KIDNEY CARE QUALITY ALLIANCE

ALL-KCQA MEETING 1 SUMMARY
JUNE 29, 2021

BACKGROUND

After welcoming participants, Dr. McGonigal reviewed the meeting agenda and provided a brief history of KCQA, an overview of the 2021-2022 KCQA Project, a progress update since the project launched, and KCQA Lead Representatives' scope and charge.

KCQA History and Project Overview

Dr. McGonigal summarized that in 2005, Kidney Care Partners (KCP) launched the Kidney Care Quality Alliance (KCQA) as a quasi-independent measure development entity with the express purpose of developing dialysis facility-level performance metrics for National Quality Forum (NQF) endorsement to address absent or faulty measures deployed in CMS's ESRD Quality Incentive Program (QIP), Five-Star Program, and now also the ESRD Treatment Choices (ETC) Model. Dr. McGonigal indicated that since its inception, KCQA has developed ten performance measures in total addressing a wide range of topics—hemodialysis vascular access, immunization, patient education, fluid management, and medication reconciliation. All ten measures were submitted to NQF, and all were either endorsed over similar competing measures or leveraged by NQF to materially refine and improve competing measures through its Consensus Development Process. KCQA's measure development activities have ultimately resulted in six measures either being directly included in the QIP or substantively and favorably altering CMS's counterpart metrics.

Dr. McGonigal noted that KCQA's dormancy in recent years has coincided with KCP's increasing concerns with federal measure development and implementation efforts. Despite several years of working with CMS to address the federal program measures' short-comings, without specific NQF-endorsed measures to offer as alternatives, progress has been slow and KCP has not achieved its desired outcomes. The result is that faulty measures populate these programs – measures that are either not statistically valid or reliable, that provide an inaccurate picture of quality, are not actionable for providers, or are unduly burdensome to patients and/or providers. In response, KCQA launched a new project cycle in May 2021 to develop metrics in five clinical priority areas consistently identified by KCP members as being particularly problematic in these federal programs: home dialysis, transplant, anemia, bone mineral metabolism, and bloodstream infection.

Consistent with KCQA's Guiding Principles, Dr. McGonigal informed Lead Representatives that all measures developed within the project must be community-supported, empirically sound, actionable, patient-centric, appropriately address social risk and health inequities, and effectively meet the needs of patients, providers, other members of the kidney care community, and federal policymakers.

Progress Update

Since the Membership's formal approval on May 7 to move forward, Dr. McGonigal noted that several items foundational to the KCQA project have been completed. The draft 2021 Project Timeline and Workplan was shared with Lead Representatives for review and approval, as were the draft KCQA Guiding Principles and Processes, updated for 2021-2022 work. The proposed Home Dialysis Workgroup roster was also shared for approval. In addition, Dr. McGonigal noted that the contract with Solid Research Group (SRG) for analytic and methodologic work had been executed and the Home Dialysis environmental scan, literature review, and prototype measure development were underway.

ITEMS FOR LEAD REPRESENTATIVE APPROVAL

Three items were presented to Lead Representatives for approval, summarized below.

Project Workplan and Timeline

Dr. McGonigal referred Lead Representatives to the detailed Workplan and Timeline and covered the basic pattern and major timeline milestones:

- All five clinical priority areas will be addressed over a span of two years.
- The home dialysis and transplant measures will be developed and tested in 2021in response to the fact that CMS has already convened Technical Expert Panels (TEPs) to develop measures in these areas and will likely submit candidate measures to NQF for endorsement consideration within the next year. Anemia management, bone mineral metabolism, and bloodstream infection will be addressed in 2022.
- A distinct and separate Expert Workgroup will be convened for each priority area.
- A separate Data/Testing Panel will be convened to assist in and help guide measure testing; the baseline composition will include KCP member dialysis organizations willing and able to run the necessary data.
- KCQA will be sequencing or "staging" the work such that home dialysis will be addressed first, with a goal of completing the measure development process by late August. The objective of this phase of the work is to have 1-2 fully specified home dialysis measures that have been approved by Lead Representatives for advancement to measure testing.
- The transplant measure development process will commence in early August, with a projected completion date of early October.
- Both the home dialysis and transplant measures will be simultaneously tested for feasibility and statistical "soundness" through the fall months.
- If the measures test well and the Steering Committee and the full KCQA approve them, the measures will be submitted to NQF for the endorsement consideration process, beginning in mid-to-late December.

