TO: KCQA Members

FR: KCQA Steering Committee—Ed Jones (Co-Chair), Allen Nissenson (Co-Chair), Scott Ash, Akhtar Ashfaq, Donna Bednarski, Barbara Fivush, Ray Hakim, Shari Ling, Chris Lovell, Tom Manley, Gail Wick

DA: September 3, 2015

RE: KCQA Cycle 2 Candidate Development Areas

As you know, KCQA completed Cycle 1 and submitted two fluid management measures to the National Quality Forum (NQF) 2015 renal project: *NQF 2701 – Avoidance of Utilization of High Ultrafiltration Rate (>/= 13 ml/kg/hour)* (previously referred to as FM7) and *NQF 2702 – Post-Dialysis Weight Above or Below Target Weight* (previously referred to as FM2). Both measures advanced from the NQF 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 NQF Committee reviewed the comments on the "consensus not reached" measures, including the weight measure, and decided not to recommend it for further endorsement consideration. KCQA's UFR measure, however, is currently undergoing NQF member voting; of note it is the only UFR measure on the ballot because the competing UFR measure from CMS was not recommended.

While our fluid management measures have been working their way through the NQF process, we also have been considering how to approach Cycle 2. This memorandum summarizes our thoughts on candidate Cycle 2 measure development areas for KCQA members' review and discussion.

BREADTH OF CYCLE 2 CANDIDATE MEASURE DEVELOPMENT AREAS

When KCQA initially relaunched, members undertook a systematic prioritization of candidate development areas that was grounded in KCP's *Blueprint* and used a modified Delphi approach. 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 developing this document, we reviewed the Cycle 1 priority list against current CMS activities. 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 on measures also were examined to glean suggestions for new measures and/or different approaches to existing domains. It was from such a review that the possibility of considering risk-standardized hospitalization, readmission, and/or mortality *rates* (as opposed to the current ratios), as well as other infection measures, was identified.

The balance of this memo first analyzes the measure development areas we believe KCQA should not pursue at this time and then presents three areas for KCQA member discussion.

MEASURE DEVELOPMENT DOMAINS NOT RECOMMENDED

Fluid management emerged as the clear choice for Cycle 1 and, as just noted, KCQA's measure development in this domain proved timely and successful. Of the remaining top candidate measure development areas from the modified Delphi, we do not recommend pursuing six at this time: *Rehospitalization* (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):

- *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.[1] Both are difficult to construct, potentially must be risk adjusted (e.g., for sociodemographic factors), and would involve costly testing.

As has been emphasized before, a recommendation not to pursue a particular area is not an indication of the 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.

MEASURE DEVELOPMENT DOMAINS FOR DISCUSSION

As with Cycle 1, Cycle 2's scope is development and testing of 1-2 related[2] measures. Thus, KCQA members should focus on identifying a single domain for Cycle 2.

Based on our assessment of the current measure development environment and the availability (or lack thereof) of existing measures, three areas have been identified for all-KCQA discussion as the measure development priority for Cycle 2: *Healthcare-Associated Infections* (5), *Medication Management* (9), and *Nutrition* (4). *Infections* and *Medication Management* are recommended by the Steering Committee, but we had a spirited discussion on whether to advance *Nutrition*, with

[1] In fact, 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 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.

[2] As an example, a vaccination and a medication management measure would not be related nor are a pneumococcal vaccination measure 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 could be considered related.

a clear majority not favoring development in this domain. In the interests of transparency and inclusion, however, we agreed it was an important area to be discussed by all KCQA members, and so it also is reviewed below.

For each of the domains or subdomains discussed in the following sections, examples of measures identified through an environmental scan are provided to give an indication of the types of measures that could be pursued. In many cases, ESRD-specific measures are not available, so measures from other care settings or conditions are presented for illustrative purposes so as to indicate the types of measures KCQA could draw upon. Again, the examples are provided merely for context, not to indicate KCQA should or would pursue similar measures for ESRD. The advantages and disadvantages with measure development in the (sub)domain also are briefly reviewed.

Infections

For purposes of this document, we defined *Infections* broadly to encompass not the only iatrogenic and nosocomial infections commonly encountered by patients on dialysis, but also the community-acquired infectious diseases to which the ESRD population is highly susceptible. (Toward this end, we noted that USRDS similarly lumps both in reporting hospitalizations due to infection.) We note that currently *NQF 1460 – NHSN Bloodstream Infection Rate in Hemodialysis (HD) Outpatients* has been incorporated into the QIP, as well as a healthcare personnel influenza vaccination measure; an influenza vaccination measure for patients has been proposed. Other measures could be pursued, however, to broaden this domain, especially since NQF 1460 currently pertains only to bloodstream infections, broadly, not specifically infections related to access, and is limited to HD patients.

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 uptake and cost as do overall outcome measures (noted above), we do not include it in this analysis. The remaining two subdomains—infection rates and vaccination measures—seem good candidates for KCQA measure development.

