KIDNEY CARE QUALITY ALLIANCE

STEERING COMMITTEE MEETING 1 SUMMARY
JUNE 21, 2021

Attendees: George Aronoff MD (Co-Chair); Keith Bellovich DO (Co-Chair); Amy Barton PharmD, MHI; Donna Bednarski MSN, RN; J. Ganesh Bhat MD; Robert S. Bomstad MS, BS, RN; Lorien Dalrymple MD, MPH; Mary Dittrich MD; James Mike Guffey; Lori Hartwell; Todd Eric Minga MD; Jeffrey Silberzweig MD; Gail Wick MHSA, BSN, RN; Kathy Lester JD, MPH; Lisa McGonigal MD, MPH

Not Present: Brigitte Schiller MD; Daniel Weiner MD, MS

BACKGROUND
After roll call, introductions, and disclosures of interest, Co-Chairs Drs. George Aronoff and Keith Bellovich welcomed Steering Committee members. Dr. McGonigal then 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 the Steering Committee's 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 the Committee 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 the Committee 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 included in the Committee's materials 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 STEERING COMMITTEE APPROVAL
Three items were presented to the Steering Committee for approval, summarized below.

Project Workplan and Timeline
Dr. McGonigal referred the Committee 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 the full KCQA body 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 priority area, Dr. McGonigal noted that there will generally be four distinct "points of contact" for the Steering Committee during the **Measure Development Phase.** The given Measure Workgroup will meet and identify candidate 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. The same process occurs once the Workgroup defines the measure specifications (numerator, denominator, and exclusions), when the Workgroup makes a recommendation on risk adjustment and/or measure results stratification, and with the "finished product" (i.e., the complete, fully specified measure with attached adjustment and stratification recommendations).

A similar process occurs during the **Measure Testing Phase** of the project. The Steering Committee will weigh in on the draft measure calculation algorithms and testing protocols developed by staff in conjunction with the Methodologist and Data/Testing Panel. The same will occur after data are run to establish the presence of a "Performance Gap" (i.e., there is room for improvement in the given aspect of clinical care), which is a "must pass" criterion at NQF. 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. Here the Steering Committee makes a final recommendation to the full KCQA on whether the measure should be advanced to NQF for endorsement consideration.

KCQA Guiding Principles and Processes
Dr. McGonigal next led the Steering Committee 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 Steering Committee 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. ***The Steering Committee 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. ***The Steering Committee approved the document update.***

Home Dialysis Workgroup and Chair Appointment
The Steering Committee was also asked to appoint the Home Dialysis Workgroup and Chair. Dr. McGonigal noted a total of ten nominations were received for the Workgroup. Staff determined that two nominations were more appropriate for other Workgroups that will be convened later this and next year, leaving eight nominees. She indicated that staff believes all are strong candidates, each bringing considerable clinical, policy, and/or data expertise specifically related to home dialysis. ***The Steering Committee unanimously approved all eight nominees.***

Dr. McGonigal indicated that the staff recommendation for the Workgroup Chair is Eric Weinhandl, PhD, MS. She reviewed Dr. Weinhandl's credentials and experience, noting his position as senior epidemiologist at the Chronic Disease Research Group (CDRG) and an adjunct assistant professor at the University of Minnesota. He has conducted research in CKD and ESRD for over 15 years, with primary areas of expertise being chronic dialysis, home hemodialysis, peritoneal dialysis, ESRD pharmacoepidemiology, and healthcare policy in all stages of CKD. She noted he is also an expert in Medicare regulations and payment policies regarding outpatient dialysis and currently serves both the United States Renal Data System and the Scientific Registry of Transplant Recipients. ***The Steering Committee unanimously approved Dr. Weinhandl's appointment.***

Pediatric Representation
Finally, Dr. McGonigal broached the issue of pediatric representation on the Home Dialysis and other workgroups. She noted that in past cycles KCQA has had pediatric representation from ASPN on both the Steering Committee and various workgroups, but not in the most recent cycles, which have addressed clinical topics oriented more towards adult patients. She remarked, however, that pediatric representation is very appropriate for a number of the priority areas being addressed in the 2021-2022 work. She thus recommended to the Steering Committee that Dr. Avram Traum be appointed as a special "Pediatric Envoy" that would float between all KCQA workgroups as needed to ensure pediatric issues are being appropriately addressed. ***The Steering Committee unanimously approved appointing Dr. Traum as KCQA Pediatric Envoy.***

PUBLIC COMMENT
There were no public comments.