For each clinical priority area, Dr. McGonigal noted that there will generally[1] be four distinct points of contact for between the given Measure Workgroup and Steering Committee and two Lead Representative Decision Points during the **Measure Development Phase**, as follows:

1. The Measure Workgroup meets and identifies the measure concept(s), using information provided through staffs' environmental scans, literature reviews, and their own knowledge and expertise. The Steering Committee will review these concepts and either approve them, make recommendations for revisions, or remand back to the Workgroup.
    - *Lead Representative Decision Point 1*: Upon Steering Committee approval, the measure concepts will be advanced to Lead Representatives for consideration and approval for full measure development.
2. Following approval of the measure concepts, the Workgroup will define the measure specifications (numerator, denominator, and exclusions). The Steering Committee will review these specifications and approve, recommend revisions, or remand back to the Workgroup.
3. The same process occurs when the Workgroup makes a recommendation on risk adjustment and/or measure results stratification.
4. The same occurs with the "finished product," the complete, fully specified measure with attached adjustment and stratification recommendations.
    - *Lead Representative Decision Point 2*: At this point, the Steering Committee will make a recommendation to the full KCQA; Lead Representatives will vote on whether the measure(s) should be advanced to the next phase of the project, measure testing.

[1] Note that some of these processes may overlap or be omitted in certain circumstances—e.g., the Steering Committee might not need to revisit a measure after approving the specifications if no risk adjustment or stratification is recommended.

Dr. McGonigal noted that the process is similar for the **Measure Testing Phase**, with three distinct Steering Committee decision points, culminating in final a Lead Representative vote:

1. The Data Panel and Methodologist (SRG), in conjunction with KCQA staff, will develop the measure calculation algorithms and testing protocols. The Steering Committee will review these deliverables and approve, make recommendations for revisions, or remand to the Methodologist and Data Panel.
2. The same process will occur after data are run to establish the presence of a "Performance Gap" (e.g., "Importance"), which is a "must pass" criterion at NQF.[2]
3. The Steering Committee weighs in a final time after full measure testing is complete – including empiric testing for measure reliability, validity, and the ability of the measure to effectively discriminate performance between providers. Testing will also consider whether the measure can be feasibly implemented in a manner that is not overly burdensome to providers or patients and whether the information provided by the measure can be used to guide choice or improve care.
    - *Lead Representative Decision Point 3:* Here the Steering Committee makes a final recommendation to the full KCQA; Lead Representatives will vote on whether the measure should be advanced to NQF for endorsement consideration.

Lead Representatives approved the Workplan and Timeline.

KCQA Guiding Principles and Processes

Dr. McGonigal next led Lead Representatives through the updated KCQA Guiding Principles and Operational Processes, a single overarching document to guide KCQA's work, output, and voting processes. She noted KCQA staff updated two items for the 2021-2022 work for Lead Representative review and approval:

- Language was added to the Guiding Principles specifically indicating that measures developed by KCQA will consider the impact of social risks on healthcare outcomes to ensure accurate reporting of quality that reduces harm and unintended consequences to marginalized patients and their providers. ***Lead Representatives approved this new language.***
- The Operational Processes Document was updated to define a voting quorum and majority threshold for the Steering Committee and full KCQA. Specifically, a quorum of fifty-one percent is required for approval on voting items. If quorum has not been achieved, deliberations may proceed, but voting will take place via an electronic ballot subsequently distributed to all voting members. For final approval of recommendations, a "healthy majority," defined as seventy percent of those voting, will be required. ***Lead Representatives approved the document update.***

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

Dr. McGonigal concluded the meeting by reviewing next steps:

- The Home Dialysis Workgroup will convene on July 1 for orientation and to identify candidate Measure Concepts.

[2] The Performance Gap effectively establishes that there is room for improvement in a given aspect of clinical care. Because the measure would be rejected by NQF in the absence of a demonstrable gap, such a measure would be removed from further consideration by KCQA.

- The Steering Committee will reconvene on or before July 9 to review and approve the candidate Measure Concepts.
- Lead Representatives will next meet in early August to consider the recommended home dialysis measure specifications for approval; a date/time will be finalized following receipt of scheduling poll responses.

