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.

KIDNEY CARE QUALITY ALLIANCE

STEERING COMMITTEE MEETING 3 SUMMARY
JULY 26, 2021

Attendees: George Aronoff MD (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; Daniel Weiner MD, MS; Gail Wick MHSA, BSN, RN; Kathy Lester JD, MPH; Lisa McGonigal MD, MPH

Not Present: Keith Bellovich DO (Co-Chair); Brigitte Schiller MD; Jeffrey Silberzweig MD

BACKGROUND

Following roll call and a welcome from Co-Chair Dr. George Aronoff, Dr. McGonigal reviewed the meeting agenda, sought Steering Committee approval of the recommended Transplant Workgroup Roster and summaries from Meetings 1 and 2, provided a project update, and reviewed the draft measure specifications as recommended by the Home Dialysis Workgroup. The ensuing Steering Committee discussion is summarized below.

STEERING COMMITTEE APPROVAL OF PRIOR MEETING SUMMARIES HOME DIALYSIS

The Steering Committee approved the Meeting Summaries from Meetings 1 and 2.

TRANSPLANT WORKGROUP AND CHAIR APPOINTMENTS

The Steering Committee approved the recommended Transplant Workgroup and Co-Chair appointments.

HOME DIALYSIS PROGRESS UPDATE

Dr. McGonigal noted that since the Steering Committee last met on July 7, the Home Dialysis Workgroup has convened on two occasions to identify and then refine measure specifications for the approved Measure Concepts. For reorientation, she provided a recap of the Workgroup's previously recommended Measure Concepts, followed by the Steering Committee's decisions and guidance on those concepts, as below:

Recap: Home Dialysis Workgroup Recommended Concepts, Steering Committee Decisions

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 and prioritized for further development.***
  - The Steering Committee agreed retention/attrition 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 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.
  - 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 attrition 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—to simplify data collection and measure implementation. 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).
    - Questions/recommendations from Concepts 1 also apply.

- **Concept 3:** Separate rate + retention measures, by dialysis duration. (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 that would not be an issue when considered within a single measure addressing both populations.

HOME DIALYSIS WORKGROUP RECOMMENDED MEASURES

Taking the Steering Committee's recommendations into consideration, Dr. McGonigal indicated that the Home Dialysis Workgroup is advancing two specified measures (numerator, denominator, exclusions) for the Committee's review.

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

After much deliberation, the Workgroup determined that the measure set (i.e., Concept 2) is superior to the single "rate + retention" measure (Concept 1). Specifically, the measure 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. The single measure would dramatically curtail such analyses, as the underlying rate would be obscured.

Draft Home Dialysis Measure Specifications

Dr. McGonigal reviewed the draft measure specifications, as follows. Steering Committee discussion points and recommendations are incorporated directly into each section below:

- The intent of the measure set is to grow overall home dialysis utilization:
    - Assessment of overall home dialysis rate will incentivize increased home dialysis uptake and will provide facilities and dialysis organizations valuable information on performance in this regard, 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.
    - The measure set will address both incident and prevalent dialysis patients, pediatric and adult 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 rate measure set will use a patient-months construct to account for patients' potentially variable time contributions to the numerator and denominator. The retention measure will use a patient construct to allow for assessment of a singular event—achievement of 3+ consecutive months of home dialysis.
- 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 Hospital Referral Region (HRR).
    - *Steering Committee Input:* Some Steering Committee members expressed reservations with the HRR grouping approach and questioned whether a novel approach should be considered and developed by KCQA during this project. This question will be taken back to the Workgroup for further consideration.
- Specific to the retention measure:
    - Three months was identified by the Workgroup as an appropriate retention goal that will serve to foster proper investment in patient support and preparation for the transition home, but is not so formidable a time requirement that it will discourage home trials in all but the most ideal candidates.
        - *Steering Committee Input:* One Steering Committee member expressed concern that the 3-month retention timeframe recommended by the Workgroup is based primarily on expert opinion and urged staff to identify peer-reviewed publications that lend further support to the recommendation. The recommendation will be taken back to the Workgroup for consideration and additional input.
    - *Consecutive* months on home dialysis will be required to discourage attempts to meet the 3-month criterion cumulatively through sporadic, repeated starts in potentially inappropriate candidates.
    - Time from prior year will contribute to the consecutive month count to ensure all patients meeting numerator criteria are captured.

- Count of consecutive time contribution to the measure will resume uninterrupted for patients with a home dialysis pause of <=30 days to differentiate "interruptions" from true "exits" due to treatment failure.

- Exclusions:
  - *Small Facilities Exclusion:* Facilities treating <25 patients during the reporting month is a standard KCQA exclusion; the Workgroup agreed it is appropriate for this measure.
  - *Transplant Exclusion:* The Workgroup did not incorporate an exclusion for patients receiving a transplant into the measure specifications.
    - *Steering Committee Input:* The Steering Committee suggested the Workgroup consider excluding kidney transplant patients from both measures to ensure facilities are not penalized for patient "exits" secondary to transplant and to avoid the potential for a perverse incentive to delay transplant in eligible patients. The recommendation will be taken back to the Workgroup for consideration and resolution.
  - *Nursing Home Exclusion:* Dr. McGonigal indicated the Workgroup was somewhat divided on how to handle patients receiving dialysis at nursing homes and other LTCFs. The majority ultimately agreed this should be an exclusion for the rationale that capturing dialysis taking place in these settings is not consistent with the intent of the measure—to shift care from the in-center setting to home. Additionally, as all NH/LTCF patients on dialysis are considered to be on "home" dialysis, the rate measure score would always be 100%. Likewise, the retention criteria would always be met except in instances of treatment cessation or death. However, some Workgroup members believed nursing homes and LTCFs should be held to the same performance measurement standards as other providers, and others recognized the intrinsic difficulties associated with NH and LTCF dialysis and believed including this population in the denominator would further incentivize improvements in care. Dr. McGonigal requested Steering Committee input.
    - *Steering Committee Input:* The Steering Committee was at odds on how best to handle this patient group as well, and also raised concerns about the reliability and validity of the necessary data elements. The Committee recommended that during measure testing KCQA conduct first a data feasibility analysis, followed by a sensitivity analysis with and without the exclusion to determine its impact on the measure. A final decision on the exclusion can then be made, informed by these analyses. This recommendation will be taken back to the Workgroup for consideration and resolution.
  - *Clinical Contraindications:* The Workgroup considered clinical diagnoses that would be contraindications to *both* home dialysis modalities; blindness and documented dementia were identified as exclusions. Dr. McGonigal asked if the Steering Committee agrees with this assessment and whether there are other diagnoses that should be considered as exclusions to *both* peritoneal and home hemodialysis.
    - *Steering Committee Input:* The Steering Committee suggested the Workgroup remove blindness and dementia from the list of exclusions due to concerns about consistent data availability across payers and increased burden, if not readily available. This recommendation will be taken back to the Workgroup for consideration and resolution.

- *Non-Clinical Contraindications:* The Workgroup considered other (non-clinical) contraindications to home dialysis and identified homelessness as an exclusion for a publicly-reported performance measure upon which penalties will be based. Dr. McGonigal asked if the Steering Committee agreed and whether there are other non-clinical exclusions that should be considered.
    - *Steering Committee Input:* The Steering Committee suggested the Workgroup remove homelessness from the list of exclusions due to concerns about consistent data availability across payers and increased burden, if not readily available. This recommendation will be taken back to the Workgroup for consideration and resolution.

Action Item

Dr. McGonigal indicated that all outstanding items identified above will be taken to the Workgroup for further consideration and resolution. With that caveat, she then asked the Steering Committee for approval for the Workgroup to continue development of the draft measures; there was unanimous approval.

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

Dr. McGonigal concluded by summarizing next project steps, as below:

- The Home Dialysis Workgroup will next meet on July 29 (10 am-12 pm ET) to address any outstanding measure specifications issues identified today. The group will also generate recommendations on risk adjustment and/or stratification.
- The full KCQA body will meet on August 5 (5-7 pm) for a progress update from the Co-Chairs.
- The Home Dialysis Workgroup will convene for its final meeting on August 10 (10 am-12 pm) to finalize the measures and make recommendations on benchmarking and reporting schema.
- The Steering Committee will reconvene on August 16 (4-6 pm) to review the final measures and to generate a recommendation to the full KCQA body (meeting on or around August 23) on whether the measures should be advanced for measure testing.

KIDNEY CARE QUALITY ALLIANCE

STEERING COMMITTEE MEETING 4 SUMMARY
AUGUST 16, 2021

Attendees: George Aronoff MD (Co-Chair); Amy Barton PharmD, MHI; Donna Bednarski MSN, RN; J. Ganesh Bhat MD; Lorien Dalrymple MD, MPH; Todd Eric Minga MD; Jeffrey Silberzweig MD; Daniel Weiner MD, MS; Gail Wick MHSA, BSN, RN; Kathy Lester JD, MPH; Lisa McGonigal MD, MPH

Not Present: Keith Bellovich DO (Co-Chair); Robert S. Bomstad MS, BS, RN; Mary Dittrich MD; James Mike Guffey; Lori Hartwell; Brigitte Schiller MD

BACKGROUND

Following roll call and a welcome from Co-Chair Dr. George Aronoff, Dr. McGonigal reviewed the meeting agenda, provided a project update, and then reviewed the revised measure specifications, risk adjustment, and stratification recommendations from the Home Dialysis Workgroup. The ensuing Steering Committee discussion is summarized below.

PROGRESS UPDATE

Dr. McGonigal updated the Steering Committee that it since it last met on July 26, the Home Dialysis Workgroup convened on two occasions and completed its work on the Home Dialysis Utilization measure set. In preparation for the next phase of the project, the transplant measures environmental scan, literature review, and prototype measure development are currently underway, and the Transplant Workgroup will convene for its first meeting on Friday, August 20.

RECOMMENDED HOME DIALYSIS MEASURES

Dr. McGonigal indicated that the Home Dialysis Workgroup is recommending a paired measure set for the Steering Committee's approval for advancement to measure testing:

- **Home Dialysis Rate (HD-a):** Percent of all dialysis patient-months in the measurement year with treatment modality *Peritoneal Dialysis* and/or *Home Hemodialysis*.
- **Home Dialysis Retention (HD-b):** 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.

Underlying Principles

Dr. McGonigal then reviewed the underlying principles and logic for the measure set. Specifically, the intent of the measure set is to grow overall home dialysis utilization. To do so effectively, both increasing prescriptions and efforts to prepare and retain home dialysis patients must be incentivized. To that end, the Workgroup has developed the measures based on the following underlying principles:

- Assessment of Home Dialysis Rate (Measure A) will incentivize increased prescription of home modalities and will provide facilities and dialysis organizations valuable performance information on such, allowing for targeted quality improvement interventions as needed.
- Assessment of Home Dialysis Retention (Measure B) will serve as a counterbalance to unopposed incentivization of home prescription. The measure will also allow facilities and dialysis organizations to assess the success of their efforts to create a sustainable home program through appropriate patient education, preparation, and support and to apply targeted quality improvement interventions as needed.
- As the intent is to grow overall home dialysis utilization, the measure set will address both incident and prevalent dialysis patients, pediatric and adult 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 rate measure set will use a patient-months construct to account for patients' potentially variable time contributions to the numerator and denominator. The retention measure will use a patient construct to allow for assessment of a singular event—achievement of 3+ consecutive months of home dialysis.
- 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 Hospital Referral Region (HRR).
- Specific to the retention measure:
    - Three months was identified as an appropriate retention goal that will serve to foster proper investment in patient support and preparation for the transition home, but is not so formidable a time requirement that it will discourage home trials in all but the most ideal candidates.
    - <u>*Consecutive*</u> months on home dialysis will be required to discourage attempts to meet the 3-month criterion cumulatively through sporadic, repeated starts in potentially inappropriate candidates.
    - Time from prior year will contribute to the consecutive month count to ensure all patients meeting numerator criteria are captured.
    - Count of consecutive time contribution to the measure will resume uninterrupted for patients with a home dialysis pause of <=30 days to differentiate "interruptions" from true "exits" due to treatment failure.

Resolution to Outstanding Issues

Dr. McGonigal next summarized the Workgroup's responses and proposed resolutions to a number of outstanding Steering Committee recommendations and questions:

- *Nursing Home/LTCF Exclusion:* Given the ongoing lack of consensus on this issue in both the Steering Committee and Workgroup (e.g., is nursing home dialysis consistent with the definition of home dialysis intended by the measure set?) and concerns about the reliability and validity of this data element, the Workgroup recommends that during measure testing KCQA conduct first a data feasibility analysis, followed by a sensitivity analysis with and without the exclusion to determine its impact on the measure. A final decision on the exclusion can then be made, informed by these analyses.
- *Clinical/Social Exclusions:* The Steering Committee had suggested the Workgroup remove blindness, dementia, and homelessness from the list of exclusions due to concerns about consistent data availability across payers and increased burden, if not readily available. The Workgroup was sensitive to the concern and agreeable to the revision.
- *Transplant Exclusion:* The Steering Committee had suggested the Workgroup reconsider excluding kidney transplant patients from both measures to ensure facilities are not penalized for patient "exits" secondary to transplant and to avoid the potential for a perverse incentive to delay transplant in eligible patients. The Workgroup was agreeable to the revision.
- *3-Month Retention Period:* The Steering Committee had expressed concern that the 3-month retention timeframe recommended by the Workgroup is based primarily on expert opinion and urged staff to identify peer-reviewed publications that lend further support to

the recommendation. While there is a paucity of studies looking at this precise question, staff and Workgroup members did locate a few publications confirming that transfer from home to in-center dialysis is in fact highest during the first 3-4 months of treatment for both peritoneal and home hemodialysis patients, providing empiric evidence to further support Workgroup's expert opinion.[1,2,3]

- *Aggregate Groupings:* As noted above, the Workgroup has recommended that the level of analysis for the measure set be aggregated by parent dialysis organization within a given Hospital Referral Region (HRR). While the Workgroup expressed some reservation with this approach, it noted the reality that CMS is using HRRs for the ETC program. Given KCQA is developing a measure intended for use in that program, the Workgroup recognized the constraints imposed by this reality. Additionally, it was acknowledged that development of a new aggregation model is beyond the scope and resources of the current KCQA mission. It was suggested that subsequent KCQA work might be undertaken in this regard; if desired, the Steering Committee could make a recommendation to KCP's Operation Committee that it consider additional funding for a future project to develop a new method for aggregating facilities.

Steering Committee Discussion: The Steering Committee was agreeable to the above. Two additional concerns were raised:

- *Exclusion for Facilities with <25 Patients:* This is a standard KCQA exclusion based on prior empirical analyses demonstrating that measure reliability drops precipitously for facilities caring for fewer than 25 patients. However, the Steering Committee noted such an exclusion may be inappropriate here, given that many home-based facilities are quite small and would, paradoxically, be excluded from the measures. Dr. McGonigal acknowledged the concern, and also noted that because the measures would be aggregated to the parent dialysis organization within an HRR, a small facility exclusion may serve no purpose. She indicated the issue would be further explored, empirically, during measure testing.
- *Home Dialysis Start Date:* Some Steering Committee members raised concerns about the fact that the retention measure does not distinguish the home dialysis training period from the true start date. Dr. McGonigal reminded the Committee that the necessary data to capture this information are only available for Medicare FFS patients, and the Workgroup was unwilling to limit the measure to this population. One Steering Committee member suggested an alternative approach might be to exclude all patients who had started home dialysis fewer than "X" number of days prior to the end of a given measurement month. Others were in agreement that this approach should be explored during testing to determine both feasibility and impact. Suggested timeframes included 30, 45, and 60 days.