Infection Rate Measures

In addition to the existing bloodstream infection rate measure (which KCQA could choose to improve upon or modify), candidate concepts include:

1. Venous catheter-associated infection rate;
2. PD-related infection rate;
3. Other infection rate (e.g., blood-born viral infection rate [Hepatitis B and C and HIV] or multi-drug resistant organism infection rate [MRSA, VISA, hVISA, VRSA, VRE, C. Diff]

- **Advantages:** High impact, patient-centered, and of great interest to CMS. A PD-related infection rate measure, while affecting a subpopulation, would round out the infection portfolio and complement the current HD measure.
- **Disadvantages:** Depending on the measure, some risk adjustment might need to be considered and so the cost of testing could be a barrier. 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.).

Vaccination Measures
For the other (sub)domains, illustrative examples are identified. Because we considered infections broadly and because the topic is narrow, two patient vaccination measures are specifically presented:

1. Pneumococcal vaccination (hospital-, home health agency-, health plan-, and nursing home-related measures have been endorsed by NQF)
2. Hepatitis B vaccination (hepatitis vaccination measures for certain populations have been endorsed by NQF)

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

Medication Management
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). Additionally, an environmental scan for medication management-/reconciliation-related measures identified a broad range of disease- and care setting-specific measures that potentially could be used to inform the development of a facility-level ESRD measure. None of the examples are specific to ESRD.

Overall, four categories of medication management measures were identified: therapeutic appropriateness; medication reconciliation/documentation; medication adherence measures; and medication safety.

Therapeutic Appropriateness Measures
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. Variations include persistence to and pharmacy fills of a prescribed medication. For example:

1. *NQF 1525 – Atrial Fibrillation and Flutter – Chronic Anticoagulation Therapy* (ACC, clinician office/clinic level)
2. *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. Some measures may have risk adjustment issues. By definition will apply only to a subset of patients.

Medication Reconciliation/Documentation Measures
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. Types of reconciliation/documentation measures are:

1. *NQF 0419 – Documentation of Current Medications in the Medical Record* (CMS clinician/population levels [ESCO measure])
2. *NQF 0554 – Medication Reconciliation Post-Discharge* (NCQA, clinician/ group/ facility/health plan levels)

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

Medication Adherence Measures
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 during the reporting period (threshold generally defined as 80%). For example:

1. *NQF 0545 – Adherence to Statins for Individuals with Diabetes Mellitus* (CMS, group/health plan/integrated delivery system/population levels)
2. *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.

Medication Safety Measures
Medication Safety measures, include adverse events, monitoring, and use of high-risk medications, and the environment scan identified (non-ESRD) measures such as:

1. *Use of Benzodiazepine Sedative Hypnotic Medications in the Elderly* (PQA, level of analysis not indicated, not endorsed)
2. *NQF 2456: Medication Reconciliation – Number of Unintentional [Admission and Discharge] Medication Discrepancies Per Patient* (Brigham and Women's, facility level)[3]

- **Advantages:** Patient-centered. Other than NHSN infection measure, the current portfolio lacks safety measures. Likely to be of high interest to CMS.
- **Disadvantages:** Potential data definition and collection issues. Small-numbers issue likely to be a significant challenge for testing. Potential locus of control/attribution issues.

[3] This measure encompasses both reconciliation and safety. A 2008 study indicated that nearly 80% of hemodialysis patients being discharged from an in-patient dialysis center to an outpatient facility had at least one unintended medication variance upon transfer. (Ledger S, Choma G. Medication reconciliation in hemodialysis patients. *CANNT J.* 2008;18(4):41-43.)

Nutrition

As noted earlier, we discussed at length [call summaries attached] whether to advance *Nutrition* as a candidate development area, 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 not clear cut. Ultimately, however, the Committee agreed that, in the interests of transparency and inclusion, it should be reviewed. Examples include:

1. *NQF 1423: Measurement of nPCR for Pediatric Hemodialysis Patients* (CMS, dialysis-facility level)
2. *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.

NEXT STEPS

Following the conference call, KCQA members will be asked to vote on a priority for Cycle 2. As with the Cycle 1, measure concepts will be developed in greater detail, along with the technical specifications, for KCQA members' review and approval. The intent is to submit the 1-2 measures to NQF for endorsement consideration at the earliest available opportunity.

Kidney Care Quality Alliance (KCQA) Steering Committee
Conference Call #1 (Cycle 2)
July 31, 2015

Attendees: Ed Jones (Co-Chair), Allen Nissenson (Co-Chair), Scott Ash, Akhtar Ashfaq, Barbara Fivush, Chris Lovell, Tom Manley, Gail Wick, Robyn Nishimi, Lisa McGonigal.

Cycle 1 Recap
After roll call and the introduction of Mr. Ash, the new FMC representative, Dr. Nishimi updated the Committee on the status of the two fluid management measures, which were being considered in the National Quality Forum's (NQF) 2015 Renal Project. KCQA's *Avoidance of Utilization of High UFR (≥13 ml/kg/hour)* measure has been recommended for endorsement by the NQF Renal Standing Committee and will be advanced to NQF Member voting in August. She noted that since the NQF Committee did not support CMS's UFR measure during either its in-person meeting in May or follow-up call earlier this week, the KCQA metric will be the only UFR measure moving forward. She then informed the Committee that the NQF Committee did not reach consensus on KCQA's second measure, *Post-Dialysis Weight Above or Below Target Weight*, at the in-person meeting and so, per NQF policy, the measure was advanced for NQF Member and public comment. During the follow-up call, the NQF Committee did not recommend the weight measure, so it will not advance to the voting phase.

