KIDNEY CARE QUALITY ALLIANCE

ALL-KCQA MEETING 1 SUMMARY
JUNE 29, 2021

BACKGROUND

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

KCQA History and Project Overview

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

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

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

Progress Update

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

ITEMS FOR LEAD REPRESENTATIVE APPROVAL

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

Project Workplan and Timeline

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

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

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

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

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

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

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

Lead Representatives approved the Workplan and Timeline.

KCQA Guiding Principles and Processes

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

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

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

Dr. McGonigal concluded the meeting by reviewing next steps:

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

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

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

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KIDNEY CARE QUALITY ALLIANCE

ALL-KCQA MEETING 2 SUMMARY
AUGUST 5, 2021

BACKGROUND

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

PROGRESS UPDATE

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

HOME DIALYSIS DELIBERATIONS AND RECOMMENDATIONS

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

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

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

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

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

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

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

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

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

RECOMMENDED HOME DIALYSIS MEASURES

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

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

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

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

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

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

REMAINING DECISIONS

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

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

Dr. McGonigal adjourned the meeting after reviewing next steps:

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

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

KIDNEY CARE QUALITY ALLIANCE

ALL-KCQA MEETING 3 SUMMARY
AUGUST 25, 2021

Attending Organizations: Akebia; American Kidney Fund; American Renal Associates; American Society of Nephrology; Astra Zeneca; Atlantic Dialysis; B. Braun Medical; Cara Therapeutics; CorMedix; Dialysis Patient Citizens; Dialyze Direct; Fresenius Medical Care North America; Greenfield Health Systems; NNCC; Rogosin; Vifor Pharma

BACKGROUND

Following roll call, 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 KCQA Lead Representative discussion is summarized below.

PROGRESS UPDATE

Dr. McGonigal updated the KCQA Lead Representatives that it since it last met on August 5 the Home Dialysis Workgroup convened on two occasions and completed its work on the Home Dialysis Utilization measure set. The Steering Committee met on August 16 to review the specifications and is recommending that the Lead Representatives approve the measures for advancement to the testing phase of the project. In addition, Phase 2 of the project has commenced; staff has completed the transplant measures environmental scan, literature review, and prototype measure development. The Transplant Workgroup convened for its first meeting on August 20 and will resume its discussions on August 27.

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 measures are 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.

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- 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.
    - *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.

Lead Representatives were supportive of the underlying principles and measure logic; there were no questions, and no suggested revisions were offered.

Resolution to Outstanding Issues

Dr. McGonigal next summarized proposed resolutions to a number of outstanding issues identified by the Steering Committee:

- *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, KCQA will during measure testing 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. Lead Representatives were supportive of this approach, also noting that analyzing the nursing home data and comparing to "traditional" home patients will provide valuable information.
- *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, such an exclusion may be inappropriate here, given that many home-based facilities are quite small and would, paradoxically, be excluded from the measures. Likewise, because the measures would be aggregated to the parent dialysis organization within an HRR, a small facility exclusion may serve no purpose. The issue will be further explored, empirically, during measure testing. Lead Representatives were supportive of this approach.

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- *Home Dialysis Start Date:* The retention measure did not distinguish the home dialysis training period from the true start date, as 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. An alternative approach is to exclude all patients who had started home dialysis fewer than "X" number of days (e.g., 30 vs 45) 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. Lead Representatives were supportive of this approach, noting that the training period for both peritoneal and home hemodialysis are variable, ranging from 15 to 60 days. It was further noted that the majority of home patients receive peritoneal dialysis and trend towards the lower end of this range. It was agreed that both 30 and 45 days should be analyzed during testing, and that KCQA should also be careful to try to align its measures to the greatest degree possible with any similar standards currently used in the QIP.

Action Item
Dr. McGonigal then asked the Lead Representatives for their 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 Lead Representatives that the Workgroup had considered and made recommendations on risk adjustment variables for the measure set, building upon a draft "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,[1,2,3] 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,

[1] 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.
[2] 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.
[3] Weiner D and Meyer K. Home dialysis in the United States: To increase utilization, address disparities. (Editorial.) *Kidney Medicine*. 2020;2(2):95-97.