Action Item
Dr. McGonigal then asked the Steering Committee for its approval to advance the measures to the measure testing phase of the project; there was unanimous approval.

Risk Adjustment
Dr. McGonigal next relayed to the Steering Committee that the Workgroup had considered and made recommendations on risk adjustment variables for the measure set, building upon a draft

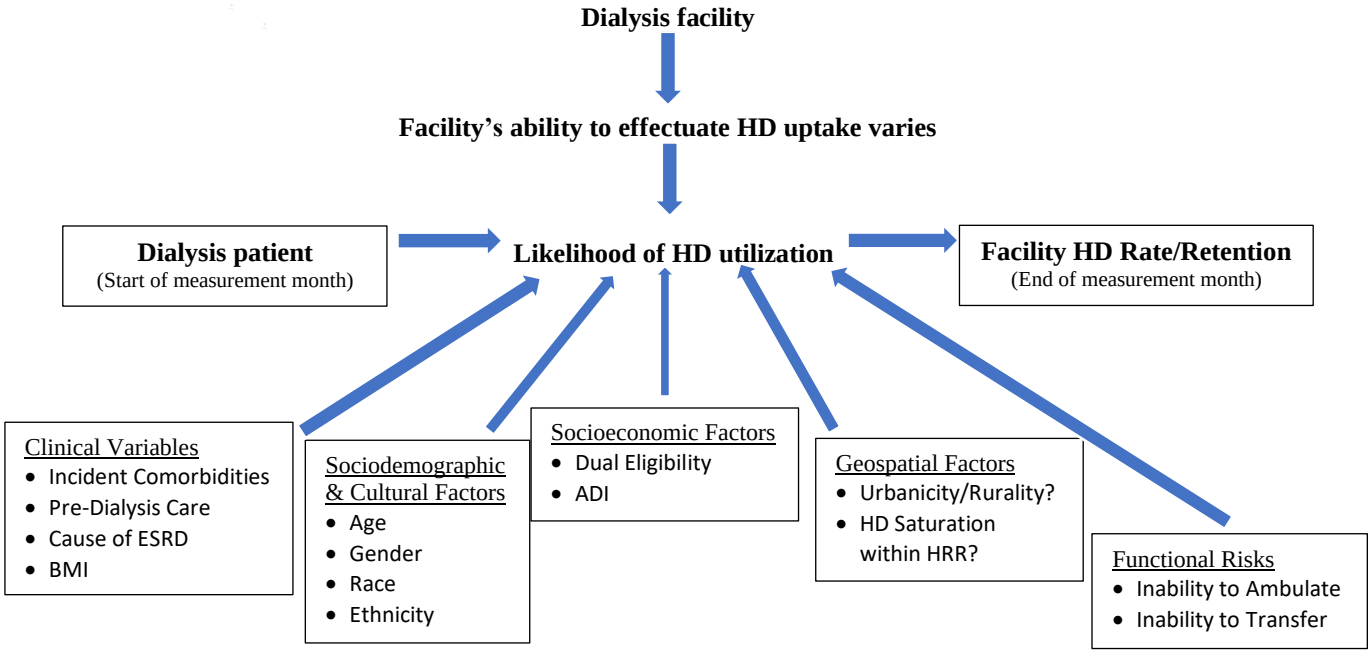
[1] Weinhandl ED, Collins AJ. Relative risk of home hemodialysis attrition in patients using a telehealth platform. *Hemodialysis International*. 2018;22:318-327.
[2] Seshasai RK et al. Factors associated with discontinuation of home hemodialysis. *AJKD*. 2016;67(4):629-637.
[3] Kolesnyk I et al. Time-dependent reasons for peritoneal dialysis technique failure and mortality. *Perit Dial Int*. 2010;30:170–177.

"Conceptual Model" developed by staff, as is now required by NQF for endorsement consideration. Dr. McGonigal indicated that the Conceptual Model, intended to guide the selection of candidate variables for risk adjustment, builds upon guidance provided by NQF in its June 2021 *Developing and Testing Risk Adjustment Models for Social and Functional Status-Related Risk Within Healthcare Performance Measurement Report* in which consideration of the following specific variables is suggested: age, gender, race/ethnicity, urbanicity/rurality, Medicare and Medicaid dual eligibility, indices of social vulnerability such as the Area Deprivation Index (ADI), and markers of functional risk such as frailty.

Dr. McGonigal noted that variables in all of the above domains have been found or are hypothesized to be associated with home dialysis utilization,[4,5,6] but differ in the extent to which an individual dialysis facility or group of facilities can be expected to be able to mitigate the barriers to home dialysis conferred by such variables. These differences inform their potential use as risk adjusters, since adjusting for factors that can be more easily mitigated by higher quality care is more likely to mask low-quality care.

Dr. McGonigal shared the model as below (Figure 1) to illustrate the pathway between home dialysis utilization and clinical, social, and functional status-related risk factors, reflecting characteristics of patients at the start of each measurement month that are independent of the quality of care provided and largely outside the control of the dialysis facility. Per NQF guidance, all demographic, clinical risk factors, social, and functional risks that *may* impact home dialysis utilization, regardless of whether they can be operationalized with available data, were included in the conceptual model. Sociodemographic, socioeconomic, geospatial, and clinical variables, including comorbidities, measures of pre-dialysis care, cause of ESRD, BMI, and measures of frailty and disability, are included.

Figure 1:



[4] United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.
[5] Mehrotra R et al. Racial and ethnic disparities in use of and outcomes with home dialysis in the United States. *J Am Soc Nephrol.* 2016;27:2123–2134.
[6] Weiner D and Meyer K. Home dialysis in the United States: To increase utilization, address disparities. (Editorial.) *Kidney Medicine.* 2020;2(2):95-97.

Dr. McGonigal reported to the Steering Committee that the Workgroup agreed the above variables are appropriate for the Conceptual Model and should be assessed for feasibility and impact during measure testing. However, she noted that the Workgroup acknowledged that many may ultimately not be able to be operationalized due to real-world data limitations or statistical issues that may be identified during testing (e.g., multicollinearity, confounding). It was also observed that many variables may be found to have little impact on home dialysis utilization; for instance, age and BMI may have minimal effect on uptake and retention except at the extremes of the variable parameters.

Steering Committee members were supportive of the proposed Conceptual Model approach; there were no questions and no suggested revisions.

Measure Stratification

Dr. McGonigal again noted that the Workgroup had agreed that the intent of the measure set is to grow overall home dialysis utilization, and as such will include all patients—peritoneal and home hemodialysis patients, incident and prevalent dialysis patients, new and established home dialysis patients.[7] However, to allow facilities and dialysis organizations to better assess and respond to variations in care across these different groups, the Workgroup recommends an assessment during testing of the feasibility and impact of stratifying results by *Peritoneal Dialysis* vs *Home Hemodialysis* and *New* (1st year) vs *Established* (>1 year) patients.

Appropriate social and functional risk variables for stratification (see the Conceptual Model, above) will also be identified during measure testing. Dr. McGonigal noted that at a minimum, NQF recommends that race/ethnicity, age, gender, dual eligibility, and Indices of social vulnerability such as the Area Deprivation Index (ADI) be considered and assessed for impact.

Steering Committee members were supportive of the proposed approach to measure stratification; there were no questions and no suggested revisions.

Benchmarking

While implementation and reporting issues fall outside NQF's scope and requirements, Dr. McGonigal suggested that KCQA could nevertheless opt to submit such recommendations to programs within which the measures may be adopted. In this regard, the Workgroup noted that a "perfect" score for home dialysis utilization measures is neither feasible nor desirable and striving to achieve unattainably high scores could be expected to have perverse consequences, adversely impacting care, outcomes, and patients' quality of life. (E.g., prescribing home dialysis to clinically and/or psychosocially inappropriate patients, exhorting patients to remain on home dialysis despite a preference for in-center care.) To mitigate these risks, the Workgroup suggests two types of performance benchmarks be established to more precisely define "success" on the measures:

- An absolute **Achievement Benchmark** for the corresponding measurement year. Dr. McGonigal noted that this recommendation contrasts with the relative achievement benchmarks proposed in the ETC Model, where the 30th, 50th, 75th, and 90th percentile values from the Comparison Geographic Area group distribution would define ranges for each score. She remarked that it has long been KCP's position that the use of such bell-curve ranking systems that rely on forced distributions to create performance differentiations that do not exist in reality is misleading and may potentiate existing healthcare inequities. This is particularly problematic in penalty-based programs, where a disproportionate share of penalties may be levied on the

[7] 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.

"lowest" performers on the curve, oftentimes the most financially-at-risk safety net types of providers that care for the poorest and otherwise underserved communities.)

- An **Improvement Benchmark**, established by the provider's own historic performance from the preceding measurement year.

However, Dr. McGonigal noted that while the Workgroup considered a variety of approaches to establish these benchmarks, it ultimately determined that the information necessary to do so is not yet available. Specifically, the most recent USRDS (2018) data are already outdated and cannot be used to reliably extrapolate current performance given the impact of COVID over the past two years. As such, the Workgroup proposes KCQA first establish current performance rates during measure testing and then revisit the issue, informed with this knowledge.

The Steering Committee was supportive of the proposed benchmarking approach.; there were no questions or additional suggestions.

PUBLIC COMMENT
There were no public comments.

NEXT STEPS
Next project steps were summarized as below:

- The Data/Testing Workgroup will convene next week (date TBD) to review/refine the Home Dialysis Measure Testing Protocol.
- KCQA Lead Representatives will reconvene on August 25 to review/approve the home dialysis measures for advancement to measure testing; testing will commence immediately following approval.
- The Transplant Workgroup will convene on August 20 to begin its work.
- The Steering Committee will reconvene in early September to review recommended Transplant Measure Concepts.

KIDNEY CARE QUALITY ALLIANCE

STEERING COMMITTEE MEETING 5 SUMMARY
SEPTEMBER 9, 2021

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

Not Present: Robert S. Bomstad MS, BS, RN; James Mike Guffey; Brigitte Schiller MD

AGENDA

- Welcome and Opening Remarks, Roll Call, Review of Agenda
- Project Update
- Overview of Transplant Project: Goals, Scope, Charge
- Transplant Data Presentation: *Rachel Patzer PhD, MPH, Transplant Workgroup Co-Chair*
- Overview and Discussion, Transplant Measure Options
- Additional Transplant Proposal Discussion: Multistep Candidate Assessment and Tracking Policy Development
- Next Steps
- Public Comment
- Adjourn

PROJECT UPDATE

Dr. McGonigal first provided an update on the overall KCQA project. She noted the project remains on time and on budget. Home dialysis measure development has been completed, and it is projected that transplant measure development will be completed by the end of October, consistent with the original timeline. She noted that measure testing of both measure sets will take place this fall, with a goal of having the metrics ready for NQF submission in early January for their spring 2022 renal project cycle, contingent on Steering Committee and full KCQA approval.

TRANSPLANT PROJECT OVERVIEW

Dr. McGonigal next provided an overview of the transplant work. She noted that the defined goal is to improve transplant access through the development of 1 (or 2 related) dialysis facility-level transplant-related performance measures for submission to NQF for endorsement consideration for subsequent use in CMS's federal ESRD quality programs.

Dr. McGonigal reminded the Steering Committee that a number of dialysis-facility-level transplant metrics already exist—specifically, CMS's Percentage of Prevalent Patients Waitlisted (PPPW), Standardized Waitlist Ratio (SWR), and the new ESRD Treatment Choices (ETC) Model transplant rate metric. She also noted that CMS has recently added two new transplant-related measure concepts to its Measures Inventory Tool (CMIT)—Waitlist Decision Rate and Transplant Referral Rate. She indicated that both are specified for use at the dialysis facility level and are applicable to prevalent patients only. While no specifications are available yet and a timeline is unclear, Dr. McGonigal remarked that this informs us that these two concepts are on CMS's radar and that we might expect to see these measures at NQF soon.

Dr. McGonigal reminded the Steering Committee that KCP has long supported the development of a dialysis facility-level transplant measure, but believes that such a measure must fall firmly within the realm of the facility's control and must be amenable to intervention by the facility—particularly in penalty-based payment programs. She remarked that the three existing dialysis facility-level transplant-related measures already been put forth by CMS—The SWR, PPPW, and the ETC Transplant Rate metric—do not meet this "actionability" criterion. Evaluation practices and decisions vary by transplant center, and so dialysis facilities have little control over what patients are ultimately waitlisted or transplanted. Additionally, Dr. McGonigal noted both the SWR and PPPW have been empirically demonstrated as lacking statistical validity, confirming that the measures don't provide an accurate assessment of dialysis facility performance. She again noted this is likely a reflection of facilities' inability to impact which patients are ultimately waitlisted by transplant centers. She further noted that the ETC metric has never been formally specified, empirically tested, or submitted to NQF for evaluation, such that we have no idea how it will perform or if the results will provide a reliable or valid representation of performance.

Dr. McGonigal reminded the Committee that historically, KCP and KCQA members have supported the development of a "transplant referral" based measure, as failure to refer is a persistent barrier to access and referrals are firmly within the facility's realm of control. However, here she noted that referral data are not currently collected on a national level. In fact, she indicated that none of the three data elements that do fall within the dialysis facility's control—education, referral, and to a lesser degree, transplant evaluation start—are collected nationally. She remarked that this is of course problematic when looking to develop a dialysis-facility centric transplant measure.

Dr. McGonigal noted that there has been a push for CMS to start collecting referral data in the CROWNWeb (EQRS) System for some time, with increasing pressure to do so recently thanks in large part to recent peer-reviewed publications drawing attention to these missing data elements and how important they could be to improving access. Dr. McGonigal also indicated that her and Ms. Lester's communications with new CMS leadership under the Biden Administration do seem receptive to working more collaboratively with the kidney care community on such issues, and that this may be an opportune time to push harder for national collection of these important data elements, with the full force of KCQA's formidable Workgroup and Steering Committee behind the request. She again noted that the new referral measure concepts in CMIT suggests that we might already expect to see the referral data element incorporated into CROWNWeb in the near future.

Dr. McGonigal reported that, given the above, the Transplant Workgroup is considering its options for measure development, but does seem to be willing to consider pushing forward on the referral data issue. Of the 3 data elements amenable to dialysis facility intervention (education, referral, start of evaluation process), the Workgroup has, thus far, been homing in on referral-based metrics as the most promising, most immediately changeable, most likely to have a big impact on transplant process, and most fully within facility's control. She noted that one of the measures being considered by the Workgroup is the Standardized Transplant Referral Ratio (STReR) measure developed by Dr. Rachel Patzer and her colleagues at the Southeastern Kidney Transplant Coalition.