KCQA Cycle 2 Work
Dr. Nishimi informed the Committee that over the course of several conversations, the Co-Chairs and consultants reviewed the modified Delphi rankings from Cycle 1 to determine candidate measure development areas for Cycle 2. She and Dr. McGonigal then performed a high-level environmental scan and literature review to provide background context on selected areas for the Committee's consideration: outcome rates (hospitalization and mortality), infections, and medication management.

Dr. Nishimi asked Steering Committee members if they had additional suggestions for consideration by the full KCQA. Mr. Lovell asked why nutrition and transplant referral, both of which were prioritized higher during the initial ranking, were not reviewed. Dr. Nishimi responded that CMS just concluded its transplant TEP, and that the report will be released in the near future. Dr. Nissenson noted that nutrition had been discussed by the Co-Chairs and consultants, but it had been determined that it was unclear that a difference could be made in this area given the existing landscape and that operationalizing a metric would be problematic. Mr. Lovell agreed, but noted that the rationale for not including either in the list of potential topics should be summarized. Dr. Nishimi agreed the information should be included in the next iteration of the document. She added that the Cycle 1 prioritization process made clear that the rankings were not "set in stone," and that the changing measure development landscape (e.g., TEPs convening, new measures developed since the modified Delphi) were to be considered when moving forward.

The Committee then discussed the three candidate areas.

Hospitalization and Mortality Rates
Dr. Nishimi reminded the Committee that KCP consistently has noted the significant

shortcomings of CMS's standardized mortality ratio (SMR), standardized hospitalization ratio (SHR), and standardized readmissions ratio (SRR) measures. Most recently, KCP recommended that CMS shift to risk-adjusted hospitalization and mortality *rates* for the Five Star program. She then reviewed the pros and cons of pursuing measure development in this area.

Advantages

- Hospitalization and readmissions are of particular interest to CMS.
- If hospitalizations/readmission rates were pursued, it would align with the priorities identified through the modified Delphi.

Disadvantages

- Development in these areas requires a much more iterative process to identify the appropriate risk adjustment; as such, it would require additional resources beyond what is currently available to KCQA and so additional funds would need to be sought.
- It is unclear the extent to which CMS is wedded to the ratio vs. rate approach.
- The extent to which favorable changes to SHR and SMR could be made in the forthcoming CMS TEP (being convened this fall) is unknown.

Drs. Jones and Nissenson reinforced that KCQA must recognize that CMS might not be receptive to rate measures. They noted that while not impossible, having CMS accept a mortality or hospitalization rate measure developed by KCQA could be a hard sell. Dr. Nishimi added that the uncertainty is such that measure development in this area is likely not a wise investment of resources. The Steering Committee agreed with these reasons and that rate measures should be removed from the list of potential Cycle 2 measure development areas.

Infections

Dr. Nishimi noted that while *NQF 1460 – NHSN Bloodstream Infection Rate in Hemodialysis Outpatients* already has been incorporated into the QIP, other infection measures could be pursued to further broaden the domain. She informed the Committee that for the purposes of this discussion, "infection" had been defined broadly to encompass both iatrogenic and nosocomial infections commonly encountered by patients on dialysis, as well as community-acquired infectious diseases to which patients with ESRD are highly susceptible. She added that USRDS similarly lumps both in reporting hospitalizations due to infection. She advised the Committee that three categories of infection measures were identified during the preliminary work: infection rates; infection-related outcomes; and vaccinations.

Infection Rates

Dr. Nishimi informed the Committee that, in addition to the existing bloodstream infection rate measure, which KCQA could choose to improve upon or modify, three additional infection rate candidates were identified for discussion in this area: venous catheter-associated infection rate; PD-related infection rate; and other infection rate (e.g., blood-born viral infection rate [Hepatitis B and C and HIV] or multi-drug resistant organism infection rate [MRSA, VISA, hVISA, VRSA, VRE, C. Diff]). She then reviewed the pros and cons of each.

Advantages

- Infection rate measures address a high impact and patient-centered topic and are also of great interest to CMS.

- A PD-related infection rate measure, while affecting a subpopulation, would round out the infection portfolio and complement the current HD measure.

Disadvantages
- Depending on the measure, some risk adjustment might need to be considered.
- Depending on the measure, small numbers could be an issue.
- Testing and data sources could be complicated—definitional issues, data availability, and/or data capture could be problematic. For example, exposure calculus may be difficult to obtain, may rely on hospitalization data, etc.

Dr. Nissenson remarked that the PD measure appeals to him because it would be feasible to consider both an adult and a pediatrics metric and would comport with what CMS has been trying to do in this area. He added that a measure in this area would resonate with stakeholders. He noted that since there are fewer PD patients and measures, developing one to ensure these patients are getting the highest level of care would be beneficial. Dr. Jones added that venous catheter-related issues were identified as a high priority area in the KCP Blueprint. Steering Committee members agreed with these points, so *Infection Rates* will be kept on the list for further consideration.