NEXT STEPS

Dr. McGonigal concluded the meeting by reviewing next steps:

- Staff will complete the Home Dialysis Environmental Scan and Literature Review.
- The full KCQA will convene on or before June 30 for orientation, a progress update, and approval of Guiding Principles and KCQA Processes.
- The Home Dialysis Workgroup will convene on or before July 2 for orientation and to identify candidate Measure Concepts.
- The Steering Committee will reconvene on or before July 9 to review and approve the candidate Measure Concepts.

KIDNEY CARE QUALITY ALLIANCE

STEERING COMMITTEE MEETING 2 SUMMARY
JULY 7, 2021

Attendees: George Aronoff MD (Co-Chair); Keith Bellovich DO (Co-Chair); Amy Barton PharmD, MHI; Donna Bednarski MSN, RN; J. Ganesh Bhat MD; Robert S. Bomstad MS, BS, RN; Lorien Dalrymple MD, MPH; Mary Dittrich MD; James Mike Guffey; Lori Hartwell; Todd Eric Minga MD; Brigitte Schiller MD; Daniel Weiner MD, MS; Kathy Lester JD, MPH; Lisa McGonigal MD, MPH

Not Present: Jeffrey Silberzweig MD; Gail Wick MHSA, BSN, RN;

BACKGROUND

Following roll call and a welcome from Co-Chairs Drs. George Aronoff and Keith Bellovich, Dr. McGonigal reviewed the meeting agenda. She then provided a high-level overview of the National Quality Forum (NQF) endorsement criteria, a brief summary of the Home Dialysis Workgroup's progress to date and recommended measure concepts, and reviewed the Data/Testing Workgroup roster for Steering Committee approval.

NQF ENDORSEMENT CRITERIA REVIEW: IMPORTANCE AND FEASIBILITY

Dr. McGonigal reminded the Steering Committee that the Kidney Care Quality Alliance initiative was launched with the express purpose of identifying facility-level measures for National Quality Forum endorsement. As such, it is critically important that both the Workgroups and Steering Committee keep the NQF endorsement criteria in mind when considering candidate concepts, and then measure specifications. Currently, there are five primary NQF criteria, broadly defined as follows:

1. **Importance to Measure and Report:** The measure focus is evidence based and there is room for improvement in the given aspect of care.
2. **Scientific Acceptability of Measure Properties.** The measure has been empirically demonstrated as being statistically reliable and valid.
3. **Feasibility.** Data necessary to calculate the measure are readily available and can be captured without undue burden on providers or patients.
4. **Usability.** Potential audiences could use measure results for both accountability and performance improvement.
5. **Comparison to Related or Competing Measures.** Measures that meet the four preceding criteria are compared with competing metrics (if any) to address harmonization and/or selection of the "better" measure.

She noted that when focusing on the identification of measure concepts appropriate for development, NQF Criteria 1 (Importance/Evidence) and 3 (Feasibility) are particularly important and will thus be the focus of the Steering Committee discussion during this meeting. Other criteria will be teed-up by staff, as pertinent, throughout the remaining meetings.