Dr. McGonigal then introduced Dr. Patzer to the Steering Committee, noting she is one of the two Co-Chairs on the KCQA Transplant Workgroup and is a true expert in the transplant evaluation process data.

Dr. McGonigal noted that Dr. Patzer is a Professor in the Department of Surgery at Emory University School of Medicine, with joint appointments in the Departments of Medicine and Epidemiology; she also serves as the Director of the Emory Health Services Research Center. Dr. Patzer's research focuses on improving quality and outcomes, primarily in kidney disease and transplantation, and reducing inequities in transplant access. Her most recent research has focused on the development of a novel surveillance data registry for kidney disease, including the collection of data on transplant referral and evaluation start among more than thirty transplant centers across the nation. She currently serves as the United Network for Organ Sharing (UNOS) Data Advisory Committee Chair, Data Chair of the Southeastern Kidney Transplant Coalition, and is a member of the Scientific Registry of Transplant Recipients (SRTR) Review Committee. Dr. McGonigal indicated that Dr. Patzer is a prolific researcher and author who also recently chaired CMS's Transplant Technical Expert Panel (TEP).

TRANSPLANT DATA PRESENTATION

Dr. Patzer presented findings from her publication around the development of the Standardized Transplant Referral Ratio (STReR) measure. The Southeastern Kidney Transplant Coalition is a grassroots organization formed in 2011 consisting of patients/families, professional membership, and ESRD Networks. The mission of the Coalition is to improve access to kidney transplantation and reduce inequities in transplant access. The project stemmed from a CMS Statement of Work promoting ESRD Networks alignment—specifically, to improve transplant coordination by promoting early referral and assisting patients and providers to improve referral patterns, and to increase rates of patients on the transplant waitlist. A pre-transplant data registry was created by nine universities and medical centers across Georgia and North and South Carolina in conjunction with the ESRD Network 6 Coordinating Center. Data from 2012-2016 were collected through REDCap, quality checks were performed for missing and incorrect values and field validation errors, missing fields were backfilled with CROWNWeb-supplied data, and a data file was created and submitted to USRDS for linkage to national surveillance data.

In 2016, additional funding was received for expansion of the registry, and NIH funding was received in 2019 to expand referral and evaluation data collection to three additional ESRD Regions.

Dr. Patzer then reviewed other national updates related to referrals, including UNOS's project on referral data collection and the SRTR Task 5 focus on transplant center quality measures to identify metrics to assess national transplantation system performance and support informed decision-making by critical audiences. She also reviewed the STReR measure specifications, reliability, validity, and sensitivity analyses.

She concluded with an assessment of whether referrals are associated with other quality metrics, finding that:

- Higher referral rates were associated with patients with a higher percentage of permanent vascular access and who were informed of transplant options, received pre-ESRD care, and who had higher levels of waitlisting and transplantation.
- Referral was not associated with most other non-transplant quality indicators such as mortality, hospitalization, and anemia management.

Steering Committee Discussion
The Steering Committee expressed their appreciation for Dr. Patzer's presentation and insights. Committee members agreed that while there is a desire to "refer everyone," this doesn't necessarily keep the interest of the patient in mind and may ultimately prove counterproductive. While it was agreed that increasing referrals is a goal worthy of pursuit, the potential adverse consequences of focusing on referrals in isolation must be kept in mind and must be properly addressed if KCQA were to develop a measure in this area.

Committee members asked Dr. Patzer if in her experience the density of the transplant centers has any impact on referral rates. She indicated they have not seen a big effect in this regard, but that regionally they have the fewest transplant centers and the most dialysis centers, so this finding may not be widely generalizable.

Dr. McGonigal asked Dr. Patzer what the actual referral rate is, currently. Dr. Patzer indicated that in Georgia it sits at approximately 25%, and at 30% across all three states. Rates vary from 0-100% across facilities. Committee members noted that what the "ideal" referral rate should be is not really known.

Others noted that wait times for the initial evaluation after referral remain considerable at 3-4 months. Dr. Patzer agreed, but noted there is considerable variation in this regard, and that organ supply is a rate-limiting factor. It was also noted that undocumented patients are generally not referred, which is problematic for facilities with a high proportion of such patients. Dr. Patzer noted that this is also a policy issue; undocumented patients are not captured in the data used in her research either, and there's a considerable need to understand performance and outcomes in this population.

Ms. Lester also informed the Committee that one Transplant Workgroup member suggested that KCP submit comments on the United Network for Organ Sharing (UNOS) pre-waitlisting transplant center measure concepts, open for comment until September 30. She noted that KCP does not have policy on the concepts specifically, and there is not sufficient time to do a deep dive into the specifications; however, KCP does have standing policy that the federal government should be removing barriers to transplant and align measures across different provider groups. She indicated that KCP's Operations Committee and broader Membership have expressed no objections to submitting comments in this regard; the Steering Committee voiced support of this proposal.

TRANSPLANT REFERRAL-BASED MEASURES
Dr. McGonigal then presented the pros and cons of pursuing a transplant referral-based metric:

- Strengths:
    - There is substantial room for improvement in this aspect of care within dialysis facilities.
    - Failure to refer has been identified as a persistent barrier to transplant access.
    - Referrals are firmly within the dialysis facility's realm of control.
    - Through the process of developing, advancing, and advocating for a referral-based measure, KCQA would likely facilitate and expedite the creation and collection of this notably absent data element.
- Potential limitations:
    - Referral data are not currently captured at the national level.

- The lack of national data may raise issues with NQF's feasibility criterion (see below); however, as previously discussed, the measure concept identified in CMIT suggests CMS does intend to begin collecting referral data in the near future.
- Unless structured properly, there is a risk a referral measure could devolve into a "check-box" construct; this could be prevented through careful measure construction, such as the inclusion of multiple "layers" of verifiable data such as date of referral, transplant center, and method of referral confirmation.
- A referral measure might spur "indiscriminate" referrals and overload transplant centers.

Dr. McGonigal indicated that questions the Workgroup has been considering include whether this KCQA opportunity should indeed be used to push for national referral data collection and whether the hypothetical fear of a "bottleneck" at the transplant centers—the fear of "overwhelming" the centers with referrals—should prevent KCQA from focusing on a known persistent barrier to access that is firmly within the dialysis facility's control. She noted that while there are opposing views on this within the Workgroup, the majority have opined that transplant centers are not overwhelmed at this point, and that this concern could be effectively addressed with proper risk adjustment, precisely defined exclusions, or establishing achievement benchmarks as a counterbalance. Most of the Workgroup concluded that a potential bottleneck at transplant centers is a separate issue that would need to be addressed via other policy levers that are really beyond the scope of our charge, and were KCQA to yield to this concern, it would perhaps squander this unique opportunity to appropriately and definitively address this one issue that it can very effectively impact.

HRSA/OPTN Guidance

Dr. McGonigal further noted that current guidance from HRSA and the Organ Procurement and Transplantation Network (OPTN) itself negates the concern about overwhelming transplant centers. Their educational guidance on patient referral to kidney transplantation document[1] indicates that referral to transplant centers for evaluation should be the default pathway for patients, and that any decision on a patient's candidacy for transplant should not be preempted upstream, before the transplant center has an opportunity to evaluate them.

NQF Feasibility Criterion

Finally, Dr. McGonigal briefly addressed NQF's feasibility criterion as it pertains to a potential referral-based metric. She noted that ideally all data required to calculate a measure are already available; however, NQF explicitly indicates that its criterion can also be satisfactorily met when data do not currently exist if testing indicates that they could be captured without undue burden. Dr. McGonigal remarked that it has been confirmed by the Transplant and Data/Testing Workgroups that most, if not all, facilities and dialysis organizations are already capturing referral data internally, the data are routinely generated during care delivery, and they're available in electronic health records. She concluded that KCQA could thus make a good case at NQF for a referral measure as being feasible without undue burden to patients or providers. She reminded the Steering Committee that there is precedent for this approach; KCQA has had success around a similar issue in the past with its Medication Reconciliation measure, which was and remains endorsed by NQF. In that instance, the case for the measure's importance was made to NQF, after which KCQA staff lobbied CMS to

[1] HRSA, OPTN Minority Affairs Committee. *Educational Guidance on Patient Referral to Kidney Transplantation.* September 2015. https://optn.transplant.hrsa.gov/.

incorporate the necessary data elements into CROWNWeb; CMS will be starting data collection for the measure in PY 2022.

Options
Dr. McGonigal then briefly presented several referral-based metrics that the Workgroup is considering:

OPTION:	**DESCRIPTION:**
Transplant Referral Rate	Percent dialysis patients referred to a transplant center for evaluation.
Referral "Opt-Out"	Percent referred patients who were waitlisted (and/or) transplanted.
Measure Set: a. **Referral Rate** b. **Percent Referred Waitlisted/Transplanted**	 Percent dialysis patients referred to a transplant center for evaluation. Percent referred patients who were waitlisted/transplanted).
STReR	Risk-adjusted ratio of observed-to-expected number of adult patients on dialysis referred for transplant evaluation.

Steering Committee Discussion
Steering Committee members agreed that overall referral rates remain quite low and that there is considerable variation in rates across facilities, supporting the underlying premise of a referral metric. It was noted that a referral measure, in isolation, would likely result in indiscriminate referrals by facilities to perform well on the metric; however, a paired set of counterbalancing measures, similar to what was done with KCQA's Home Dialysis Measures, might effectively address this concern.

One Committee member did not agree with the HRSA/OPTN recommendations to leave the assessment for patient suitability for transplant fully in the hands of the transplant center, noting that patients who are not adherent to their dialysis treatments, for instance, may not be ideal transplant candidates and that the treating nephrologist is capable of such discernment. Another disagreed, stating his belief that all patients who want a transplant should be referred, even if not "ideal" patients. It was also noted that the referral process is slow; a prior contraindication may have resolved by the time a patient is evaluated, and the preemptively deciding a patient is not a transplant candidate is not prudent. Another Member agreed, but noted dialysis providers do have some say in what's in the patient's best interest, and we must strike a delicate balance here as misallocation of limited resources is a concern.

One Steering Committee member remarked that getting medical clearance for a patient after referral can take six or more months and is a tremendous barrier that slows the process down considerably. She suggested clearly defined exclusions—preferably consistent across transplant centers—would facilitate the process. Another member noted the discordance between dialysis facilities and transplant centers. She suggested that perhaps transplants centers would be the better data source for a referral metric, over dialysis facilities. Dr. McGonigal indicated that the Workgroup has not yet discussed data sources and she would bring this issue back to the Steering Committee for consideration once the Workgroup has made a recommendation in this regard.

Of the options presented above, several Steering Committee members expressed interest in the measure set, pairing a referral rate metric with a measure assessing the waitlisting/ transplantation rate among those referred. It was noted that limiting the waitlist/transplant denominator to patients referred by the dialysis facility would provide the facility with considerable agency over the measure; this is in contrast to existing metrics such as CMS's Percentage of Prevalent Patients Waitlisted (PPPW), in which the denominator includes all patients assigned to a facility, regardless of referral status. It was also noted that waitlisting/transplantation rate among referred patients might perversely curtail referral rates if used alone, as facilities might limit referrals to patients with a very high likelihood of being waitlisted. Pairing it with the referral rate measure would provide a counterbalancing force against this tendency.

ADDITIONAL WORKGROUP PROPOSAL

Dr. McGonigal then reviewed the final agenda item for the day—an additional proposal put forth by the Workgroup for consideration. Specifically, she noted that one Workgroup member believes KCQA should seize this rare opportunity of having convened clinical, data, and other experts in the field of kidney transplantation to push for something broader in scope than development a performance measure to help enact real and lasting change in the transplant processes and outcomes. This member instead proposed pursuit of a multi-step pre-transplant continuum guideline within which dialysis facilities would develop, institute, and report on a policy for documenting and tracking steps along the transplant evaluation process continuum. While not intended to be prescriptive in the granular sense, he proposed the guideline would consist of the following elements:

- Transplant education (type/date);
- Identified absolute and relative contraindications to transplantation and timeframe for revisiting those conditions;
- Timing and destination of executed transplant referral;
- Date/time of transplant center acceptance or refusal of referral;
- Documentation of detailed iterative process for assessing and updating status and progress of evaluation for all patients whose referral has been accepted by transplant center;
- Identification of referred patients whose evaluation process has gone "off track," with a rapid-turn-around plan for intervention;
- Date of waitlisting or waitlist removal (and reason for removal);
- Each facility would also be required to develop, in writing a QAPI project, using their tracking tool(s) of choice, to identify system-level barriers in access to various stages of the pre-transplant process, with concomitant opportunities for intervention, e.g., using PDSA methodology or any other QAPI-appropriate method.

The underlying rational for the proposal is that the pre-transplant continuum is a multi-step process that involves many care providers across various sites of care during which there is ample opportunity for patients to "get lost" along the way. He opined that any discrete data element, such as referrals, would only provide a limited view of the process and so may have limited impact. As already discussed, he was also concerned about potential unintended consequences if we're to focus on a discrete element such as referrals, such as overwhelming transplant centers.

Dr. McGonigal acknowledged that this proposal is much grander in scope than the project with which the Workgroup has been tasked and would thus require significantly more time

and resources than currently allotted. She noted that the proposal would require identification of best practices, agreement on standardized protocols along the continuum of care, and field testing. However, while the Workgroup agreed to continue its pursuit of the nearer-term, more limited measure scope, as initially defined, all Workgroup members support the underlying ~~premise~~ of this proposal and requested it be brought to the Steering Committee for consideration as a future, follow-on project, at which time the proper time and resources could be committed to the work.

Dr. McGonigal asked the Steering Committee if this proposal is something it would wish to consider, reminding members that KCQA has done similar work in the past around developing best practices for first-year mortality reduction (the PEAK Project) and recommendations around patient-reported outcome measures (PROMs) for use in the ESRD population.

Steering Committee Discussion

The Steering Committee expressed its appreciation for the proposal and voiced its support of the underlying premise and its belief in the need for this work. However, the group ultimately agreed that the proposal is broader in scope and would require significantly more time and resources than has been allotted to KCQA at this juncture. Likewise, it falls outside KCQA's explicitly defined mission of developing dialysis facility-level performance measures intended for use in CMS's federal ESRD quality programs. As such, the Committee concluded that the narrower focus on nearer-term measures more immediately within KCQA's realm of control remains the appropriate approach for this current work.

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

Next project steps were summarized as below:

- The Transplant Workgroup will reconvene on September 27 to resume its work, based on the Steering Committee's guidance and recommendations.
- The Steering Committee will reconvene in mid-October to review/approve the recommended Transplant Measure Specifications, after which the full KCQA will review/approve the measures for advancement to measure testing.
- KCQA staff is also working with the Data/Testing Workgroup to finalize measure testing protocols for the Home Dialysis Measures; it is anticipated that measure testing will commence in early October.