Infection-Related Outcomes
Dr. Nishimi stated that rather than pursue hospitalization, rehospitalization, or mortality rates, as just discussed, KCQA could instead pursue measures addressing hospitalization or mortality resulting specifically from infection. She noted, however, that the same advantages and disadvantages discussed for the general measures carry over—i.e., it is unclear that CMS has interest in such subset measures and testing will be costly and complex. The Steering Committee agreed this topic should be removed from the list.

Vaccination Measures
Dr. Nishimi informed the Committee that because infections were defined broadly, two vaccination measures were identified for consideration: pneumococcal vaccination and Hepatitis B vaccination. She reviewed the identified pros and cons.

Advantages
- Vaccinations are a potentially high impact and patient-centered area.
- Pneumococcal vaccination is of interest to CMS, which developed a candidate measure through its Prevention TEP, although the measure did not advance at NQF because of a lack of testing data.
- KCQA has experience with developing a vaccination measure (influenza).
- A vaccination measure would not require risk adjustment.

Disadvantages
- A data granularity issue exists in CROWNWeb in light of the 2014 recent guidelines for pneumococcal vaccination (PCV13 and PPSV23); CROWNWeb does not currently differentiate pneumococcal vaccinations by type.
- Vaccination ranked lower in KCQA's modified Delphi.

Dr. Nishimi also noted that a workgroup related to the National Adult and Influenza Immunization Summit, lead by individuals from CDC and the Pharmacy Quality Alliance, has

contacted her and hopes to develop a composite pneumonia, influenza, and Hepatitis B vaccination measure for the ESRD population in the near future. She remarked that this might present a potential competing measure, should KCQA choose to pursue this path.

Dr. Ashfaq suggested that an alternative approach could be to develop a measure that captures how many patients developed immunity following vaccination. He noted that this would be a more complicated measure, but addresses the true underlying issue of protection from disease. Dr. Nissenson agreed that this is a good point, but added that even with 100% immunization, there still would be patients who fall ill. Assuming the vaccine is given correctly, he noted that facilities should not be held accountable for whether a given patient does not respond to the vaccine. He added that while a process immunization measure is not directly linked to the outcome, it nevertheless has value: If 0% of patients are immunized, no one is protected. Dr. Fivush added that developing a measure looking at seroconversion rates would be complex and expensive. Mr. Lovell remarked that PEER data indicate that mortality rates skyrockets every January, suggesting a strong association with pneumonia and influenza infection. He noted that the data do not make clear whether the people who die were vaccinated or not, but that assessing vaccination rates is an important first step. He concluded that this is a very important topic.

Dr. Nissenson then asked if, rather than pursuing a measure de novo, whether KCQA consider working with the CDC and PQA on this. He noted that this would allow KCQA to provide input and influence the process without a significant use of resources. Dr. Fivush and Mr. Lovell concurred that collaboration would be a reasonable approach. Mr. Lovell asked if a composite measure (as is being pursued by the aforementioned workgoup) is preferable to individual vaccination measures. Dr. Nishimi responded that she is not sure why the group is focused on a composite, and remarked that since it would be important to look at the individual vaccination rates, it is possible the group plans to break out the separate rates and then "roll up" to a composite score. Dr. Nissenson noted that it's important for KCQA to get involved in their process to ensure that nuances such as variable inclusions and exclusions are considered. Dr. Nishimi suggested that she follow-up with the workgroup leads to gather additional information and determine the extent to which KCQA can be involved in their process. Committee members agreed with this approach, noting this would free up KCQA's resources for other areas, but also concluded that *Vaccinations* should remain on the list until the workgroup's intent is better understood.

Medication Management

Dr. Nishimi reminded the Committee that medication management is of significant and ongoing interest to CMS, and that two measures are currently 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). She noted that while no ESRD-specific medication management measures were identified by staff, NQF has a broad portfolio of disease-specific and care-setting specific medication-management/ reconciliation-related measures that could be mined for applicability and suitability for an ESRD facility-level measure. She then reviewed the identified pros and cons of measure development in this area.

<u>Advantages</u>

- Medication management is a high impact and patient-centered area that is of significant

interest to CMS.
- A medication management measure would not require risk adjustment.

Disadvantages
- There are potential data definition issues, as well as the issue of multiple data sources.
- To improve endorsement potential, measure construction would need to address NQF's inclination away from "check-box" measures.

Dr. Manley acknowledged the complexities of data collection and the fact that this would be a process measure, but noted that a dialysis facility medication management metric would still add tremendous value and improve monitoring and reconciling patients' medications. Ms. Wick noted that facilities are already required to review medications by the Conditions for Coverage. She questioned how developing a measure in this area would further improve quality. Dr. Nissenson agreed that a measure that just required an accurate medications list would not be very helpful, but noted that if the Steering Committee agrees that this is an important area, there are many resources that could be used to develop a more meaningful measure. Dr. Ashfaq concurred that while it would be a difficult venture, the depth and breadth of expertise within KCQA is such that the group could create a meaningful metric in this area; he encouraged serious consideration of this area.

Dr. Nishimi suggested that before moving forward, she and Dr. McGonigal should build out the details of potential medication management measure development for additional Steering Committee discussion, so that members could assess the feasibility of development in this area. Dr. Nissenson noted that he has been conferring with a colleague who has worked with the Pharmacy Quality Alliance (PQA) developing medication management measures to get a better sense of what has already been done in this area and could make that available to the consultants.

