCQA members that all Lead Representatives are voting to represent the views of their respective organizations and that the allotted period is intended to allow sufficient time for Lead Representatives to converse with other decisionmakers within their

organizations to establish internal consensus and to vet their intended input prior to casting their vote.

Dr. Nishimi thanked call participants for their time, and the conference call was adjourned.