KIDNEY CARE QUALITY ALLIANCE

STEERING COMMITTEE MEETING 6 SUMMARY
OCTOBER 21, 2021

Attendees: Amy Barton PharmD, MHI; Keith Bellovich DO (Co-Chair); J. Ganesh Bhat MD; Lorien Dalrymple MD, MPH; Mary Dittrich MD; James Mike Guffey; Lori Hartwell; Todd Eric Minga MD; Rachel Patzer PhD, MPH (Transplant Workgroup Co-Chair); Jeffrey Silberzweig MD; Daniel Weiner MD, MS; Gail Wick MHSA, BSN, RN; Kathy Lester JD, MPH; Lisa McGonigal MD, MPH

Not Present: George Aronoff MD (Co-Chair); Donna Bednarski MSN, RN; Robert S. Bomstad MS, BS, RN; Brigitte Schiller MD

AGENDA

- Welcome and Opening Remarks, Roll Call, Review of Agenda
- Review/Discussion/Approval of Draft Transplant Measure Specifications
- Update on Measure Testing
- Next Steps
- Public Comment
- Adjourn

TRANSPLANT PROJECT BACKGROUND AND OVERVIEW

After welcoming remarks from Steering Committee Co-Chair Dr. Keith Bellovich, Dr. McGonigal provided an overview of the transplant work., to date. She reminded the Committee that the defined goal of the project is to improve transplant access through the development of 1 (or 2 related) dialysis facility-level transplant-related performance measures for submission to NQF for endorsement consideration for subsequent use in CMS's federal ESRD quality programs.

Dr. McGonigal reviewed that during its last meeting, the Steering Committee had discussed that when considering care along the transplant continuum, only three data elements fall within the dialysis facility's realm of control—education, referral, and, to a lesser degree, transplant evaluation start. She further noted that none of those three data elements are currently collected nationally, creating challenges when looking to develop a dialysis-facility centric measure. She reminded the Committee that it had previously discussed why referrals are the most viable of these three options, being the most easily quantifiable, the most amenable to intervention by the facility, and the most fully within the facility's control. Additionally, she noted that most dialysis facilities are already tracking and documenting referral data internally, and CMS has indicated it's ready to start developing a dialysis facility referral-based metric and has expressed an interest in working with KCQA on this.

Accordingly, the Steering Committee discussed the potential strengths and limitations of a referral-based transplant metric on its last meeting. Strengths include that there is substantial room for improvement in dialysis facility referral rates, that this failure to refer has been identified as a significant and persistent barrier to transplant access, and when considering the transplant evaluation process continuum, referral is the only easily quantifiable step that falls firmly within the dialysis facility's realm of control. Dr. McGonigal also reported that she and Ms. Lester recently spoke with the team at CMS's center for clinical standards and quality (CCSQ), at which time the team confirmed that CMS will be pursuing a dialysis facility-level referral measure in the near future. She remarked that knowing now with certainty that this is CMS's intent, it would be prudent for KCP and KCQA to be proactive and lead this effort to

ensure that the measure that is ultimately adopted into the federal programs is valid, reliable, meaningful, and community-supported. Finally, Dr. McGonigal noted that developing, advancing, and advocating for a referral-based measure would expedite and facilitate the creation and collection of this important data element and would position KCQA to ensure that the data element is feasible, yet rigorous enough to provide an accurate, valid picture of care.

Potential limitations of a referral-based measure include that national data do not currently exist. Dr. McGonigal reminded the Committee that this, theoretically, could raise issues at NQF in regards to its "feasibility" criterion; however, the criterion can be met if testing indicates that the necessary data could be captured without undue burden. As facilities are already capturing and documenting referral data internally, if testing confirms the necessary data can be collected, she remarked that the Workgroup believes KCQA can make a strong case for feasibility at NQF. She also noted that there's also a risk that a referral measure, if not constructed properly, could devolve into a "check-box" measure. Likewise, focusing in on referrals in an accountability program could end up spurring "indiscriminate" referrals by dialysis facilities to perform well on the measure—which could theoretically end up overwhelming transplant centers. However, as previously discussed, Dr. McGonigal noted that pairing a referral measure with a well-constructed "counterbalancing" metric would effectively curb this tendency toward "over-referring."

TRANSPLANT MEASURES

Dr. McGonigal then reminded the Committee that of those paired "counterbalancing" measure sets that were suggested as options on the last call, the greatest interest was expressed in a measure set pairing a referral rate metric with a measure assessing the waitlisting rate among those patients who were referred:

- Measure A: Percent of dialysis patients with a documented referral to a transplant center for evaluation.
- Measure B: Percent of patients with a documented referral who were placed on the transplant waitlist and/or received a transplant.

She reported that this is where the Transplant Workgroup landed as well, for the following reasons: Waitlisting is an "outcome" measure, which is a strong preference by both NQF and CMS; the necessary data are present and accessible to dialysis facilities; waitlisting is a high priority for all ESRD stakeholders; and development of a waitlisting measure would move KCP closer towards its goal of removing/replacing the existing waitlisting/transplant measures in the QIP and ETC programs.

Dr. McGonigal reported that similar to what KCQA did with the home dialysis set, the Workgroup is recommending the two measures to be used together. The referral rate measure would incentivize referrals—but if used alone, it might lead to "indiscriminate" referrals, or "over-referring." The waitlisting measure, because its denominator is limited to those patients who were deliberately referred by the dialysis facility, gives facilities considerably more agency over the measure than existing metrics such as the PPPW, where the denominator includes all patients, regardless of referral status. If used alone, however, this measure might actually *reduce* referral rates, as facilities might limit referrals to patients with a very high likelihood of being waitlisted. Dr. McGonigal noted that pairing the measures will counterbalance both tendencies—i.e., towards over- and under-referring.

MEASURE SPECIFICATIONS
Dr. McGonigal then reviewed the measure specifications, as follows.

Overarching Considerations:

- **Data Source:** The Workgroup agreed the data should come from the dialysis facility rather than the transplant center. Dr. McGonigal noted again that most dialysis facilities are already collecting referral data and have expressed willingness to use this data to advance care. Additionally, CMS has indicated it will pursue facility data to support a referral measure in the near future, noting that it does not currently have the authority to require reporting of the necessary data elements from transplant centers. However, Dr. McGonigal informed the Committee that the Workgroup *does* believe using transplant data would be the ideal, if and when CMS obtains the statutory authority to require such, because it would allow for a broader, population health-based measure where even pre-emptive referrals and transplants could be tracked effectively. But given the immediate need for a measure in this area, the Workgroup agreed KCQA should move forward with what's feasible in the near-term to incentivize high-quality referrals now, sooner than later—and they do believe this measure set will do that. She noted that the Workgroup will nevertheless convene for one final call later this or early next year to generate a series of formal recommendations around national data collection over the longer-term to allow for a broader, more unified approach to incentivizing appropriate care and coordination along the transplant evaluation continuum; staff will bring those recommendations to the Steering Committee at its next meeting for consideration.
    - *Steering Committee Discussion:* The Steering Committee was agreeable with the Workgroup's recommendation in favor of using facility-level data for the measure(s), as well as with the plan for the Workgroup to reconvene to develop formal recommendations on national data needs and priorities.
- **Patient Construct:** The Workgroup selected a "patient construct" over "patient-months" because variable patient time contributions are not a factor for the dichotomous outcomes being assessed. E.g., because patients either were or were not referred for transplant evaluation during the measurement year, variable time contributions do not come into play.
    - *Steering Committee Discussion:* The Steering Committee was divided on this point, with some noting that a patient-month construct would incentivize early referrals and would more clearly delineate facility attribution if a patient were to switch facilities mid-year. Other Committee members agreed with the Workgroup that the patient construct makes more sense when measuring dichotomous outcomes such as referrals and waitlisting, for which contributed time has no intrinsic value *per se*—and is generally more intuitive and easier for patients and providers to understand. Dr. McGonigal remarked that either construct would serve KCQA well and would produce meaningful, valid, reliable information that could be used by patients to effectively inform care decisions and by providers to improve processes and outcomes. She noted that a final decision will ultimately come down to the Steering Committee's priorities, weighing incentivizing earlier referrals against clarity of construct. She suggested a formal survey vote to gather additional input for absent Steering Committee members, after which results would be taken back to the Workgroup for additional consideration. The Steering Committee was agreeable with this approach.

Measure A, Referral Rate:

- **Denominator**: All dialysis patients permanently assigned to a given facility during the measurement year. Dr. McGonigal noted that "all patients" includes in-center and home, incident and prevalent, pediatric and adult, peritoneal and hemodialysis patients, regardless of payer.
- **Numerator:** Patients from the denominator for whom there is a documented referral to a transplant center within the preceding 24-month period.
    - *Time Parameter:* Dr. McGonigal noted that that Workgroup agreed there should be a two-year time parameter around the referral to establish a timeframe after the referral within which there should be discernable progress made in the evaluation process. The intent of this parameter is to help ensure patients don't "fall through the cracks," while still allowing ample time for progress in the evaluation process.
    - *"Documented" Referrals:*
        - Core Data Elements: A "documented" referral is defined as a referral that has been documented in the medical record and includes the name (or other identifying information) of the transplant center and the date of the referral.
            - *Steering Committee Discussion:* Dr. McGonigal noted that both the Transplant and Data/Testing Workgroups confirmed that referral, transplant center, and date of referral should all be documented in the dialysis facility medical records and should be readily retrievable. She also remarked that CMS has confirmed its intent to implement these particular dialysis facility-level data elements in EQRS in near future. The Steering Committee was in agreement that these core data elements should be feasible and consistent across facilities.
        - Additional Data Elements: The "documented referral" should also include documentation in the medical record that the transplant center confirmed receipt of the referral by means of a letter, email, phone call, or fax, as well as documentation in the medical record that the dialysis facility informed the patient of the referral.
            - *Steering Committee Discussion:* Dr. McGonigal noted that while the Conditions for Coverage *do* require dialysis facilities to track results of each transplant center referral, the Workgroup acknowledged that it is feasible that these two items may not be as consistently documented by facilities as the prior items (preceding bullet); as such, the Workgroup and staff are recommending a feasibility assessment during measure testing. If it's found that these data elements are *not* feasible, the Workgroup will consider making a recommendation to NQF/CMS that collection of these data elements would strengthen the measure (and the referral process) and should be incorporated into EQRS, and then the measure specifications, when feasible. The Steering Committee agreed that these data

elements may not be discretely captured and was agreeable with the proposed investigative approach during testing.

- **<u>Exclusions</u>:** The Workgroup recommends the following denominator exclusions:
    - Patients already on the waitlist.
    - Patients receiving dialysis for AKI only.
    - Patients >=75 years of age.
    - Patients enrolled in hospice.
    - Patients discharged from the facility (e.g., secondary to death, transfer of care to another dialysis facility, resumed renal function).
    - Patients residing in a nursing home or other LTCF.
        - *Steering Committee Discussion:* Dr. McGonigal noted here again that the nursing home data element may not be consistently reliable and/or valid across facilities. As with the home dialysis measures, a feasibility assessment will be performed during measure testing; if feasible, a sensitivity analysis will be performed to determine the impact of the exclusion on measure scores, reliability, and validity. She indicated, however, that the Workgroup noted that this exclusion *does* align with the ETC model, which would be to our benefit should we pursue adoption of the measure there, and it would 't *preclude* referrals of nursing home residents who *are* appropriate candidates for transplant. The Steering Committee was agreeable with this approach.
    - New patients—e.g., patients admitted to the facility for <30 days.
        - *Steering Committee Discussion:* Dr. McGonigal noted that this is a standard KCQA exclusion. The Workgroup agreed the exclusion would also provide balance between opposing concerns about potentially penalizing facilities for patients who "crash in" to dialysis, and so are unlikely to be immediately referred for transplant, and *disincentivizing* early referrals. Here again, the Steering Committee was divided on the exclusion timeframe. Specifically, some Committee members suggested 90 days would be more appropriate, so as to allow sufficient time to admit, orient, and educate patients adequately. Additionally, Medicare doesn't "kick in" until 90 days, which may impact whether a transplant center accepts the referral. Dr. McGonigal suggested she take these concerns back to the Workgroup for additional consideration, after which results would be brought back to the Steering Committee for a final decision. The Committee was agreeable with this approach.
    - Patients previously evaluated by a transplant center and determined to *not* be a transplant candidate, when the identified contraindication is still present and relevant.
        - *Steering Committee Discussion:* Dr. McGonigal informed the Committee that both the Transplant and Data/Testing Workgroups again confirmed that a transplant center rationale for not waitlisting should be documented in the dialysis facility medical records and should be retrievable. She indicated this will be confirmed during measure testing. The Committee was agreeable.

- Patients with any one or more of the following clinical contraindications:
    - Active and/or untreated malignancy;
    - Active substance abuse likely to limit adherence to immunosuppressive regimen;
    - Current BMI >40;
    - End-stage ASCVD;
    - End-stage heart failure;
    - End-stage lung disease;
    - Chronic continuous supplemental oxygen dependence;
    - Critical PVD;
    - End-stage liver disease where not a multiorgan transplant candidate;
    - Untreated infection likely to be exacerbated by immunosuppression (exceptions = HBV, HCV, HIV);
    - Severe irremediable cognitive deficits or psychological disorders likely to materially interfere with ability to comply with immunosuppressive regimen without caregiver/appropriate support.
    - *Steering Committee Discussion:* While not exhaustive, Dr. McGonigal indicated that these clinical diagnoses were identified by the Workgroup as the most common and consistently applied "absolute" contraindications across transplant centers. In accordance with the CFC's "patient assessment" and "reassessment" criteria, and confirmed by both the Transplant and Data/Testing Workgroups, any clinical contraindication that is the reason a patient hasn't been referred for transplant evaluation should be documented annually in the dialysis facility medical records and should be retrievable. Again, she noted this will be confirmed during measure testing. The Steering Committee agreed that these data elements may not be discretely captured and was agreeable with the proposed investigative approach during testing.

- **Risk Adjustment:** The same conceptual model that we used with the home dialysis measures will be applied, assessing the impact of sociodemographic, socioeconomic, geospatial, and functional risk variables such as age, gender, race/ethnicity, dual-eligibility, pre-ESRD care, and, if feasible, transplant center saturation within a given region.
    - *Steering Committee Discussion:* Dr. McGonigal noted that with the exceptions of dual eligibility and geospatial factors, the workgroup leans towards stratification over risk adjustment for fear of masking disparities. The impact of both will be assessed during measure testing. The Committee was agreeable.
- **Risk Stratification:** In addition to the variables listed above for risk adjustment, time on dialysis and in-center vs. home dialysis will be assessed for risk stratification.
    - *Steering Committee Discussion:* The Workgroup believes stratifying by these variables might allow facilities to analyze and target differential performance between these groups to facilitate quality improvement. The Committee was agreeable.
- **Benchmarks**: The Workgroup will also consider making recommendations on establishing performance benchmarks after reviewing data from measure testing.

Measure B, Waitlisting Among Referred:

- **Denominator**: Dr. McGonigal noted that the *numerator* for Measure A—patients with a documented referral within the preceding 24 months—becomes the *denominator* for Measure B, making this a truly paired measure set where the first measure flows directly into the second.
- **Exclusions:** Because of the above, all exclusions will have already been applied in Measure A.
- **Numerator**: The number of patients referred by the dialysis facility for a transplant evaluation who were waitlisted or transplanted during the measurement year.
- **Risk Adjustment, Stratification, and Benchmarking:** The same approach proposed for Measure A will be applied in Measure B.