Cycle 2 Process Issues

Dr. Jones thanked everyone for their efforts to date. He noted that the NQF Renal Standing Committee did not support KCQA's *Post-Dialysis Weight Above or Below Target Weight* measure during its reconsideration of the metric yesterday. He further noted that the NQF Committee was originally one vote short of reaching consensus on the measure to recommend it. Per NQF protocol, the measure had been forwarded for public review and comment as "consensus not reached". Comments opposing the weight measure were received from three KCQA member organizations during the comment period, which contributed to the NQF Committee's decision to reverse its support and now vote against recommending the measure for endorsement. Dr. Jones noted that all KCQA member organizations supported the measure during the development process, and all voted in favor of submitting the measure for NQF endorsement consideration.

Dr. Jones suggested that the KCQA process be reviewed to ensure everyone is in agreement as we begin Cycle 2. He requested input from the Steering Committee, noting that much time and effort went into both fluid management measures, only to have the weight measure fail to advance at NQF based on comments from KCQA members that could have been discussed had they been raised earlier within KCQA. He remarked that each individual on the KCQA Steering Committee, Workgroup, and full KCQA represents his or her organization, and he wants to ensure that there is a consistent message conveying this as we move forward.

Dr. Nissenson emphasized he feels there is no problem with a KCQA member voting no or abstaining on a measure within KCQA, and that doing so as part of our process allows an understanding of the objections, which could then be addressed as needed. He concurred that it is important to ensure that KCQA representatives understand that they are representing their organization when they vote. He also noted the importance of representatives expressing their opinions during conference calls and meetings throughout the process, adding that organizations revoking support without explanation after the conclusion of the process undermines KCQA's ability to advance measures through NQF.

Dr. Ashfaq agreed with Dr. Nissenson, in particular noting that KCQA members that vote in favor of a measure during the development process, only to subsequently submit negative comments to NQF, is disappointing and counterproductive since it prevents KCQA from addressing concerns preemptively. Ms. Wick concurred, adding that the fact that individuals participating in the measure development process and voting on the disposition of the measures are representing their respective KCQA member organizations was made very clear at the beginning of the Cycle 1 work; she suggested that the point clearly needs to be re-emphasized for Cycle 2 work. Mr. Lovell also concurred with this sentiment and noted the importance of individuals informing KCQA leadership on when their organizations disagreed with the consensus opinion. He asked whether anyone had spoken with the three organizations to determine what led to the change since the vote in favor of the measures was unanimous. He questioned what made the organizations change their opinion or whether perhaps the representatives did not feel comfortable expressing their concerns during the process.

Dr. Nissenson noted that he, Dr. Jones, and Dr. Nishimi will be speaking to the three organizations within the next couple of weeks and will be able to provide more detailed information to the Steering Committee on the next call. Dr. Jones appreciated the feedback and noted this was very useful to avoid similar issues going forward.

Next Steps
Dr. Nishimi outlined the next steps:

- She and Dr. McGonigal will bring back a revised document to the Committee for discussion, removing the areas agreed upon, expanding the rationale for why certain areas are excluded or de-emphasized, and outlining in greater detail medication management as a candidate development area.
- Dr. Nissenson, Dr. Jones, and Dr. Nishimi will reach out to the organizations that commented negatively on the weight measure and report back to the Steering Committee on the next call.

Drs. Jones and Nissenson concluded the meeting by thanking the Steering Committee members for their time.

Kidney Care Quality Alliance (KCQA) Steering Committee
Conference Call #2 (Cycle 2)
August 26, 2015

Attendees: Ed Jones (Co-Chair), Allen Nissenson (Co-Chair), Donna Bednarski, Barbara Fivush, Ray Hakim, Chris Lovell, Gail Wick, Robyn Nishimi, Lisa McGonigal.

AGENDA
After roll call, Drs. Jones and Nissenson thanked the Steering Committee for its Cycle 1 work, noting that KCQA's successes to date at NQF in the measure development realm are quite commendable, particularly given limited resources.

Dr. Nishimi reminded the Steering Committee that it agreed on its last call to update the initial review of candidate measure development areas to remove outcome rate measures (e.g., hospitalization rate, mortality rate, infection-specific outcome rates); expand on why certain areas are not viewed as likely candidates for Cycle 2; and provide additional detail on how a medication management domain might be approached. She noted that the Committee also agreed to explore the efforts of a subgroup of the National Adult and Influenza Immunization Summit (NAIIS), lead by individuals from the Centers for Disease Control and Prevention (CDC) and the Pharmacy Quality Alliance (PQA), that is hoping to develop a composite vaccination measure for the ESRD population.

VACCINATION MEASURES AND NAIIS INITIATIVE
Dr. Nishimi informed the Committee that she spoke with the PQA lead and, while the NAIIS Measure Workgroup refers to developing a composite influenza+Hepatitis B+pneumococcal vaccination measure for the ESRD population, the group is not, in fact, developing specifications. Rather, the group's focus is to gather background information that it hopes to then provide some entity to develop specifications and perform testing. She added that the group does not currently have any particular entity in mind, nor have members approached any parties, but has recently identified the need to reach out to key kidney care organizations to get their input on whether a composite adult vaccination measure is of interest (e.g., ASN, RPA, ANNA, ESRD Networks).