Importance to Measure and Report: Evidence and Performance Gap

NQF defines its Criterion 1 as the extent to which the specific measure focus is evidence-based and important to making significant gains in healthcare quality where there is variation in or overall less-than-optimal performance. Dr. McGonigal noted that measures must be judged to meet both of the following sub-criteria to pass this "must-pass" criterion:

- ***Sub-Criterion 1: Evidence to Support the Measure Focus.*** Dr. McGonigal indicated that NQF's evidence requirements vary by measure type. A home dialysis utilization measure would quality as an intermediate outcome measure, for which the "gold standard" for evidence is a systematic assessment and grading of the quantity, quality, and consistency of the body of

evidence supporting that the measured intermediate clinical outcome leads to a desired health outcome. As is the case with home dialysis utilization, if there is no existing systematically graded body of evidence (e.g., as with a formal guideline), a summary of all studies submitted by the developer to NQF as the body of evidence supporting the measure must be provided, and the NQF Standing Committee must be convinced by that evidence that the potential benefits of the measure will outweigh undesirable effects.

- ***Sub-Criterion 2: Performance Gap.*** There must also be evidence of suboptimal quality in the aspect of care addressed by the measure and that an opportunity for improvement exists, with one or more of the following being met:
    - There is considerable variation in the quality of care (i.e., performance scores) between providers; and/or
    - There is overall less-than-optimal performance across providers; and/or
    - There are demonstrable disparities in care across population groups.

  Dr. McGonigal indicated that it is not expected there will be any difficulty establishing a performance gap for home dialysis utilization.

Feasibility
Dr. McGonigal noted that NQF defines feasibility as the extent to which the specifications require data that are readily available, can be captured without undue burden, and can be implemented for performance measurement. For home dialysis utilization, preliminary analyses indicate that all required data elements are available in the ESRD Quality Reporting System (EQRS).

HOME DIALYSIS PROGRESS UPDATE
Project Scope
Dr. McGonigal informed the Steering Committee that in accordance with KCQA's mission to meet the needs of its stakeholders, home dialysis measure development will focus specifically on *utilization*. She noted that the July 2019 Executive Order on Advancing American Kidney Health envisions much higher utilization of home dialysis than is current practice in the United States. Additionally, the recently finalized ETC payment model includes as a core measure the utilization of home dialysis among Medicare patients with ESRD, and CMS has also recently convened a Technical Expert Panel (TEP) to develop a home dialysis utilization measure and will likely submit the metric to NQF for endorsement consideration within the next year. She remarked that the topic is thus known to be an immediate priority for policymakers and CMS, and will soon be brought to NQF's floor for debate.

Home Dialysis Workgroup Charge
Dr. McGonigal noted that the Home Dialysis Workgroup has been charged with first identifying 1-4 home dialysis utilization measure concepts, and from there measure specifications (numerator, denominator, exclusions) with risk adjustment and/or stratification approaches (if deemed necessary). Of these, the KCQA Steering Committee will select and recommend to the KCQA Voting Body 1 (or 2 related) measure(s) be advanced for empiric testing for the purpose of submitting to NQF for endorsement consideration.

Home Dialysis Timeline
Dr. McGonigal indicated that the fully specified home dialysis measures must be completed no later than mid-August to allow sufficient time to also complete Transplant measure development for testing in the fall. The high-level home dialysis timeline is as follows:

1. **Step 1: Identify Candidate Concepts.** The first meeting of the Home Dialysis Workgroup took place on July 1. The meeting focused on the identification of 1-4 home dialysis utilization measure concepts for the Steering Committee's consideration, which Dr. McGonigal indicated would be reviewed for approval during this meeting. To facilitate this process, staff conducted an Environmental Scan to identify existing measures and crafted a measure "prototype" to be

used as a starting point for workgroup's deliberations. Both documents are discussed in detail below.