KIDNEY CARE QUALITY ALLIANCE

ALL-KCQA MEETING 2 SUMMARY
AUGUST 5, 2021

BACKGROUND

After a welcome and opening remarks from the KCQA Steering Committee Co-Chairs, Drs. George Aronoff and Keith Bellovich, Dr. McGonigal reviewed the meeting agenda and provided a brief project update, a summary of Steering Committee and Home Dialysis Workgroup deliberations and recommendations, and an overview of the draft home dialysis measure specifications, as follows.

PROGRESS UPDATE

Dr. McGonigal informed participants that since the KCQA Lead Representatives last met on June 29, the Steering Committee and Home Dialysis Workgroup have each convened on several occasions to first identify appropriate and feasible home dialysis measure concept(s), and then through an iterative process, to define and refine the measure specifications (numerator, denominator, and exclusions) for each identified concept (see below and Attachment 3). The Steering Committee has also appointed the Transplant and Data/Testing Workgroups in preparation for the next phases of the project, and the transplant measures environmental scan, literature review, and prototype measure development are currently underway.

HOME DIALYSIS DELIBERATIONS AND RECOMMENDATIONS

Before turning to the measure specifications, Dr. McGonigal provided a chronologic summary of the Home Dialysis Workgroup and Steering Committee deliberations and recommendations. She reminder participants that in accordance with KCQA's mission to meet the needs of its stakeholders, home dialysis measure development has focused specifically on *utilization*, as this topic is an immediate priority for CMS, federal policymakers, and KCP and KCQA Membership. She indicated that the intent of any measure(s) generated through this work is to offer superior alternatives to the home dialysis metrics currently in use or in development by CMS for its ESRD Treatment Choices (ETC) payment model and QIP, respectively, neither of which KCP and KCQA believe will provide meaningful, actionable, or statistically sound information or will sufficiently drive improvements in care or outcomes.

Dr. McGonigal noted that the Home Dialysis Workgroup's preliminary deliberations culminated in a recommendation that three candidate measure concepts be advanced to the Steering Committee for consideration:

- **Concept 1:** Rate + retention measure addressing all (incident + prevalent) home dialysis patients. (E.g., "*Percent of all patients attributed to a facility who received home dialysis for >=3 consecutive months during the measurement year.*")
    - ***Workgroup Rationale:***
        - Retention/attrition should be captured as a component of the KCQA measure(s) to counter unopposed incentivization of home dialysis prescription. Workgroup members were not in agreement what the appropriate "retention" timeframe should be. Staff proposed six months, but the Workgroup was concerned that too long a retention period would discourage home dialysis attempts in all but the most ideal patients. Three months was tentatively suggested.
        - There was consensus that requiring *consecutive* months on home dialysis will discourage attempts to meet the retention criterion cumulatively through sporadic, repeated starts in potentially inappropriate candidates.
        - While some Workgroup members believe the greatest potential for dramatic improvements in home dialysis utilization lies with the incident population,

others noted there is considerable room for improvement with the prevalent population, as well. The Workgroup ultimately reached consensus to include both groups in the candidate concepts.

- Although definitions vary, the Workgroup tentatively defined "incident" patients as those in their first year of dialysis; this is consistent with both CMS's proposed definition in its forthcoming home dialysis measure and (largely) USRDS methodologies.
- All members agreed both peritoneal and home hemodialysis should be addressed in the KCQA home dialysis measure(s).

- **Steering Committee Decision:** ***Approved for further development.***
  - The Steering Committee agreed retention/attrition is necessary but recommended the Workgroup find the "ideal" time period. Six months is too long and might serve as a barrier to home dialysis prescription; two months is too short, as many patients are just completing training at that time. The Steering Committee also noted that a solid rational for the decision is needed to meet NQF's Evidence Criterion.
  - The Committee recommended the Workgroup find a mechanism to differentiate home dialysis "exits" due to transplants from those due to treatment failure (e.g., denominator exclusion).
  - The Committee asked the Workgroup to consider how home dialysis "interruptions" (e.g., hospitalizations) should be accounted for in the measure(s).
  - To address the fact that many facilities don't offer home dialysis, the Steering Committee asked the Workgroup to consider whether the measure's level of analysis should be at an aggregate level rather than the individual facility. If yes, the Committee requested the Workgroup consider how that aggregation might be done—e.g., by parent company, by locality (agnostic to business), a hybrid approach?
  - The Steering Committee requested consideration of whether a "patient-months" construction might be appropriate, particularly if the measure is calculated across aggregate groups.
  - The Committee instructed the Workgroup to appropriately consider social risks, perhaps through use of dual eligibility as a proxy marker. (Note: Will be addressed when the Workgroup considers risk adjustment.)