Additional Steering Committee Discussion: In addition to the discussion points summarized above in the preceding sections, the Committee raised the concern about the potential unintended consequence of not appropriately rewarding those facilities that are already performing well in this area and have an existing, well-established waitlist. After considering possible solutions, the Committee agreed a viable approach to this issue would be to incorporate previously waitlisted patients into the numerator and denominators of both measures. Dr. McGonigal indicated that the specifications would be so revised and the measures tested as such.

MEASURE SET APPROVAL

Dr. McGonigal next asked the Steering Committee for approval to advance the measure set to the full KCQA for a vote on whether the measures should proceed to the testing phase of the project—noting the caveat of the two outstanding items pending resolution (i.e., patient-month construction and the 30 vs. 90 day new patient exclusion). There were no objections.

MEASURE TESTING

Dr. McGonigal concluded with a brief update on measure testing. She informed the Committee that participating Dialysis Organizations are in the process of running the home dialysis data this and next week. Upon receipt, Solid Research Group will assess for a performance gap, measure reliability and validity, and the impact of risk variables. Preliminary home dialysis results are expected by early to mid-November. Pending approval by the full KCQA, the transplant measures would follow shortly thereafter, with results expected back for those measures by early December.

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

Next project steps were summarized as below:

- The full KCQA will convene on October 29 to review the transplant measures for approval for testing.
- The Steering Committee will reconvene in mid-December to review testing results for both the home dialysis and transplant measure sets.

Kidney Care Quality Alliance

STEERING COMMITTEE MEETING 7 SUMMARY
DECEMBER 15, 2021

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

Not Present: Mary Dittrich MD; James Mike Guffey; Lori Hartwell; Brigitte Schiller MD

AGENDA

- Welcome and Opening Remarks, Roll Call, Review of Agenda
- Review/Discussion/Approval of Home Dialysis Measures
- Review/Discussion/Approval of Transplant Measures
- Next Steps
- Public Comment

NQF ENDORSEMENT REQUIREMENTS

After welcoming remarks from Steering Committee Co-Chairs Drs. George Aronoff and Keith Bellovich, Dr. McGonigal noted that the consulting team has been working with two KCQA member dialysis organizations, DaVita and Fresenius, on testing the specifications for the Home Dialysis and Transplant Measure Sets. Final data pulls were received last week, the results of which will be reviewed during today's meeting. She then reminded participants of the three main NQF endorsement requirements:

- **Performance Gap:** This is evidence of overall "less-than-optimal" performance across providers or of significant variation in performance between providers.
- **Measure Reliability:** Empirical evidence showing that the measure score is precise and would yield the same result a high proportion of the time when the measure is applied to the same population in the same time period—i.e., repeatability.
- **Validity:** Evidence that the measure "accurately measures what it is intended to measure." Dr. McGonigal noted that this is usually done by correlating the measure scores with an existing outcome measure that would be expected to be directionally impacted by whatever is being measured. She added that for new measures, as is the case here, an assessment of face validity will suffice at NQF. Validity also considers whether the measure can distinguish meaningful differences in performance, whether exclusions are supported by the evidence, risk-adjustment strategy (if applicable), and includes an assessment of the impact of missing data.

She indicated that each of these will be reviewed for both the Home Dialysis and Transplant Measure Sets today.

HOME DIALYSIS MEASURE SET

Dr. McGonigal reminded the Steering Committee that the Home Dialysis Measure Set pairs a "core" Home Dialysis Rate Measure with a "guardrail" Home Dialysis Retention, intended to counterbalance the unopposed incentivization of home prescription that might occur if the rate measure were implemented alone:

- **Home Dialysis Rate (Measure A):** Percent of all dialysis patient-months in the measurement year using a home dialysis treatment modality (peritoneal dialysis and/or home hemodialysis).

- **Home Dialysis Retention (Measure B):** Percent of all new dialysis patients in the measurement year for whom >=3 consecutive months of home dialysis was achieved.

Measure A assesses the overall home dialysis rate for a given facility. To address the fact that many facilities don't offer home dialysis, scores are subsequently rolled up into parent organization by Hospital Referral Region [HRR]). All dialysis patients are captured in the denominator, regardless of modality, patient age, or ESRD duration. And because of patients' potentially varying time contributions across the measurement year, a "patient-months" construct is used.

Measure B assesses the percentage of *new* home dialysis patients (< 1 year duration) from Measure A who achieved >= 3 consecutive months of home dialysis. Only facilities with new home dialysis patients in the measurement year are captured, and the measure uses a "patient" construct (rather than patient-months), because a single annual event (3+ consecutive months of home dialysis) is being measured.

Data Set

Dr. McGonigal indicated that the measures were tested this fall using data from two KCQA member large dialysis organizations (LDOs), each with the capacity to provide retrospective analyses from a data repository. All pertinent data from all eligible patients in all facilities of the participating organizations during the testing period (January 1-December 31, 2020, with a 2-month "look-back" into November and December of 2019, as needed, for the Retention Measure) were included in the datasets.

Data were collected at the dialysis facility level; to account for home dialysis–only facilities, performance was then aggregated by Parent Organization within Hospital Referral Regions (HRRs). All 5,699 facilities in the two participating LDOs were included in the analysis, comprising 296 HRRs. All eligible patients (i.e., adult and pediatric in-center and home hemodialysis and peritoneal dialysis, as applicable) in all facilities of the participating LDOs during the testing period were included in the analysis, translating to approximately 418,000 patients and 4.5 million patient-months across the measurement year. The range of contributed patient-months across facilities was 1 to 4,372, with a mean contribution of 792.9 patient-months. Patient characteristics were as follows:

Group	Patients (Average[1])	Annual Patient-Months Contributed
Overall	417,807	4,514,892
Age 0-<18 years	326	3,909
Age 18-<25 years	2,357	28,284
Age 25-<35 years	14,031	168,368
Age 35-<45 years	30,796	369,550
Age 45-<55 years	60,564	726,764
Age 55-<65 years	93,918	1,127,012
Age 65-<75 years	98,497	1,181,962
Age 75+ years	75,754	909,043
Male	218,180	2,618,161
Female	158,061	1,896,731
White	210,312	2,523,747
Black	125,700	1,508,398
Other Race	33,356	400,276
Dual-Eligible	82,727	992,723
Not Dual Eligible	293,514	3,522,169

[1] Patient counts vary across months.

Of the 5,699 facilities in the two participating LDOs, 2,581 facilities across 292 HRRs had new home dialysis patients to "contribute" to the Retention Measure denominator. This translated to 24,858 patients across the measurement year, with a facility mean contribution of 9.63 patients (range 1-122).

Performance Gap

Dr. McGonigal reported that testing confirms both measures meet NQF's performance gap criterion, with room for improvement and considerable variation across providers at both the facility and HRR levels. The mean facility score for Measure A was 14.5%; when rolled up into the HRR, it only increased to 16.4%, confirming continued room for improvement in this aspect of care. There was also a wide variation in performance across both facilities and HRRs for Measure A, with a range of 0-100% for facilities and 0-47% for HRRs.

For Measure B, testing indicated that facilities that start new patients on home dialysis are currently doing a good job keeping them on the modality for at least three consecutive months, illustrated by a mean score of 86% at the facility level and 89% across HRRs. This still leaves room for overall improvement, however; and again, there was considerable variation in performance across facilities and HRRs, with a performance range of 0-100% at both levels. Dr. McGonigal concluded that these data make a strong case for the existence of a performance gap for both measures.

Discussion: One Steering Committee member expressed concern that because performance for the Retention Measure is relatively high, the measure may ultimately not be prioritized by NQF's Renal Standing Committee when reviewed. Other members acknowledged this was a conceivable outcome, but because the measure does meet NQF's Gap Criterion, there was consensus to proceed with the review.

Validity

Dr. McGonigal again noted that NQF considers "face validity" sufficient for new measures and doesn't require empirical validity testing. However, to lend further support to KCQA's endorsement bid, an empirical "correlative validity assessment" of the Rate Measure was also conducted, comparing measure scores to an "authoritative data source." Specifically, Dr. Solid explained that measure validity was examined by aggregating measure scores to obtain a percent home dialysis at the HRR level; a Pearson Correlation Coefficient was then calculated between those results and CMS's "Percent Home Dialysis Utilization by HRR" from December 31, 2018, the most recently available Dialysis Facility Reports data (FY 2020).[2] He noted that, as expected, there was a strong positive correlation between HRR-level home dialysis rates from our 2020 data and CMS's December 2018 data (both are pre-ETC model implementation). The Pearson Correlation Coefficient was 0.706 (95% Confidence Interval 0.644, 0.759); the p-value for the null hypothesis that the correlation = 0 was < 0.0001. Dr. McGonigal added that no such available "authoritative data source" was identified for Measure B, limiting its analysis to face validity.

Dr. McGonigal noted that "face validity" will also be assessed for both measures. As in past cycles, and consistent with NQF guidance,[3] face validity will be assessed through a systematic and transparent process by surveying KCQA Members, as well as a small panel of 5-6 "other experts" not involved in the measure development process.

[2] Centers for Medicare and Medicaid Services. Dialysis Facility Reports for Fiscal Year 2020, ETC Public Use File. https://data.cms.gov/quality-of-care/medicare-dialysis-facilities.

[3] NQF Measure Evaluation Criteria.

Discussion: There were no questions; Steering Committee members agreed with the approach and conclusions.

Meaningful Differences in Performance

Dr. Solid next reported that to examine the measures' capability of discerning true differences in performance, the overall spread of performance was calculated and the 95% confidence interval for mean performance was identified. The percent of providers that fall outside that confidence interval were then determined, indicating "better" or "worse" performance than average. Descriptive statistics for the performance measure scores were also constructed for all tested entities (facilities and HRR aggregates), including the mean, 95% confidence interval, median, range of scores, and the interquartile range of scores across the measured entities; "meaningful difference" is defined as a significant spread (>20%) between minimum and maximum scores, between mean and minimum or maximum scores, and/or between the interquartile range. The distributions of performance are displayed in the following tables.

Rate Measure:

	Min	Q1	Median	Mean	Q3	Max	95% CI for Mean	% Outside CI
Facility-Level	0.0%	83.3%	96.2%	**86.0%**	100.0%	100.0%	(85-87%)	96.63%
HRR Aggregate	0.0%	88.9%	91.7%	**91.3%**	95.1%	100.0%	(90.4-92.2%)	84.3%

Retention Measure:

	Min	Q1	Median	Mean	Q3	Max	95% CI for Mean	% Outside CI
Facility-Level	0.0%	0.0%	0.1%	**14.5%**	19.9%	100.0%	(14-15%)	98.30%
HRR Aggregate	0.0%	12.7%	15.6%	**16.4%**	19.2%	47.1%	(15.19-16.49%)	89.89%

For the Rate Measure, Dr. Solid reported that over 96% of facilities perform outside the 95% confidence interval of mean performance, as do approximately 93% of the aggregate units. Additionally, overall spread between the minimum and maximum scores is again 100% at both the facility and HRR level, with a spread of approximately 90% between the mean and minimum scores at both levels of analysis.

For the Retention Measure, over 98% of facilities perform outside of the 95% confidence interval of mean performance and approximately 90% of the aggregate units. Home dialysis rates ranged from 0-100 percent at the facility level and 0-47.1% at the HRR level, with a mean performance of 14.5% and 16.4%, respectively. At the facility level there is significant spread between the minimum and maximum scores (0-100), the mean and maximum scores (14.5-100), and Q1 and Q3 (0-24.2). At the HRR aggregate level, we see a significant spread between the minimum and maximum scores (0-47.1) and the mean and maximum scores (16.4-47.1).

Dr. Solid concluded that these findings support that both measures effectively identify clinically, statistically, and practically meaningful differences in performance between the measured entities at both the facility and HRR aggregate levels.

Discussion: One Steering Committee member was concerned that the approach as described is a departure from approaches typically submitted to NQF and may not meet the defined endorsement criteria.

Missing Data

To identify the extent and distribution of missing data, Dr. Solid indicated that the overall number and percentage of patient-months with missing data were reported by data element, after which a sensitivity analysis of the impact of the missing data on performance was conducted.[4]

He reminded the Steering Committee that both measures are based on data from CMS's CROWNWeb/ESRD Quality Reporting System (EQRS). Consequently, the data necessary to calculate the measure are generally directly and routinely entered by dialysis facility personnel into the EQRS repository and are readily available. Missing data were thus very rare, occurring most frequently with nursing home/LTCF residence status, discharge disposition, and insurance status (for determination of dual-eligibility):

Data Element	Missing Denominator Patient-Months	Missing Numerator Patient-Months
Missing Discharge Disposition	85 (0.004%)	5 (0.002%)
Missing NH/LTCF Residence	91,129 (4.2%)	1,875 (0.6%)
Missing Insurance Status	1,754 (0.8%)	207 (0.07%)

The Retention Measure denominator is built directly from the Rate Measure numerator. By far, then, the largest amount of missing data for both measures is for Nursing Home/Long Term Care residence, with participating facilities indicating this data point is not always reflected in the medical records. Dr. Solid noted, however, that missingness for even this data element is quite low. Based on testing data, he postulated that the inability to appropriately exclude patients due to this amount of missing data will not appreciably impact performance. For example, using the above data, the raw overall Home Dialysis Rate across all facilities is 300,096/2,176,646 = 13.8%; if patients with missing nursing home data were removed from numerator and denominator, the new rate would be 298,221/2,085,517 = 14.2%, a difference of only 0.4%. Dr. Solid indicated that his interpretation for both measures is that missing data are rare, have minimal effect on the overall performance, and do not introduce significant bias.

Dr. McGonigal also again noted that the KCQA Home Dialysis Measures are intended for use by CMS in its ESRD Quality Reporting System (EQRS). During testing, KCQA did not have access to the complete scope and range of data available to CMS within its national ESRD patient database. Most notably, KCQA does not have ready access to data from the Nursing Home Minimum Dataset or claims data. As such, she speculated that if/when the measures are adopted by CMS for use in its ESRD accountability programs, missing data counts for these three data elements will be virtually eliminated.

Discussion: The Steering Committee agreed with the approach and conclusions.

Exclusions

Dr. McGonigal noted that the following exclusions are applied to the Rate Measure denominator:

1. Patients receiving dialysis for AKI only at any time in the measurement month.
2. Patients enrolled in hospice at any time in the measurement month.

[4] We received information on missing data from one of the two participating LDOs, accounting for > 2 million denominator patient-months and > 300,000 numerator patient-months. We will seek to gather and incorporate these data from the other LDO prior to submission of the final documents to NQF.

3. Patients residing in a nursing home or other LTCF at any time in the measurement month.
4. Patients admitted to the facility <=30 days prior to the first day of the measurement month (new dialysis patients).
5. Patients with home dialysis start date <=30 days prior to the first day of the measurement month (new home dialysis patients).
6. Patients discharged from the facility secondary to transplant, death, and/or discontinuation of dialysis at any time in the measurement month.