2. **Step 2: Define Measure Specifications.** For its second meeting (July 16), Dr. McGonigal reported that the Workgroup will identify a preliminary numerator, denominator, and exclusions for all approved measure concept(s). These specifications will be advanced to the Steering Committee for consideration during its July 26 meeting.
3. **Step 3: Assess Need for Risk Adjustment/Stratification**. For each Steering Committee-approved preliminary measure, the Workgroup will in its third meeting (date TBD) revise specifications as necessary and will consider the need for risk adjustment and/or stratification to appropriately address clinical, social, and functional risks.
4. **Step 4: Finalize the Measure(s).** To complete its charge, Dr. McGonigal noted the Workgroup will in its fourth (date TBD) and fifth (if needed) meeting(s) make any final revisions to the measure specifications and will finalize its recommendations on risk adjustment/ stratification. The resulting completed measure(s) will then be reviewed by the Steering Committee at its August 16 meeting to formulate a recommendation to the KCQA Voting Body to advance the measure(s) to the testing phase of the project, which will take place in the fall. Risk adjustment/stratification recommendations will also be advanced to KCQA's Methodologist (Dr. Craig Solid or Solid Research Group) to inform his work in preparation for measure testing.

Environmental Scan

Dr. McGonigal informed the Steering Committee that the Environment Scan was developed to inform the Home Dialysis Workgroup on what home dialysis utilization measures and measure concepts already exist and are in use and to stimulate discussion and creativity for its brainstorming session. She noted that the scan sets forth the 40 unique[1] home dialysis utilization measures/measure concepts identified through a review of public sources, grey and international literature, and a survey of KCQA member dialysis organizations for applicable measures being used internally for quality improvement. As anticipated, many identified metrics are similar, with the majority being variations on one of three overarching themes:

1. Simple rate measures, such as *Overall Home Dialysis Rate*, *Incident [or Prevalent] Home Dialysis Rate*; *Overall Peritoneal Dialysis Rate*, etc.
2. Modality "switch" measures with a specified timeframe—for instance, *Percent of In-Center Patients Who Transitioned to Home Dialysis within X Days/Weeks/Months of Dialysis Initiation*.
3. Retention/attrition measures, e.g., *Home Dialysis Exits at X Months*, *Home Dialysis Attrition Due to Technique Failure*.

Despite the commonalities, however, Dr. McGonigal noted there are nuanced but substantive variations in the measure details that the Workgroup found useful to facilitate brainstorming.

Home Dialysis Utilization Measure Prototype

Dr. McGonigal reported that staff also drafted a home dialysis utilization measure "prototype" to be used as a starting point for the Workgroup's deliberations. She noted that the Workgroup was informed that the prototype was not intended to be prescriptive or to push the Workgroup towards a particular measure or measure type, but rather to stimulate discussion, kick off the consensus process, and to allow the group to visualize what a "finished" measure in this area might look like. Dr. McGonigal reminded the Steering Committee that while a full set of preliminary specifications for the prototype are included with the meeting materials, the focus at this point in the process is limited to the measure *concept* and whether it might be a viable candidate for full development.

RECOMMENDED HOME DIALYSIS MEASURE CONCEPTS

[1] Redundant metrics were eliminated, e.g., if a KCP organization is using a USRDS metric to track internal quality, we did not list the measure twice.

Dr. McGonigal reported that the Workgroup spent the majority of its first meeting brainstorming to identify its top 1-4 home dialysis utilization measure concepts for advancement to the Steering Committee for consideration. The Environmental Scan, Measure Prototype, NQF's Importance and Feasibility Criteria, and Workgroup members' own insights and expertise were called upon to inform this discussion. She reported that the Workgroup ultimately identified and recommends three measure concepts for further exploration. She asked the Steering Committee to review the Concepts with an eye towards approval for further exploration and development, noting the Committee may approve one, all, or none of the concepts. She also asked the Committee to provide the Workgroup with additional guidance and/or recommendations around these or any other concepts it believes bear consideration and to consider whether any of the candidate concepts should be prioritized by the Workgroup moving forward.

Concept 1: Rate + retention measure addressing all (incident + prevalent) home dialysis patients.