- **Concept 2:** Set of separate rate and retention measures addressing all (incident + prevalent) patients. (E.g., *"Percent of all patients attributed to a given facility receiving home dialysis during the measurement year"* combined with **"***Percent of all home dialysis patients attributed to a given facility who received home dialysis for >=3 consecutive months during the measurement year."*)
  - ***Workgroup Rationale:***
    - Some Workgroup members suggested Concept 1 would better be split into two distinct but complementary metrics—a home dialysis rate measure balanced with a separate retention measure. Having a distinct measure for each would allow for a more nuanced assessment of—and more precise and effective interventions in response to—performance.
    - The measure set would again address all patients (incident and prevalent), both peritoneal and home hemodialysis, would employ a "consecutive months" construct, and would (tentatively) define "retention" as three months.
  - ***Steering Committee Decision: Approved for further development.***

        - The Steering Committee agreed the measures should be recommended/ implemented as "set" to avoid unintended consequences (e.g., unopposed incentivization of home dialysis prescription).
        - The Steering Committee requested the Workgroup further explore/explain any potential benefits over Concept 1 (e.g., more actionable).
        - Other Steering Committee questions/recommendations from Concept 1 also apply.

- **Concept 3:** Separate incident + prevalent measures. (E.g., "*Percent of all incident patients attributed to a given facility receiving home dialysis for >=2 consecutive months during the measurement year*" and "*Percent of all prevalent patients attributed to a given facility receiving home dialysis for >=6 consecutive months during the measurement year.*"
    - ***Workgroup Rationale:***
        - Some Workgroup members suggested addressing incident and prevalent patients separately, given the intrinsic differences between the two populations; having a distinct measure for each would allow for a more nuanced assessment of—and more precise and effective interventions in response to—performance.
        - Because the two populations would be handled separately, the Workgroup believed there would also be room for a more nuanced consideration of the retention timeframes. The group agreed the incident population would benefit from a briefer retention requirement (tentatively, 2-3 months) to avoid the creation of additional barriers to a trial of home dialysis in new patients. Conversely, a longer retention timeframe would be appropriate for the prevalent population to help minimize pressure providers may feel to push long-standing in-center patients towards a modality they may not want or may not be compatible with their current psychosocial circumstances.
    - ***Steering Committee Decision: Not Approved.***
        - The Steering Committee unanimously agreed that Concept 3 was overly complicated. Specifically, the lack of empiric evidence underlying the suggested differing retention timeframes may compromise the measures' ability to pass NQF's Evidence Criterion. Similarly, there is a lack of evidence supporting the Workgroup's defined cut-point between incident and prevalent patients (1 year) that would not be an issue when considered within a single measure (or measure set) addressing both populations.

RECOMMENDED HOME DIALYSIS MEASURES

Dr. McGonigal informed participants that after much deliberation, the Home Dialysis Workgroup and Steering Committee have determined that the measure set (Concept 2) is superior to the single "rate + retention" measure (Concept 1). Specifically, the paired set will allow facilities and dialysis organizations to more effectively visualize, assess, and respond to their performance on home dialysis uptake, as well as on the success of their efforts to create a sustainable program through appropriate patient education, preparation, and support. Conversely, the single measure would dramatically curtail such analyses, as information on the underlying rate would be obscured. As such, she noted that the Workgroup is currently completing development of a paired measure set assessing home dialysis rate and home dialysis retention for Steering Committee and KCQA consideration and approval:

- *Measure A, Home Dialysis Rate:* Percent of all dialysis patient-months in the measurement year with treatment modality *Peritoneal Dialysis* and/or *Home Hemodialysis*.
- *Measure B, Home Dialysis Retention:* Percent of all *Peritoneal Dialysis* and/or *Home Hemodialysis* patient-months in the measurement year for which >=3 consecutive months of home dialysis was achieved.