Based on this information, Dr. Nishimi reported that, after consulting with the Co-Chairs, *Vaccination* has been left as a candidate development area. She informed the Steering Committee that the NAIIS workgroup will be holding twice monthly 1-hour conference calls over the next few months and that she (or Dr. McGonigal when she is unable) will be attending those calls as a KCP representative (not KCQA so as to avoid conveying a measure development affiliation) and will keep the Committee informed as the NAIIS project unfolds.

CANDIDATE DEVELOPMENT AREAS
Dr. Nishimi then reviewed the changes to the memo: expansion of why certain areas were not proposed as priorities for measure development and the types of measures that might be considered in the medication management domain. Regarding the priority areas not proposed at this time:

- ***Rehospitalization*** (or hospitalization or mortality) rates 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, increasing the potential for lack of uptake of any new KCQA measures in the area. Also unknown is the extent to which favorable changes to SHR and SMR could be made in the ongoing CMS TEP. Dr. Hakim suggested that KCQA should do more than simply object to CMS's approach to hospitalization, readmission, and mortality ratio measures. He noted that it would be better to proactively define the desired outcomes than to leave it in others' hands. Dr. Nishimi responded that KCP has, in fact, consistently recommended that risk-adjusted *rate* measures should instead be used. No other questions or objections were raised to the rationale for not pursuing this priority area.
- ***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. No objections were voiced to not advancing these areas as candidates for Cycle 2 measure development.
- ***Nutrition*** is not explored further because of the uncertainty that a difference could be made in this area given the existing evidentiary landscape and because operationalizing a metric could be problematic. Dr. Hakim felt that *Nutrition* should be a candidate area for development. He noted that nutrition is the second most modifiable factor to affect outcomes, and that its impact on hospitalization and mortality is exponential. Dr. Jones acknowledged that nutrition is an important topic and that all clinics follow nutrition and its biomarkers, but that putting together a performance measure in this area is a different issue. He noted that there are no randomized controlled trials to support a nutrition metric that would satisfy NQF criteria. He added that some clinics would necessarily be marginalized by a nutrition measure—e.g., those with a preponderance of older patients or those in nursing homes. Mr. Lovell noted that the same could be said for any measurement area; Dr. Hakim agreed. Mr. Lovell suggested that *Nutrition* should be taken to the full KCQA for consideration, particularly given that it was #4 on the modified Delphi prioritization list. Dr. Nissenson remarked that if several experts were convened, not all would feel as strongly about the available evidence supporting a nutrition measure; KCQA would have to overcome this fact at NQF. He also noted that DaVita has always had an intense focus on nutrition, as do all dialysis organizations. He indicated that albumin was even integrated into DaVita's Quality Index for two years, but that despite attention to it, including numerous tools, no significant impact was evident. He concluded that while everyone knows that nutrition is critically important and that focusing on malnourished patients will help them, how to evaluate these patients from a performance measure standpoint and what to do to influence performance makes it unlikely that NQF will support a measure in this area. Dr. Hakim responded that studies clearly indicate that oral nutritional supplements make a significant difference in patients with low albumin levels. He questioned how this fact can be ignored. Dr. Nissenson noted that not selecting a topic for pursuing a quality metric to be endorsed by NQF is not the equivalent of saying that it's not an important topic or that interventions cannot help. He remarked that it is easy to fall into a trap that measures in all areas are important. Ms. Wick agreed that nutrition is an important clinical issue, but that KCQA must choose an area where a measure is likely to be endorsed by NQF. She noted that there are many important clinical areas that don't fit that bill; just because KCQA does not pursue these areas does not mean that they are not important. Ms. Bednarski agreed, noting that she does not downplay the area's

importance, but that KCQA must select an area that can be measured appropriately. Dr. Hakim suggested that not selecting nutrition would in effect be ignoring its importance. Dr. Jones remarked that this is an inaccurate and unfair conclusion. He noted that he and his partners concentrate heavily on nutrition at all times and that it is a driving force in their practices. However, holding people accountable within a performance measurement program is a different scenario. Mr. Lovell suggested noting that the Steering Committee members clearly have a difference of opinion in this area, and that the topic be kept on the list of candidate areas to allow the full KCQA to opine on the matter. Dr. Fivush agreed that nutrition is a critical area for pediatric patients as well as for adults, but she acknowledged that measure development in this area would be extremely difficult; she questions whether this is the appropriate time to devote resources to pursuing measures in this area.

Dr. Nishimi recommended that the Committee include the domain on the list of potential measure development areas, but note that the clear majority of the Committee did not favor it as a priority and that there was a spirited discussion on whether it should advance for further consideration. Dr. Nissenson agreed that for the benefit of transparency and inclusiveness, the domain should remain on the list. No other comments were offered or objections raised to this approach.

- ***Care Transitions*** is not recommended at this time 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. No objections were voiced to not advancing this area as a candidate for Cycle 2 measure development.
- Measure development in the areas of patient engagement and education in ***Frequency and Duration of Dialysis*** **(patient engagement/education aspect)** or ***Modality Options*** **(patient engagement/education aspect)** would be difficult because NQF currently seeks measures in such areas that take a patient comprehension and/or patient-reported outcome approach. Dr. Nishimi noted that both types of measures are difficult to construct, potentially must be risk adjusted (e.g., for sociodemographic factors), and would involve costly testing. She also reminded the Committee that KCQA in fact 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 endorsed by NQF, 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. No objections were voiced to not advancing these areas as candidates for Cycle 2 measure development.