- *Preliminary Proposal: Percent of all patients attributed to a given facility who received home dialysis for >=3 consecutive months during the measurement year.*
- *Workgroup Discussion Points:*
    - Dr. McGonigal noted that Concept 1 is the previously described Prototype Measure, revised with an abbreviated retention requirement.
    - She reported that all Workgroup members agreed that retention/attrition should be captured as a component of the KCQA measure(s) to dissuade prescription of home dialysis to patients who may not be good candidates for the modality. While the Workgroup recognizes that any amount of time on home dialysis is important and meaningful to patients, it agreed that defining some retention period is vital to appropriately balance any perverse pressure providers may feel as a result of the measure(s) to be less discriminate in prescribing the modality.
    - Workgroup members were in agreement, however, that the appropriate "retention" timeframe should be shorter than the 6 months proposed in the Prototype; there was concern that too long a retention period would discourage home dialysis attempts in all but the most ideal patients. The Workgroup tentatively suggested 3 months as a reasonable period in a measure addressing both incident and prevalent patients. It was noted that there is no existing evdience to support this—or any—decision on an "appropriate" retention timeframe; this is an instance in which "expert opinion" will ultimately serve as the basis of the recommendation.
    - There was consensus among the Workgroup that requiring *consecutive* months on home dialysis will discourage attempts to meet the retention criterion cumulatively through sporadic, repeated starts in potentially inappropriate candidates.
    - Some Workgroup members voiced belief that the greatest potential for dramatic improvements in this aspect of care lies with the incident population, and that including prevalent patients will dilute the impact of the measure. Others argued there is considerable room for improvement with the prevalent population, as well; as the underlying intent of the measure is to increase utilization of home dialysis, the exclusion of prevalent patients is necessarily contradictory that goal. Ultimately, the Workgroup came to unanimous consensus that both patient groups should be addressed in any home dialysis utilization measure (or measure set) put forth by KCQA.
    - Although definitions vary, in its preliminary discussions 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 and prioritized for further development.***
    - The Steering Committee agreed that the retention/attrition component is necessary but recommends 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 or there is a risk of the measure failing NQF's Evidence Criterion.
    - The Committee noted that the Workgroup would need to find a mechanism to differentiate home dialysis "exits" due to transplants from those due to treatment failure, noting that this can likely be addressed through a careful consideration of denominator exclusions.
    - The Committee advised the Workgroup to consider how home dialysis "interruptions" (e.g., hospitalizations) should be accounted for in the measure.
    - The Committee questioned whether the Workgroup should consider defining a measure "end-point." It was noted that many peritoneal dialysis patients develop uremia within 3-5 years and that retention will likely drop at that point; the measure needs to account for that.
    - 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? They also requested consideration of what the appropriate data source(s) might be under the various scenarios.
    - 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.

Concept 2: Separate rate and attrition measures addressing all (incident + prevalent) patients.

- *Preliminary Proposal:*
    a. *Percent of all patients attributed to a given facility receiving home dialysis during the measurement year.*
    AND
    b. *Percent of all home dialysis patients attributed to a given facility who received home dialysis for >=3 consecutive months during the measurement year.*
- *Workgroup Discussion Points:*
    - Dr. McGonigal noted that some Workgroup members suggested Concept 1 should be split into two distinct but complementary metrics—a home dialysis rate measure balanced with a separate retention measure. It was suggested that the two measures might prove more informative and actionable as they would allow for separate analyses and targeted interventions for uptake and retention performance.
    - Dr. McGonigal noted that because of the "balancing" nature of the two metrics, the measures may be deemed a "compound" measure by NQF, which has a separate set of criteria and considerations that may complicate the endorsement process.
    - Other pertinent issues were captured in the Workgroup's Concept 1 deliberations, above.

- ***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 Concepts 1 apply.

Concept 3: Separate rate + retention measures, by dialysis duration.