She reminded the Steering Committee that the intent of the "new dialysis patient" exclusion (#4) is to allow facilities adequate time to orient and educate new patients on modality options. This is particularly important in facilities where a substantial proportion of patients have not received sufficient (or any) pre-dialysis care to allow for adequate preparation for initiation on a home modality. As many such facilities treat small rural or low-income communities, this exclusion is an important safeguard for financially vulnerable facilities treating the most socially and medically disadvantaged patients. The "new home dialysis patient" exclusion (#5) is intended to account for the requisite home dialysis training period, wherein a certain proportion of patients can be expected to drop out before completion. The rationale is to avoid creating a disincentive for a home dialysis trial by penalizing providers for treatment failures during this time period.

For the Retention Measure, patients are excluded from the annual denominator count if any of the following events occur less than 3 months following the "Home Dialysis Treatment Start Date:"

1. Transplantation.
2. Death.
3. Discontinuation of dialysis.
4. Admission to hospice.
5. Admission to a nursing home or other LTCF.

Dr. McGonigal reminded the Steering Committee that these particular exclusions are reapplied in the Retention Measure to ensure providers aren't inappropriately penalized for favorable (e.g., transplant) or unforeseen outcomes (e.g., death, discontinuation of dialysis) occurring after commencement of home dialysis but before 3 consecutive months of treatment could be achieved.

Dr. Solid then explained that for both measures, the distribution of the number and relative frequency of excluded patient-months was examined, then the facility-level mean home dialysis rate calculated and compared with and without the patient-month exclusions.

Overall, with all exclusions applied to the Rate Measure, less than 10% of patient-months were removed from the denominator:[5]

Exclusion (during the measurement month)	Number of Patient-Months Removed	% Total Patient-Months Removed
Discharge due to death	53,056	1.1%
Discharge due to transplant	6,746	0.1%
Discharge to hospice	5,732	0.1%
Discharge due to discontinuation/recovery/other	12, 325	0.1%
Discharge to another facility	36,617	0.7%
Discharge to nursing home or other LTCF	0	0.0%
AKI	90,619	1.8%

[5] The same patient and patient-month can appear in multiple exclusions.

Nursing home or LTCF resident	153,929	3.1%
Admitted to facility < 30 days (new patients)	201,500	4.0%
Home dialysis start date < 30 days (new home patients)	31,359	0.6%

The distribution of measure performance, with and without the exclusions applied, was as follows:

	Min	Q1	Median	Mean	Q3	Max
Exclusions Applied	0.0%	0.0%	0.1%	**14.5%**	19.9%	100.0%
Exclusions Not Applied	0.0%	0.0%	0.1%	**13.0%**	17.8%	98.4%

Dr. Solid indicated that results show that mean performance is appreciably impacted (~1.5% change) when all exclusions are applied; however, the overall frequency of the individual exclusions is low, with new patients (admitted to the facility for < 30 days prior to the first day of the measurement month) and nursing home/LTCF residence resulting in the most exclusions (4.0% and 3.1%, respectively).

Despite the low frequency of the exclusions, however, Dr. McGonigal recommended to the Steering Committee that the following exclusions should be retained to minimize capture of patients for whom home dialysis prescription may not be suitable, desirable, or relevant:

- **Discharges due to death (1.1%):** Home dialysis no longer relevant.
- **Discharges due to transplant (0.1%):** Home dialysis no longer relevant.
- **Discharges to hospice (0.1%):** Limited life expectancy; financial incentivization of home dialysis prescription in this population not appropriate.
- **Discharge due to discontinuation/recovery (0.1%):** Home dialysis no longer relevant.
- **AKI (1.8%):** Variable duration/prognosis; routine incentivization of home dialysis prescription in this population not appropriate.
- **Nursing home/LTCF residence (3.1%):** Complex, vulnerable patient population with frequent and multiple co-morbidities, many with limited life expectancy; financial incentivization of home dialysis prescription in this population not appropriate.
- **Admitted to facility < 30 days (4.0%):** Avoidance of penalizing facilities that have not had sufficient time for orientation, preparation, and training of new patients; important safeguard for financially vulnerable facilities within small rural or low-income communities treating the most socially/medically disadvantaged populations, wherein pre-dialysis care may be less common.
- **New home dialysis patients, < 30 days (0.6%):** Avoidance of creating a disincentive for home dialysis by penalizing facilities during the home dialysis training period, wherein a certain proportion of patients can be expected to drop out before completion.

Conversely, she recommended two exclusions be removed:

- **Discharge to another facility (0.7%):** Despite the low occurrence of this exclusion, home dialysis treatment failures may be inadvertently and inappropriately captured here when a patient is readmitted for in-center care.
- **Discharge to nursing home/LTCF (0.0%):** Facilities participating in measure testing indicate that the "nursing home discharge" data point is not consistently captured in the medical records; while "nursing home residence" data were missing in

approximately 4.2% of the annual denominator patient-months (see above), participants nevertheless believed that the majority of patients discharged to a nursing home or LTCF were correctly captured in the appropriate month via the "residence" exclusion. Testing thus indicates the "discharge" exclusion is both unreliable and redundant.

She also recommended that the "other" characterization from the "Discharge due to discontinuation/ recovery/other" exclusion be removed for increased precision.

Discussion: The Steering Committee agreed with the described approach and conclusions and approved the above recommendations.

For the Retention Measure, with all exclusions applied, approximately 5% of patients were removed from the denominator:[6]

Exclusion (within 3 months of home dialysis start date)	Number of Patients Removed	% Total Patients Removed
Death	466	1.8%
Transplant	91	0.4%
Admission to hospice	46	0.2%
Admission to nursing home or other LTCF	0	0.0%
Discontinuation or dialysis/recovery	41	0.2%

The distribution of measure performance, with and without the exclusions applied, follows:

	Min	Q1	Median	Mean	Q3	Max
Exclusions Applied	0.0%	83.3%	96.2%	**86.0%**	100%	100%
Exclusions Not Applied	0.0%	79.4%	90.0%	**83.2%**	100%	100%

Again, Dr. Solid indicated that results show that mean performance is appreciably impacted (~3%) when all exclusions are applied; however, the overall frequency of the individual exclusions is low, with death accounting for the most exclusions at 1.8%. Nevertheless, Dr. McGonigal recommended that all original exclusions be retained to minimize capture of patients for whom home dialysis prescription may not be suitable, desirable, or relevant:

- **Death (1.8%):** Home dialysis no longer relevant.
- **Transplant (0.4%):** Home dialysis no longer relevant.
- **Discontinuation of dialysis/recovery (0.2%):** Home dialysis no longer relevant.
- **Admission to hospice (0.2%):** Limited life expectancy; financial incentivization of home dialysis prescription in this population not appropriate.
- **Admission to nursing home/LTCF (0.0%):** Complex, vulnerable patient population with frequent and multiple co-morbidities, many with limited life expectancy; financial incentivization of home dialysis prescription in this population not appropriate. Note that while no nursing home admissions within 3 months of commencing home dialysis were captured during testing, we maintain that this exclusion is important to avoid creation of a disincentive for home dialysis trials specifically in older patients.

Discussion: The Steering Committee agreed with the described approach and conclusions and approved the above recommendations.

Risk Adjustment Analysis

[6] The same patient can appear in multiple exclusions.

In accordance with NQF's recent social and functional risk variable selection guidance,[7] Dr. Solid reported that Poisson regression models and reliability measures were used to estimate adjusted outcomes to assess the effect of various social risk factors on the Rate Measure. Risk factors for which data were readily available and assessed include age (10-year increments from birth to 85+ years), gender, race (black/white/other), and dual eligibility status. Due to data privacy concerns, LDOs provided data aggregated to the risk sub-category level; that is, in addition to the overall facility numerator and denominator, facility-level numerator and denominator within each sub-category were provided, such that each risk factor could be assessed separately. Results of the quasi-Poisson regression are below:

Risk Factor	Estimate	Standard Error	t Value	P-Value
Age				
Age_0-<18	2.17	0.14	15.4	p<0.001
Age_18-<25	1.35	0.09	14.86	p<0.001
Age_25-<35	1.15	0.06	18.02	p<0.001
Age_35-<45	1.04	0.06	17.38	p<0.001
Age_45-<55	0.86	0.06	14.91	p<0.001
Age_55-<65	0.68	0.06	12.01	p<0.001
Age_65-<75	0.58	0.06	10.09	p<0.001
Age_75-<85	0.39	0.06	6.63	p<0.001
Gender				
Male	-0.004	0.03	-0.13	0.89
Race				
Other	0.45	0.05	9.43	p<0.001
White	0.46	0.03	15.2	p<0.001
Dual Eligible				
No	0.57	0.04	13.43	p<0.001

Differences in overall performance, when adjusted, are shown below:

	Min	Q1	Median	**Mean**	Q3	Max
Age Adjusted	0.0%	0.2%	0.6%	**14.9%**	20.8%	137.7%
Gender Adjusted	0.0%	0.2%	0.5%	**14.7%**	20.1%	130.4%
Race Adjusted	0.0%	0.2%	0.5%	**14.2%**	20.7%	166.4%
DE Adjusted	0.0%	0.2%	0.5%	**14.3%**	20.1%	130.4%
Unadjusted	0.0%	0.0%	0.1%	**14.5%**	19.9%	100.0%

Thus, Dr. Solid noted models for age, race, and dual eligibility were statistically significant, but that changes in overall measure scores were slight with application of the models, indicating that risk-adjustment has little impact on measure performance. Taken in conjunction with the concern that adjustment for such sociodemographic variables could obscure important, well-documented, and persistent disparities in home dialysis use in the US,[8,9] potentially setting lower standards of quality for more disadvantaged patient populations, the Steering Committee agreed that risk-adjustment of this measure is both unnecessary and inappropriate.

As the Home Dialysis Retention Measure denominator is built directly from the Home Dialysis Rate Measure numerator, a separate risk adjustment analysis was not performed for the Retention Measure.

Discussion: Lead Representatives agreed with the approach and conclusions.

Risk Stratification Analysis

[7] National Quality Forum. Developing and Testing Risk Adjustment Models for Social and Functional Status-Related Risk within Healthcare Performance Measurement: Final Technical Guidance.

[8] United States Renal Data System. 2020 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020.

[9] Thorsness R, Wang V, Patzer R, et al. Association of social risk factors with home dialysis and kidney transplant rates in dialysis facilities. JAMA. 2021;326(22):2323-2325.

Dr. Solid indicated that variations in overall measure performance across various sociodemographic and socioeconomic variables were also examined. Facility-level performance for the Rate Measure within risk strata is as follows:

Category	Min	Q1	Median	Mean	Q3	Max	Facilities included
Age 0 to < 18	0.0%	0.0%	0.0%	39.5%	100.0%	100.0%	132
Age 18 to < 25	0.0%	0.0%	0.0%	23.2%	37.5%	100.0%	2316
Age 25 to < 35	0.0%	0.0%	0.0%	18.6%	27.9%	100.0%	4954
Age 35 to < 45	0.0%	0.0%	0.0%	17.4%	26.7%	100.0%	5477
Age 45 to < 55	0.0%	0.0%	0.0%	15.9%	23.5%	100.0%	5641
Age 55 to < 65	0.0%	0.0%	0.0%	14.5%	20.3%	100.0%	5670
Age 65 to < 75	0.0%	0.0%	0.0%	13.6%	17.4%	100.0%	5665
Age 75 to < 85	0.0%	0.0%	0.0%	12.1%	13.0%	100.0%	5636
Age 85+	0.0%	0.0%	0.0%	8.5%	0.0%	100.0%	5041
Male	0.0%	0.0%	0.0%	14.5%	20.2%	100.0%	5690
Female	0.0%	0.0%	0.0%	14.4%	20.1%	100.0%	5685
White	0.0%	0.0%	0.0%	15.4%	22.4%	100.0%	5671
Black	0.0%	0.0%	0.0%	12.7%	13.5%	100.0%	5349
Other Race	0.0%	0.0%	0.0%	17.3%	22.6%	100.0%	4422
Dual eligible	0.0%	0.0%	0.0%	11.8%	11.5%	100.0%	5570
Overall	0.0%	0.0%	0.1%	**14.5%**	19.9%	100.0%	5699

For the Retention Measure:

Category	Min	Q1	Median	Mean	Q3	Max	Facilities Included
Age 0 to < 18	75%	100%	100%	**98.4%**	100%	100%	43
Age 18 to < 25	0%	100%	100%	**90.5%**	100%	100%	344
Age 25 to < 35	0%	100%	100%	**89.4%**	100%	100%	1020
Age 35 to < 45	0%	100%	100%	**90.8%**	100%	100%	1356
Age 45 to < 55	0%	100%	100%	**90.0%**	100%	100%	1738
Age 55 to < 65	0%	100%	100%	**90.0%**	100%	100%	1942
Age 65 to < 75	0%	100%	100%	**89.3%**	100%	100%	1958
Age 75 to < 85	0%	100%	100%	**89.5%**	100%	100%	1415
Age 85+	0%	100%	100%	**91.2%**	100%	100%	369
Male	0%	84.2%	100%	**87.6%**	100%	100%	2411
Female	0%	87.5%	100%	**88.3%**	100%	100%	2237
White	0%	85.7%	100%	**87.8%**	100%	100%	2366
Black	0%	90.9%	100%	**88.2%**	100%	100%	1544
Other Race	0%	100%	100%	**91.1%**	100%	100%	1029
Dual eligible	0%	100%	100%	**88.7%**	100%	100%	1421

Thus while risk-adjustment has little impact on overall measure performance, Dr. Solid noted that stratification by risk category highlights appreciable variations in performance across various sociodemographic and socioeconomic variables. Stratified analysis demonstrates that White patients (15.4%) are considerably more likely to utilize home dialysis modalities than Black patients (12.7%). There is also an incremental and steady decline in home dialysis with increasing age, with nearly 40% of patients < 18 years on home modalities, 17% among those aged 35-45, and < 12% among the 75+ age group. And less than <12% of dual-eligible patients use a home modality. While risk-adjustment might obscure these important inequities, potentially setting lower standards of quality for more sociodemographically vulnerable populations, Dr. McGonigal recommended to the Steering Committee that providers can and should use these stratified performance results to facilitate quality improvement efforts and focus resources on disparities reduction strategies. While scores do not vary as dramatically with Measure B, she again noted that this might be expected to change as overall home dialysis rates increase with implementation of the ETC Model.

Discussion: The Steering Committee agreed with the approach and conclusions and recommended that performance scores for the Home Dialysis Measures be stratified by age, gender, race, ethnicity,[10] and dual-eligibility.

Reliability

Dr. Solid reported that empirical reliability testing was conducted at the measure score level. Each LDO pulled 2020 data in accordance with the measure specifications, then provided anonymized datasets for analysis. The combined dataset were assessed using the beta-binomial test for reliability, assessing signal-to-noise as described by J.L. Adams, NQF's preferred approach.[11] The ratio of facility-to-facility variance (signal) was compared to within-facility variance (noise) to produce an estimate of measure reliability at each facility, with a reliability of 0 implying that all variability is due to measurement error and a reliability of 1 indicating that all variability is due to real differences in performance.