Dr. Nishimi then turned to the two priority areas identified for consideration for Cycle 2 work: *Infections* and *Medication Management*.

Infections

Dr. Nishimi noted that the Committee had reviewed this material on the previous call and that *Infection Outcomes* (e.g., hospitalization or mortality due to infection) had been removed per that discussion because of the costs of such development due to the need for risk adjustment. She again noted that two remaining categories of infection measures seem good candidates for KCQA measure development: *Infection Rate* and *Vaccination*.

Dr. Nishimi asked if there were any questions or additional thoughts regarding infection measures. Mr. Lovell remarked that the NHSN measure currently pertains only to bloodstream

infections, broadly, not specifically infections related to access, and that it doesn't include peritoneal dialysis patients. He also noted that CDC, as the measure steward, has not been receptive to recommendations by CMS or KCP. Dr. Nishimi responded that that she will make the distinction about scope clear when describing the NHSN measure. She also noted that in the current NQF Renal Project, both KCP and the NQF Standing Committee opposed the addition of the Adjusted-Ranking Metric to the measure, and the measure was ultimately revised accordingly. No other questions or objections were raised to moving forward with *Infection Rates* as a candidate development area.

Medication Management

Dr. Nishimi again noted that medication management is of significant and ongoing interest to CMS and that two measures are currently 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). Additionally, an environmental scan for medication management-/reconciliation-related measures identified a broad range of disease- and care-setting specific that potentially could be used to inform the development of a facility-level ESRD measure. Overall, she indicated that four categories of medication management measures were identified: therapeutic appropriateness; medication reconciliation/documentation; medication adherence measures; and medication safety. No measures were specific to ESRD.

Therapeutic Appropriateness Measures

Dr. Nishimi advised the Committee that the 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. Variations include persistence to and pharmacy fills of a prescribed medication. She provided two examples, then the pros and cons of pursuing measure development in this area:

1. *NQF 1525 – Atrial Fibrillation and Flutter – Chronic Anticoagulation Therapy* (ACC, clinician office/clinic level)
2. *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 that individuals receive appropriate medications is patient-centered.
- **Disadvantages:** Potential evidence and risk adjustment issues. By definition, a measure in this area will apply only to a subset of patients.

Medication Reconciliation/Documentation Measures

Dr. Nishimi noted that the *Medication Reconciliation/Documentation* measures identified through the 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. She provided examples of reconciliation/documentation measures and the pros and cons of pursuing measure development in this area:

1. *NQF 0419 – Documentation of Current Medications in the Medical Record* (CMS clinician/population levels [ESCO measure])

2. *NQF 0554 – Medication Reconciliation Post-Discharge* (NCQA, clinician/ group/ facility/health plan levels)

- **Advantages:** High impact, patient-centered, and potentially applicable to all patients. The topic is of interest to CMS. Risk adjustment would not be required.
- **Disadvantages:** There are potential data standardization issues and it would be necessary to avoid a "check box" approach. Additionally, there would likely be locus of control issues.

Medication Adherence Measures

Dr. Nishimi noted that the *Medication Adherence* measures identified generally assess medication possession ratios or the proportion of days a patient is "covered" by a prescription during the reporting period (e.g., a threshold generally defined as 80%).

1. *NQF 0545 – Adherence to Statins for Individuals with Diabetes Mellitus* (CMS, group/health plan/integrated delivery system/population levels)
2. *NQF 1799 – Medication Management for People with Asthma* (NCQA, health plan/integrated delivery system levels)

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

Medication Safety Measures

Lastly, Dr. Nishimi noted that *Medication Safety* measures include adverse events, monitoring, and use of high-risk medications. Examples and pros and cons were reviewed:

1. *Use of Benzodiazepine Sedative Hypnotic Medications in the Elderly* (PQA, level of analysis not indicated [not endorsed])
2. *NQF 2456: Medication Reconciliation – Number of Unintentional [Admission and Discharge] Medication Discrepancies Per Patient* (Brigham and Women's, facility level)[1]

- **Advantages:** Patient-centered. Other than NHSN infection measure, the current portfolio lacks safety measures. Likely to be of high interest to CMS.
- **Disadvantages:** Potential data definition and collection issues, and the small-numbers issue is likely to be a problem for testing. There are also potential locus of control/attribution issues.

Dr. Nishimi asked if there were any questions or additional thoughts regarding any of the four identified medication management topics. Dr. Nissenson asked if the role of the Steering Committee is to say that these two domains (*Medication Management* and *Infections*) look

[1] This measure encompasses both reconciliation and safety. A 2008 study indicated that nearly 80% of hemodialysis patients being discharged from an in-patient dialysis center to an outpatient facility had at least one unintended medication variance upon transfer. (Ledger S, Choma G. Medication reconciliation in hemodialysis patients. *CANNT J.* 2008;18(4):41-43.)

feasible, and the next step would be for the full KCQA to agree or disagree. He noted that the Steering Committee might not be the most appropriate group to get into technical measure construct details, and asked whether a technical workgroup would be convened, as in Cycle 1. Dr. Nishimi noted that she intended the Committee to discuss this under next steps—i.e., whether the Committee wants to recommend only the high-level domains, or whether it wants to drill down and eliminate some of the proposed options. She indicated that she had assumed the technical specifications would be developed by a Feasibility and Testing Workgroup, as in Cycle 1.