Dr. McGonigal then reviewed the measure specifications with participants. She conveyed the Workgroup's intent that the measure set be used to grow overall home dialysis utilization. To do so effectively, both new prescriptions and efforts to retain new and existing home dialysis patients must be incentivized. To that end, she noted that the Workgroup and Steering Committee agreed to the following underlying principles:

- Assessment of overall home dialysis rate will incentivize increased utilization and will provide facilities and dialysis organizations valuable information on performance in this area, allowing for targeted quality improvement interventions as needed.
- Assessment of overall home dialysis retention will serve as a counterbalance to unopposed incentivization of home dialysis prescription and will allow facilities and dialysis organizations to assess the success of their efforts to create a sustainable program through appropriate patient education, preparation, and support, applying targeted quality improvement interventions as needed. Notably, such support should not be limited to new patients, as attrition of existing patients is a similarly modifiable outcome, with appropriate intervention.
- As the intent is to grow overall home dialysis utilization, the measure set will address both incident and prevalent dialysis patients, pediatric patients, and both new and established home dialysis patients. Likewise, consistent with KCQA's existing measures and guiding principle of inclusivity, the measure set will capture all patients, regardless of payer (i.e., not limited to Medicare patients).
- The measure set will use a patient-months construction to account for patients' potentially variable time contributions to the numerators and denominators.
    - Note: Facilities receive "credit" for the retention measure once a patient achieves three months at home. However, the patient-months construct will also provide incentive for facilities to help patients stay on home dialysis beyond the three-month minimum required for measure success; the longer a patient remains at home, the more numerator and denominator patient-months are accrued towards the total annual performance score. By design, this both provides impetus to support patients as needed for long-term success at home and balances any perceived perverse incentive to keep patients on home dialysis beyond what is clinically or psychosocially appropriate for each individual.
- To address the fact that many facilities don't offer home dialysis, and for compatibility with facilities' existing organizational structure, the level of analysis will be aggregated by parent dialysis organization within a given region. (Regions TBD during testing; for example, by Hospital Referral Region, as is the existing approach in the ETC Program).
- It is recommended that results be stratified by *Peritoneal Dialysis* and *Home Hemodialysis* patients and *New* (1st year) and *Established* (>1 year) home dialysis patients to allow facilities to analyze and target differential performance for these groups.[1]
- Specific to the retention metric (Measure B), the Workgroup and Steering Committee struggled with the appropriate retention timeframe. Some argued any retention requirement would serve as a barrier to increased home dialysis uptake. Others suggested a timeframe of 6—or even 12—months is necessary to ensure facilities are sufficiently preparing and supporting patients in the transition home. Ultimately, there was consensus that 3 months is a reasonable compromise that will promote appropriate investment in patient support and preparation without appreciably blunting home dialysis prescription. In addition, staff and Workgroup members identified peer-reviewed publications indicating that home dialysis attrition is

[1] Given the fundamental differences between the two modalities, there was interest in considering separate *Peritoneal Dialysis* and *Home Hemodailysis* measures; however, it was agreed that home hemodialysis numbers are currently too small to allow for reliable, valid measurement.

generally highest during the first 90 days of treatment, providing empiric evidence to further support the Workgroup's expert opinion in this regard.[2,3]

REMAINING DECISIONS

Dr. McGonigal indicated that the Workgroup and Steering Committee will conclude the home dialysis work in mid-August, finalizing recommendations on measure risk adjustment/stratification, performance benchmarking approaches, and reporting schema.

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

Dr. McGonigal adjourned the meeting after reviewing next steps:

- The Home Dialysis Workgroup will conclude its work on August 10 to finalize recommendations on measure risk adjustment/stratification and benchmarking approaches.
- The Steering Committee will meet on August 16 to generate a formal recommendation to the KCQA Voting Body on whether the measures should be approved for measure testing this fall.
- Lead Representatives will reconvene on or around August 25 to review/approve the final complete measures for advancement to measure testing; date/time will be finalized following receipt of scheduling poll responses.

[2] Seshasai RK et al. Factors associated with discontinuation of home hemodialysis. *AJKD*. 2016;67(4):629-637.
[3] Kolesnyk I et al. Time-dependent reasons for peritoneal dialysis technique failure and mortality. *Perit Dial Int*. 2010;30:170–177.