Using this approach, he reported that reliability estimates for the Home Dialysis Rate Measure were found to be 0.9989 at the facility level and 0.9943 at the HRR level, generally interpreted as "excellent" in the statistical literature.[12] For the Retention Measure, however, reliability estimates were only 0.5241 at the facility level, fluctuating by facility size, with a large percentage of facilities having estimated reliability below the "acceptable" range of >= 0.6:

	N facilities	Mean
All	2581	**0.5241**
denom < 10	1646	0.6629
denom 10-19	650	0.4343
denom 20-49	266	0.4142
denom 50+	19	0.5682

Mean reliability for the Retention Measure was low even at the aggregate level, at 0.3787 at the HRR level.

Dr. Solid noted that these findings may be multifactorial in nature. First, many facilities do not offer home dialysis. It was found that roughly half of the facilities included in the Home Dialysis Rate Measure are not captured in the Retention Measure because they did not have home dialysis patients to contribute. As home dialysis utilization increases, as would be expected with the recent implementation of the ETC model, Dr. Solid postulated that more facilities will be included in the Retention Measure and reliability could be expected to increase.

Second, he reported that a large number of facilities scored at 100% for the Retention Measure, reducing between-facility variability and lowering reliability estimates. He noted that this is not surprising, given the prior point. During the defined testing year (2020, pre-ETC model implementation), it would be expected that facilities offering home dialysis would have invested the necessary resources to develop a sustainable program, resulting in reasonably robust retention rates and uniformly high performance. This may change considerably, however, as providers strive to achieve the formidable benchmarks established in the ETC Model. Indeed, he reminded the Steering Committee that the Retention Measure was explicitly designed to function as a "guardrail" metric, to ensure that sufficient efforts and

[10] Final recommendation pending. To date, we have received ethnicity data from only one of the two participating LDOs. We will seek to gather and incorporate data from the other LDO prior to submission of the final documents to NQF.

[11] Adams, JL. *The reliability of provider profiling: A tutorial.* RAND Health, 2009.

[12] A generally accepted rule in the statistical literature is that a reliability of 0.6-0.7 indicates an "acceptable" level of reliability, 0.7-0.8 is a "good" level, 0.8-0.9 is "very good" level, and > 0.9 is "excellent."

resources are focused on patient education, training, and support in the transition home. Dr. Solid suggested, then, that as mean performance on the Home Dialysis Rate Measure increases, Retention Measure scores will decline, introducing greater between-facility variation and improved reliability estimates.

Dr. McGonigal acknowledged, however, that these findings do raise concerns for NQF endorsement for Measure B. She noted that the reliability estimates may not be sufficient to support Measure B as a standalone measure. But as there is strong support around the measure, particularly within patient groups, she recommended that the measure be advanced to NQF during the "Intent to Submit" period, at which time the Consulting Team can work with NQF staff to determine if there's a path forward and what that path might be. She indicated that the consulting team would ask NQF that if KCQA were explicit that Measure B is intended only for use as a "guardrail measure," would this lower reliability suffice? She also noted that a review by NQF's Scientific Methods Panel is the first step in the endorsement review process. If the measure is not viewed favorably there, KCQA will at that time consider other options. Such options might include temporary withdrawal of the Retention Measure from NQF to field test with newer, post-ETC implementation data to determine if the hypothesis that measure reliability will improve as retention rates start to vary/decline as home dialysis rates increase is correct. KCQA would then resubmit the measure to NQF with this new information. Potential field testing options could include collaboration with CMS to implement the Retention Measure as a "reporting-only measure" for one year, or retesting the measure within KCP Member Organizations using more contemporary (post-ETC) data.

Discussion: The Steering Committee shared the above-noted concern about low reliability estimates for the Retention Measure, but were supportive of the plan to advance both measures to NQF during the Intent to Submit period for a review by NQF staff and the Scientific Methods Panel. Next steps will be considered depending on the input received from these analyses.

APPROVAL OF MEASURES FOR NQF SUBMISSION

Upon complement of the preceding discussion, Dr. McGonigal asked the Steering Committee for approval to advance the Home Dialysis Measure Set to NQF for endorsement consideration. There were no objections.

TRANSPLANT MEASURE SET

Dr. McGonigal reminded the Steering Committee that the Transplant Measure Set pairs a "core" Transplant Referral Measure with a "supporting" Waitlisting/Transplantation Among Referred Patients Measure, intended to counterbalance the indiscriminate referrals that might occur if the referral rate measure were implemented alone:

- **Transplant Referral Measure (Measure A):** Percent of all dialysis patients a) already on the transplant waitlist or b) with a documented referral[13] to a transplant center for evaluation during the measurement period.
- **Waitlisting Measure (Measure B):** Percent of patients a) previously waitlisted or b) with a documented referral who were placed on the waitlist and/or received a transplant during the measurement year.

She noted that here both measures use the "patient" construct (rather than patient-months) to allow

[13] A "documented referral" required documentation of the following three items in the medical record: 1) Referral made; 2) Date of the referral recorded; and 3) Name [or other identifying information] of the transplant center recorded.

for assessment of the single events being measured annually—referrals and waitlisting/transplantation.

Data Set
Dr. McGonigal informed the Steering Committee that secondary to superseding priorities, one testing organization was unable to supply the necessary transplant data in the required timeframe; consequently, results are based exclusively on data from a single LDO. She noted that the consulting team will work with the second LDO to determine if the necessary data can be procured and incorporated into results prior to the final NQF submission date in April.

As with the home dialysis set, Dr. Solid reported that all pertinent data from all eligible patients (i.e., adult and pediatric in-center and home hemodialysis and peritoneal dialysis, as applicable) in all facilities of the participating organization during the testing period were included in the dataset.

Testing Dates
January 1-December 31, 2020.

Measured Entities
Dr. Solid reported that the measured entity is the dialysis facility. All facilities were included in the analysis:

	Measure A: Transplant Referral Rate	Measure B: Waitlisting/Transplant Among Referred
Facilities	2,994 facilities[14]	2,841 facilities contributed patients
Patients	189,673 patients (Facility Mean = 64.38 patients) (Facility Range = 1-343 patients)	29,985 patients (Facility Mean = 10.55 patients) (Facility Range = 1-74 patients)

Performance Gap/Variation
Dr. Solid indicated that testing confirms that both measures meet NQF's criteria for performance gap, with considerable room for improvement and/or variation across providers at both the facility and aggregate levels:

	Measure A: Transplant Referral Rate	Measure B: Waitlisting/Transplant Among Referred
Facilities	**Mean Score = 15.1%** Range = 0-57.1%	**Mean Score = 63.2%** Range = 0-100%

Discussion: Given that that Referral Rate Measure captures referrals plus previously waitlisted patients and the current mean performance on the Percentage of Prevalent Patients Waitlisted (PPPW) measure is approximately 18%, one Steering Committee member raised concerns that performance for Measure A seems too low. She ultimately questioned the veracity of the waitlisting data used to calculate the measures, indicating that this issue would also impact Measure B. Two additional Steering Committee members concurred with this assessment, and the full Committee ultimately determined that NQF submission should be delayed to allow the consulting team to investigate the issue in more depth. If needed, alternative data sources could be explored. Dr. McGonigal recommended that the consulting team meeting with the data team within the LDO after the holidays to determine the underlying issue and potential solutions. The Steering Committee was agreeable with this approach.

PUBLIC COMMENT
There were no public comments.

NEXT STEPS
Next project steps were summarized as below:

[14] Six facilities contributed 0 patients to the denominator after exclusions were applied.

- The consulting team will proceed with the SurveyMonkey face validity assessments and with completion of the NQF forms for the Home Dialysis Measure Set. Final "Intent to Submit" documents will be submitted to NQF by January 5.
- The Transplant Measure Set will not be submitted to NQF for the Spring 2022 Project Cycle to allow the consulting team time to explore potential issues with the waitlisting data used in testing. The team will meet with the LDO's data team after the holidays to begin the necessary analyses.

Kidney Care Quality Alliance

STEERING COMMITTEE MEETING SUMMARY
FEBRUARY 10, 2022

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

Not Present: Lorien Dalrymple MD, MPH; Mary Dittrich MD; Lori Hartwell; Brigitte Schiller MD; Jeffrey Silberzweig MD

AGENDA

- Welcome and Opening Remarks, Roll Call, Review of Agenda
- 2022 KCQA Strategic Plan Overview:
    - Ongoing Work: Home Dialysis and Transplant Measures
    - Measure Maintenance Work: Medication Reconciliation and Influenza Immunization
    - New Work: Anemia, Bloodstream Infection (BSI), Bone Mineral Metabolism
- Identification of Anemia and BSI Workgroups

2022 KCQA STRATEGIC PLAN OVERVIEW

Following roll call and welcoming remarks from the Co-Chairs, Dr. McGonigal proceeded through agenda, starting with an overview of the proposed KCQA strategy, workplan, and timeline for the 2022 and 2023 calendar years. She noted that there are a number of activities required to achieve the Committee's goals in the upcoming year, many of which will occur simultaneously or have considerable overlap. Specifically:

- **Home Dialysis Measure Set:** KCQA will present and defend these newly developed and tested measures within NQF's upcoming Spring 2022 Project Cycle.
- **Transplant Measure Set:** Submission of the Transplant Measure Set was deferred to allow time to confirm the accuracy of the waitlisting data received by our testing sites from UNOs. Following this review, KCQA's Consulting Team will complete measure testing, seek Steering Committee and full KCQA approval, and submit the measures for endorsement consideration within NQF's Fall 2022 Project Cycle.
- **Endorsement Maintenance Activities:** Two previously endorsed KCQA measures—Medication Reconciliation (NQF 2988) and Influenza Immunization (NQF 0226)—will require endorsement maintenance, including additional empirical testing to meet new NQF criteria, within the Fall 2022 Cycle.
- **Remaining Priorities Areas:** Work on the three remaining priority areas identified for the current KCQA project—Anemia, Bloodstream Infection, and Bone Mineral Metabolism—will commence in 2022 as well.

Dr. McGonigal referred the Committee to the provided Workplan and Timeline document, noting that work on much of the above is already in progress. She indicated that staff will reach out to the Steering Committee as needed for guidance around the on-going work with the home dialysis and transplant measures and the measure maintenance activities. She then reviewed the proposed approach to the remaining priority areas, as summarized in the following sections.

ANEMIA MANAGEMENT

Background

Dr. McGonigal suggested beginning with anemia as the most straightforward of the three remaining topic areas. She reminded the Steering Committee that KCP has long urged CMS to replace the Standardized Transfusion Ratio (STrR) in the QIP with a more appropriate anemia management measure, specifically noting that "Hemoglobin <10 g/dL" would be one such metric. While a Hgb <10 measure was previously endorsed by NQF, CMS (the developer/steward of that measure) removed the metric from NQF's portfolio in 2012 following updated FDA labeling for Epogen. Nevertheless, KCQA staff believe the measure represents a framework to which updated specifications, exclusions, and business rules could be applied, and that NQF's updated evidence algorithm would provide a path for its consideration anew.

Recommended Approach

Given the above history, Dr. McGonigal proposed that KCQA's work in this area be largely centered around "dusting off" and updating/revising the prior measure specifications to meet KCQA's needs and criteria; de novo development would not be required. To streamline the process, staff recommends convening a small Workgroup consisting of 5-6 individuals well-versed in the clinical, data, and/or patient issues related to anemia management, to be appointed by the Steering Committee. Again, as KCQA would be "recycling" a previously existing measure, it would be both feasible and desirable to keep the project "lean" and agile; staff doesn't believe a larger Workgroup will be needed or prudent. After necessary updates have been identified, Dr. McGonigal indicated KCQA consensus would be sought around the revised specifications, after which the measure would be tested and submitted to NQF for consideration within its Fall 2022 or Spring 2023 Cycle.

Discussion

The Steering Committee was in agreement with the approach proposed above. Dr. McGonigal requested Steering Committee input on who should be asked to participate in the Workgroup, with the following individuals being preliminarily suggested:

1. Lori Hartwell - RSN
2. Wendy St. Peter – Special Invite, University of Minnesota College of Pharmacy
3. Eric Weinhandl – Satellite
4. Steve Fishbane – American Society of Nephrology
5. Todd Minga – Akebia
6. Mahesh Krishnan – DaVita
7. Jeff Berns – Special Invite, Penn Medicine

BLOODSTREAM INFECTION

Background

Dr. McGonigal indicated that the BSI situation is somewhat more complex. Specifically, the current measure is stewarded by the CDC and uses the National Healthcare Safety Network (NHSN) infection tracking system. Problematic issues identified by KCP and other stakeholders are not related to the measure specifications per se; rather, there are considerable concerns around measure validity, stemming largely from the perverse incentive the measure creates for dialysis facilities to under-report infections. CMS data shows that as many as 60-80 percent of dialysis events may be under-reported with the measure, suggesting that the measure in many instances may incorrectly report that a facility has a low number of bloodstream infections when, in fact, the facility has a higher number.

Recommended Approach

Given the above, Dr. McGonigal reported that KCQA staff believes the appropriate approach with the BSI measure is to address identified flaws related to the data capture and reporting process. As such, it is recommended to proceed in a manner similar to that proposed for anemia by convening a small,

streamlined Workgroup of KCP policy experts in this area, to be appointed by the Steering Committee. The Workgroup will serve as a KCQA "think tank" to tease out and develop recommendations on how best to address the identified validity issues. Depending on the Workgroup's recommendations, Dr. McGonigal indicate that staff believes measure testing and NQF submission will likely not be necessary; instead, the deliverables for the BSI measure may be more of a policy push, working with CMS and CDC to implement KCQA's (and KCP's) recommendations.

Discussion

Again, the Steering Committee had no objections to the proposed approach. The following individuals were suggested for consideration for the BSI Workgroup:

1. Brendan Bowman – Renal Physicians Association
2. Emel Hamilton – Fresenius Medical Care
3. Tony Pfaffle – CorMedix
4. Alan Kliger – American Society of Nephrology
5. Ronald Pisoni – Special Invite, DOPPS/Arbor Research
6. Dan Weiner – American Society of Nephrology
7. Kim Deaver – Renal Healthcare Association

BONE MINERAL METABOLISM

Background

Dr. McGonigal reminded the Steering Committee that the bone mineral metabolism measure currently included in the QIP is CMS's Hypercalcemia Clinical Measure, which has been placed in "reserve status" by NQF secondary to the measure being "topped out" (i.e., performance is uniformly high, such that there is little room for continued improvement). A phosphorus reporting measure, similarly relegated to NQF reserve status for being topped out, was removed from the QIP in PY 2020. Finally, a PTH >400 pg/ml measure was considered by NQF in 2011 but was rejected due to insufficient evidence to support the measure concept. Beyond its position that CMS should retire the hypercalcemia measure from the QIP, KCP does not have a unified position around how bone mineral metabolism measurement should be approached.

Recommended Approach

Given we lack a general consensus around the best approach to bone mineral measurement, Dr. McGonigal acknowledged that the Bone Mineral work will likely prove more challenging and time consuming than the Anemia or BSI measures. Thus, while staff does expect to be able to begin the preliminary bone mineral work in the latter half of this year, given limited KCQA staffing, Dr. McGonigal indicated that the bulk of the work around this final priority area will take place in 2023.