Dr. Fivush said she felt the process should be the same as previously—i.e., that the Steering Committee should make high-level recommendations, then a technical workgroup should be convened to dive more deeply. She suggested that there should be better communication between the Steering Committee and the Workgroup—particularly in regards to what the Steering Committee believes is important.

Dr. Nissenson asked for clarification on the specific charge and budget from KCP to the Steering Committee regarding how many topics and measures can be addressed in this cycle. Dr. Nishimi responded that the budget is for the development of 1-2 related measures. She provided examples: A vaccination and a medication management measure would not be related nor are a pneumococcal vaccination measure and a Hepatitis vaccination measure—both pairs are based on different evidence and would require different testing. Conversely, two medication reconciliation measures that address the same topic could be considered related.

Mr. Lovell and Ms. Wick asked for clarification as to whether the examples provided are meant only to give a sense of what already exists in this domain, and whether the Workgroup, once appointed, can select something else altogether. Dr. Nishimi answered yes, though based on the scan they believed that a measure would fall into one of these four categories. She noted that it is difficult for some to think in the abstract about measures when brief labels are provided and so specific examples were identified. Dr. Nissenson added that, while there are no existing *Medication Management* measures pertaining to ESRD, the examples provided demonstrate that there are other clinical areas with such measures that could be explored for ideas, and that many of the listed subdomains appear to be fertile for ESRD measure development.

Dr. Nishimi asked if there were subdomains within *Medication Management* that the Committee feels should be removed at this time. Committee members agreed that no subdomains should be removed from consideration.

DOMAIN RECOMMENDATION

Dr. Nishimi asked the Steering Committee if it wants to make a recommendation to the full KCQA on what specific domain should be selected, or if it would rather forward a document with the three areas (*Medication Management*, *Infections*, and *Nutrition*) for discussion without a recommendation. Ms. Wick asked for confirmation that the Committee did forward a recommendation to the full KCQA during the Cycle 1 work. Dr. Nishimi confirmed that it did, but in that instance there was a clear and large separation between the selected domain (i.e., *Fluid Management*) and other candidates; she noted that that is not the case here. Dr. Hakim commented that he believes forwarding all three candidate domains for discussion among the full KCQA is a reasonable approach. Dr. Nissenson agreed. Mr. Lovell also concurred, adding that because there is no strong preference for any of the proposed domains by the Steering

Committee it makes sense to let the larger KCQA discuss. He inquired how a final determination would be made, and Dr. Nishimi indicated that surveymonkey would be used, as had been done for other KCQA voting.

CYCLE 2 PROCESS ISSUES

Dr. Nishimi updated the Committee on the Cycle 2 process issues that were discussed on the previous call. Specifically, she reminded the Steering Committee that three organizations opposed KCQA's weight measure during the NQF process, despite unanimous support for the measure during the KCQA measure development process. She informed the Committee that since the last call she and Drs. Nissenson and Jones had spoken with individuals from each of the organizations to determine the underlying cause of the disconnect. She noted that the reasons were varied: one organization did not remember that it had supported the measure within the KCQA process; the second explained that the decision for NQF voting was fanned out to a different group of individuals within the organization from those who had been directly involved in the KCQA process, and apologized for not alerting KCQA of the change before voting; the third noted that it handles review and voting within NQF and KCQA differently.

Dr. Nishimi again noted that it will be important to remind individuals that voting within KCQA is within an organizational context, as well as that it is okay to vote against or abstain on a measure. Drs. Nissenson and Jones reemphasized that individuals acting within KCQA need to vote to represent their organization. They acknowledged that everyone won't always agree, but if an organization opposes a measure, it is important to make KCQA aware of that fact during the measure development process so that issues can be appropriately addressed and perhaps resolved. Dr. Hakim remarked that the process needs to allow for some organizational process differences. Dr. Nissenson agreed that every organization will have its own internal processes and protocols, but suggested that effective internal communication between the decisionmakers and individual representatives makes sense, would prevent controversy after the fact, and would provide an accurate reflection of how the organization as a whole thinks. He added that if such processes don't fit within existing policies, at least providing KCQA with advance knowledge of the discrepancy would be helpful.

NEXT STEPS

Dr. Nishimi outlined the next steps:

- She will produce a document for an all-KCQA call that updates the candidate development areas and adds context by the end of the week or early next week; she believes that the review can be handled via email, but another call can be added if necessary.
- Three areas—*Infections, Medication Management*, and *Nutrition*—will be presented for discussion, noting that while the clear majority of the Steering Committee does not support the *Nutrition* domain, it agreed that the differences of opinion on this topic merited advancing it to discussion by all KCQA members.
- Following the Steering Committee's sign-off, the materials will be distributed to the full KCQA for consideration during its first conference call.

Drs. Jones and Nissenson concluded the meeting by thanking the Steering Committee members for their time and efforts.