- *Preliminary Proposal:*
    a. *Percent of all incident patients attributed to a given facility receiving home dialysis for >=2 consecutive months during the measurement year.*
    AND
    b. *Percent of all prevalent patients attributed to a given facility receiving home dialysis for >=6 consecutive months during the measurement year.*
- *Workgroup Discussion Points:*
    - Dr. McGonigal indicated that Concept 3 is, in effect, Concept 1 divided into separate metrics for incident and prevalent patients.
    - Here, because the two populations are being handled separately, the Workgroup believed there was room for a more nuanced consideration of the retention timeframes. As such, the group agreed that the incident population measure would benefit from an even briefer retention requirement to avoid the unintentional creation of additional barriers to a trial of home dialysis in new patients. Two months was suggested.
    - Conversely, the Workgroup tentatively suggested a longer retention timeframe for the prevalent population—with six months tentatively suggested. Again, the rationale for this decision is to minimize pressure providers may feel to push long-standing in-center patients towards a modality they may not want and may not be clinically appropriate. However, the Workgroup indicated they would like to have additional opportunity for discussion around this point in future meetings.
    - Although both measures could theoretically stand alone, as with Concept 2, Dr. McGonigal noted there is risk that NQF may determine that the metrics should be considered together as a compound measure, again raising the possibility of a more complex endorsement process.
- ***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 that would not be an issue when considered within a single measure addressing both populations.

Other Considerations

Dr. McGonigal reported the Workgroup also noted the following in its deliberations:

- The greatest opportunity for improving home dialysis utilization is during the pre-dialysis phase of care. Early patient education is critical to improving home dialysis uptake, and "upstream" efforts will necessarily have the most substantial impact on this aspect of care.

- Not all patients are appropriate candidates for home dialysis; any measure generated through these efforts must consider what home dialysis rates truly should be and should strive to define what "success" looks like for the measure. These considerations could be addressed through the identification and recommendation of benchmarks, for instance.
- It must be acknowledged that a patient's decision for home dialysis is complex and requires consideration of clinical, socioeconomic, and psychosocial factors; even under "ideal" circumstances, patients will sometimes "fail" a trial of home dialysis, and a measure in this area must not be so punitive as to prohibit providers from encouraging their patients to consider this life-changing and underutilized modality.

DATA WORKGROUP APPOINTMENT

Dr. McGonigal then asked the Steering Committee to review and appoint the recommended Data/Testing Workgroup roster. She noted that as in previous KCQA cycles, this Workgroup will assist staff and the Methodologist in crafting measure calculation algorithms and testing protocols, will make recommendations to the Steering Committee on specification revisions if and as needed, and will run data to empirically test the measures. The baseline composition of the Workgroup is to include individuals from KCQA member large and medium dialysis organizations with the capacity to efficiently run existing data sets to confirm the existence of a performance gap and to assess and establish the statistical soundness of the measures. Prerequisites are that the individual must be well-versed in the organization's data and have a firm grasp of the statistical analyses required to establish measure reliability, validity, and risk modeling (if required). Selected individuals will meet with KCQA staff, other Workgroup members, and our Methodologist approximately every 2-3 weeks during the testing phase of the 2021 work (focusing on home dialysis and transplants), tentatively commencing in early October and concluding in late November. The Workgroup will also be engaged at strategic points during the earlier measure development phases to assess for potential feasibility issues with measure concepts, specifications, and data sources.

Dr. McGonigal reported that Davita, Fresenius Medical Care North America, and U.S. Renal Care were invited to identify candidates to serve on this Workgroup (Satellite Healthcare also received an invitation but had not yet responded) and recommended the Steering Committee appoint all nominees. ***The Steering Committee approved the recommendation.***

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

Dr. McGonigal concluded by summarizing next project steps:

- The Home Dialysis Workgroup will next meet on July 16 to identify measure specifications (numerator, denominator, exclusions) for all Steering Committee-approved concepts.
- In preparation for the Workgroup's deliberations, staff will draft preliminary measure specifications (numerator, denominator, exclusions). To further inform the Workgroup's Evidence and Feasibility discussions, staff will also for each measure concept:
  - complete its preliminary literature review of existing evidence in support of the measure(s);
  - complete its assessment of existing EQRS data elements; and
  - draft the measure calculation algorithm(s).
- The Steering Committee will reconvene on July 26 to review and approve the Workgroup's preliminary measure specifications for completion. Other agenda items will include a review of NQF's Usability and Scientific Acceptability criteria and appointment of the Transplant Workgroup and Chair.