Discussion

The Steering Committee had no questions or objections to the proposed approach.

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

Dr. McGonigal closed the meeting by indicating that the Steering Committee will next meet in April, following NQF's Scientific Methods Panel's review of the Home Dialysis Measures. In the interim, the BSI and Anemia Workgroup membership will be finalized, and the review of the Transplant Measures' data elements will be completed, with any necessary revisions recommendations to ensue.

Kidney Care Quality Alliance

STEERING COMMITTEE MEETING SUMMARY
APRIL 22, 2022

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

Not Present: George Aronoff MD (Co-Chair); Mary Dittrich MD; Brigitte Schiller MD; Daniel Weiner MD, MS

AGENDA

- Welcome and Opening Remarks, Roll Call, Review of Agenda
- Proposed KCQA Staffing Update
- Anemia and Bloodstream Infection (BSI) Workgroups and Workplan Update
- Measure Endorsement Maintenance Update
- Home Dialysis and Transplant Measures Update
- KCQA Transplant Workgroup Data Element Recommendation Purview

PROPOSED KCQA STAFFING UPDATES

Following roll call and welcoming remarks from Dr. Bellovich and Michele Kimball, Dr. McGonigal announced to the Steering Committee that Dr. Craig Solid has departed from KCQA to pursue outside opportunities that would limit the amount of time he would be able to dedicate to the work. She recounted Dr. Solid's numerous and formidable contributions over his many years of consulting with KCQA, and noted that he will be difficult to replace. She indicated that since learning of the news several weeks ago, she, Ms. Lester, and Ms. Kimball have been searching for a new statistician or statistics team to take his place and have identified the Chronic Disease Research Group (CDRG) as the strongest candidate for this role. She added that as Ms. Lester is also working to bring the CDRG team on board for KCP's analytic work on the QIP and ETC programs, there will be some congruity across the quality and regulatory work, as well. Dr. McGonigal reported that the CDRG lead for this work would be Dr. David Gilbertson, with whom she noted many Steering Committee members are already quite familiar. She expressed the consultants' excitement at the prospect of working with his talented team and reported that Ms. Kimball is in the process of reviewing their proposal and seeking approval from the Operations Committee. Ms. Lester added that Dr. Eric Weinhandl (Satellite Healthcare), who served on KCQA's Home Dialysis Workgroup and will also be a member of the Anemia Workgroup (see below), was instrumental in communicating with Dr. Gilbertson about the KCQA work, so there is a solid connection at the Workgroup level as well.

Dr. McGonigal next informed the Committee that she, too, will be stepping away from her role at KCQA on July 1. She noted that here again, she, Ms. Lester, and Ms. Kimball have been searching for an individual or team to step in and take over management of the project; Health Management Associates (HMA) quickly rose to the top of the list of candidates. She remarked that she is aware many Steering Committee members are already familiar with Amy Bassano from HMA, with Ms. Lester adding that Ms. Bassano is Managing Director of Medicare at HMA, and was previously the Deputy Director of the Center for Medicare and Medicaid Innovation (CMMI) and Acting Director of various administrations when a political has not held the chair. She also worked as Director of the Hospital and Ambulatory Policy Group at CMS doing hospital inpatient and outpatient work. Ms. Lester indicated that Ms. Bassano can help KCQA think through how our measures can meet some of CMS's needs, noting that Ms. Bassano was quite excited upon hearing that KCQA would be tackling transplant and home dialysis measures for the ETC Model. She noted that Ms. Bassano will not be the lead on the project, but she will oversee the team

taking over Dr. McGonigal's role as we complete our current work and transition into the next phase of our work.

Ms. Kimball thanked Ms. Lester and Dr. McGonigal for their summaries, adding that these proposed changes will require some additional funding. She noted that this has resulted in a brief pause in the work while we consider funding options, but she is confident we will find a path forward and will get the two teams in place quickly so work can continue uninterrupted. Dr. McGonigal added that she has a lot of faith in both groups, and expects that they will bring a richer data analytic capacity and broader policy perspectives to the work and will be able to move KCP's work forward in new and exciting ways.

The Steering Committee had no objections to the proposed staffing changes.

ANEMIA AND BLOODSTREAM INFECTION (BSI) WORKGROUPS AND WORKPLAN UPDATE

Dr. McGonigal next reported that despite these transitions, KCQA staff has finalized the anemia and BSI Workgroup rosters, as follows:

Anemia Workgroup:

1. Lori Hartwell - RSN
2. Wendy St. Peter – Special Invitee, University of Minnesota College of Pharmacy
3. Eric Weinhandl – Satellite
4. Steve Fishbane – American Society of Nephrology
5. Todd Berner – Akebia
6. Henry Cremisi – Astra Zeneca

BSI Workgroup:

1. Brendan Bowman – Renal Physicians Association
2. Emel Hamilton – Fresenius Medical Care
3. Tony Pfaffle – CorMedix
4. Dan Weiner – American Society of Nephrology
5. Kim Deaver – Renal Healthcare Association

Dr. McGonigal noted that both Workgroups are largely consistent with the Steering Committee's suggestions provided on their last call in February; however, Dr. Ronald Pisoni of DOPPS/Arbor Research did decline the invitation to sit on the BSI Workgroup because of concerns about potential real or perceived conflicts of interest. She remarked that both are strong groups that will bring a wide and balanced variety of viewpoints and the depth of expertise that is one of KCQA's notable strengths. She indicated that work in both areas will commence once we have our new consultants on board and in place, projected by mid-May.

The Steering Committee had no objections to the Anemia and BSI Workgroup rosters.

HOME DIALYSIS AND TRANSPLANT MEASURES UPDATE

Next, Dr. McGonigal reminded the Steering Committee that staff moved the Home Dialysis Measure Set forward for review by NQF's Scientific Methods Panel (SMP) in early January. She reviewed that the measure set pairs a Home Dialysis Rate measure with a 3-month Home Dialysis Retention measure, with the Retention Measure intended to counterbalance any tendency facilities might have to overprescribe home modalities to perform well on the Rate Measure. She reported to the Steering Committee that the SMP agreed that both measures are important, but the Panel remanded the measures back to KCQA to address a couple of issues.

Dr. McGonigal reported that the major issue is that the SMP viewed our reliability assessment as limited because we did not have access to patient-level data for testing. She reminded the Committee that one

of KCQA's two testing organizations was unwilling to provide patient-level data, so KCQA's approach to reliability was necessarily limited to facility-level analyses. However, the SMP has indicated that absent that patient-level data—or, more precisely, absent a patient-level reliability assessment—the measures will not meet NQF's reliability criterion. She also noted that while our second testing organization *is* willing to share patient-level data with us, the SMP also indicated that limiting our assessment to a single organization might create a scenario in which our analyses may not be viewed as sufficiently demonstrably generalizable to the larger dialysis population, putting KCQA in a "Catch-22" situation. However, she reported that she and Ms. Lester have been reaching out to additional members–SDOs and MDOs–for a commitment to participate in testing and to provide the necessary de-identified patient-level data. She indicated that a couple of organizations have already assented on both counts, and she and Ms. Lester are reaching out to additional groups right now, suggesting KCQA will ultimately be able to overcome this hurdle.

Dr. McGonigal reported that the second suggestion from the SMP was to consider submitting the Home Dialysis Measures into a single composite measure, rather than a paired set. She indicated that some SMP members thought this might address the low reliability estimates we found with the Retention Measure that stemmed from the consistently high performance and resultant minimization of inter-facility variation (i.e., a low "signal" in our signal-to-noise analysis).

She noted that the first agenda item with the new stats team will be to review these recommendations and come up with a path forward to both retest the measures using patient-level data and assess composite options. Likewise, now armed with this feedback from the SMP, she recommended the same path with the Transplant Measures. She noted that because we had previously been limited to facility-level data there, as well, it would be prudent to also retest those measures using patient-level data and to consider if we might be better served with a composite measure prior to NQF submission. She indicated that staff would come back to the Steering Committee with both protocols once drafted and ready for review, as well as any recommended specification revisions coming out of the original testing.

Ms. Lester added that Drs. McGonigal and Solid did do due diligence, spending considerable time communicating with and seeking guidance from NQF staff on these very issues prior to submitting the Home Dialysis Measures. However, it became clear during the SMP review that the SMP was either not communicating with NQF staff or was not in agreement with the guidance provided. She noted that she and Dr. McGonigal have since reached out to NQF's new President, Dr. Dana Gelb Safran, who is in the process of revamping NQF's Consensus Development Process and has expressed significant interest in our specific thoughts and input for process improvements. Ms. Lester added that there was also sympathy from some SMP members that things aren't working the way they're supposed to. She concluded that NQF leadership is committed to working through the problems, but this won't be a quick fix, which is why Dr. McGonigal is proposing the above approaches in the interim.

The Steering Committee had no questions or objections to proposed approach.

MEASURE ENDORSEMENT MAINTENANCE UPDATE

Regarding endorsement maintenance activities, Dr. McGonigal reported that two KCQA measures were up for review this year. The Medication Reconciliation Measure (NQF 2988) has since been deferred until NQF's Fall 2023 Project Cycle; because the measure was just implemented in the QIP in January, the data necessary to allow for a meaningful performance review won't be available until next year.

The Influenza Immunization Measure (NQF 0226) is scheduled for review this fall within the Population Health Project. Dr. McGonigal reported that this measure may need to be retested using new data, given that original testing took place in 2008. She noted that staff is currently conferring with NQF on this; depending on NQF's recommendations, staff will confer with KCQA's incoming stats team when up and

running to determine the best approach. Regardless, she remarked that the necessary data elements are very straight forward and are already reported in EQRS; as such, this should be a "light lift" if new testing data are needed.

The Steering Committee had no questions or suggested revisions to the recommended approach.

KCQA TRANSPLANT WORKGROUP DATA ELEMENT RECOMMENDATION PURVIEW

Dr. McGonigal then reminded the Steering Committee that it had previously approved a recommendation from the KCQA Transplant Workgroup that it reconvene for 1-2 additional ad hoc meetings this year to discuss the current state of transplant data elements–i.e., what data are lacking, what would be useful to us, how we can move forward in this space to support measurement and, by proxy, improved access and care. The Workgroup was scheduled to meet last Friday, but was asked to postpone their meeting because of concerns raised by one Workgroup member that this work falls under the realm of policy development, which is outside the defined purview of the KCQA. Ms. Lester added that the intent of the Workgroup was to try to get at data issues they found frustrating when trying to develop the transplant measures. The Workgroup thus made a recommendation, which was approved by both the Steering Committee and the larger KCQA, that they would develop a white paper laying out what data elements would be necessary to allow for the development of effective performance measures, similar to the work KCQA did in the past with the Patient-Reported Outcome Measures (PROMs) Framework Report. The resulting recommendations would go through the KCQA approval process, then would go to KCP for potential adoption as formal policy and subsequent outreach to disseminate the work more broadly and to work with HHS to get greater transparency around those data elements. Ms. Lester reiterated that the Workgroup had been scheduled to meet on Friday, but one Workgroup member raised concerns that this work may be outside the realm of KCQA's defined role; consequently, Ms. Kimball asked Dr. McGonigal to postpone the meeting to review the issue and to discuss again with the Steering Committee.

Ms. Lester noted that there are two sets of documents that govern KCQA—the Guiding Principles and Governing Processes. She reviewed both, noting that neither limit KCQA's activities to only measure development and reiterated that KCQA does have a history of performing similar work with the PROMs Report, which KCP has since taken and shared with CCSQ. She noted that KCQA operates in transparency. Workgroups do the initial work that subsequently goes to Steering Committee for consideration and approval, then goes out to full KCQA. To pass any item, a "healthy majority" of any voting body is required; a healthy majority is defined as 70% of a quorum, which is defined as 51% of the full body in question.

Ms. Kimball then thanked the Steering Committee for its patience and understanding as she works through this process. She noted that she asked for a pause to allow for clarification of the processes between the KCQA and KCP in the midst of the changes currently unfolding in KCP under her leadership, which will include support for the work of KCQA. She reminded the Steering Committee that KCP is going through a strategic planning exercise; part of what's anticipated is that KCP will be putting significantly more emphasis on transplantation. She is recommending that KCP establish a subgroup of the Legislative and Policy Workgroups focused on transplants that will include the top experts from across KCP's membership—and potentially from outside KCP, if recommended by a member. The purpose of that group will be to develop policy that KCP will advocated for either regulatorily or legislatively, through Congress. She concluded that she wanted to ensure that what is produced by KCQA is in the form of a white paper that would then be taken as recommendations to KCP's Transplant Policy Workgroup. The Policy Workgroup would then hammer out appropriate policies and strategies for success to be recommended to KCP's Legislative Workgroup to put into action.

Dr. Silberzweig requested a clearer picture of how we might view the relationship between the KCQA Transplant Workgroup and the KCP Transplant Workgroup. He noted that KCQA took great pains to

assemble a transplant workgroup with very deep and broad expertise that should be both utilized and respected; as such, there should be interaction and cross-fertilization across the various groups. Ms. Kimball responded that the KCQA Workgroup members could certainly serve on the KCP Workgroup; it will be up to the members to decide. But she noted that the KCP Workgroup will be more expansive.

Ms. Wick asked what was being proposed that would be different from the previous plan. Ms. Kimball responded that she wanted to clarify and confirm that the intent of the KCQA Transplant Workgroup is to develop a white paper that could then be used as basis for recommendations to KCP's Transplant Policy Workgroup to develop policy and strategy for advocating for enactment of those recommendations. Dr. Bellovich noted that, historically, transplants have been a poorly organized part of KCP's portfolio. The broader KCP Workgroup would provide direction to inform the KCQA Workgroup deliberations. He added that it's important to make sure there's clear alignment in what KCP is trying to accomplish, then let the KCQA Workgroup refine that message more clearly in defining what data elements are needed for meaningful quality measure development. Ultimately, what is being recommended is a two-step process to be more precise in measurement design. Ms. Lester requested clarification that the KCQA Workgroup's work would not necessarily just be legislative and that it could also flow into the regulatory work. Ms. Kimball confirmed that this is correct.

Ms. Lester then noted that there are two questions for the Steering Committee today:

1. Is it within the scope of KCQA to develop a white paper to highlight data elements that would be needed to develop and implement meaningful transplant measures that could be used by KCP and others in policy activities?
2. Does the Steering Committee agree this recommendation should go to the existing KCQA Transplant Workgroup, as was initially intended and planned?

There was unanimous consent from the Steering Committee on both questions.

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

Dr. McGonigal closed the meeting by reviewing next steps:

- Ms. Kimball and KCQA staff will seek approval of new consultant proposals from KCP's Operations Committee.
- Once the new stats team is in place, the Home Dialysis and Transplant Measures will be re-tested using patient-level data and options for use of a composite construct will be assessed.
- Once the new project management team is in place, the Anemia and BSI Workgroups will convene to begin their work.
- The Transplant Workgroup will reconvene for 1-2 ad hoc meetings to develop transplant data element recommendations for consideration by KCP.
- The Steering Committee will next meet in early or mid-June (date TBD), once the new consulting teams are in place.