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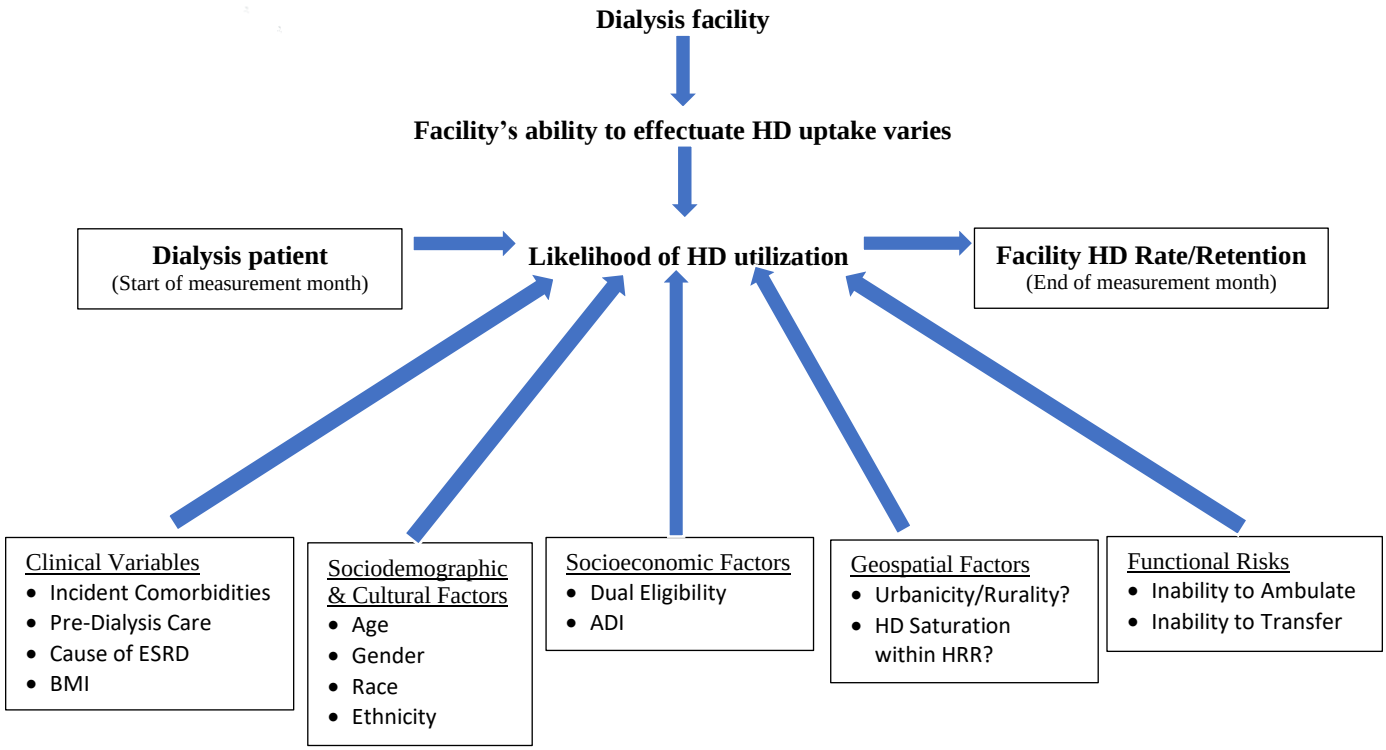
including comorbidities, measures of pre-dialysis care, cause of ESRD, BMI, and measures of frailty and disability, are included.

Figure 1:



Dr. McGonigal reported 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.

Lead Representatives 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.[4] 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

[4] 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.

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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.

Lead Representatives 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 "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.

Lead Representatives were 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; measure testing will commence immediately upon approval.
- The Transplant Workgroup will reconvene on August 27 to continue its work.

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- The Steering Committee will reconvene in early September to review recommended Transplant Measure Concepts.

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KIDNEY CARE QUALITY ALLIANCE

ALL-KCQA MEETING 4 SUMMARY
OCTOBER 29, 2021

Attending Organizations: Akebia; American Kidney Fund; American Nephrology Nurses Association; American Society of Nephrology; Atlantic Dialysis; B. Braun Medical; Centers for Dialysis Care; CorMedix; DaVita, Inc; Dialyze Direct; Fresenius Medical Care North America; NNCC; Renal Healthcare Association; Renal Physicians Association; Rogosin Institute; Rachel Patzer (Transplant Workgroup Co-Chair); Lisa McGonigal (KCQA Staff); Kathy Lester (KCQA Staff)

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. George Aronoff, Dr. McGonigal provided an overview of the transplant work, to date. She reminded the attendees 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.

Existing Transplant Measures

Dr. McGonigal next reviewed existing measures addressing this priority area, noting that three dialysis-facility-level metrics—CMS's Percentage of Prevalent Patients Waitlisted (PPPW), Standardized Waitlist Ratio (SWR), and the End-Stage Renal Disease Treatment Choices (ETC) Model Transplant Rate Metric—are already in use in some capacity. She reminded attendees that KCP has long supported the concepts 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 be amenable to intervention by the facility—particularly when used in penalty-based payment programs. The three existing dialysis facility-level transplant-related measures put forth by CMS do not meet this "actionability" criterion. Specifically, transplant evaluation practices and decisions vary considerably by transplant center, such that dialysis facilities have little control over what patients are ultimately waitlisted or transplanted. Additionally, the SWR and PPPW have both been empirically demonstrated as lacking statistical validity, confirming that these measures don't provide an accurate assessment of dialysis facility performance—again, likely a reflection of facilities' inability to impact which patients are ultimately waitlisted by transplant centers. Finally, because the ETC metric has never been formally specified, empirically tested, or submitted to NQF for evaluation, it is unclear how the measure will perform or if the results will provide a reliable or valid representation of performance.

Dr. McGonigal also reported that two new measure concepts were recently added to CMS's Measure Inventory Tool (CMIT). The measures address monthly waitlist decision rate and transplant referral rate, respectively, both at the dialysis facility level and both for prevalent

patients only. She noted that these are not yet fully specified and have not been tested, so the timeline within which the measures might be rolled out is unclear. However, this finding did bring clarity to the fact that dialysis facility transplant measures are, in fact, on CMS's radar.

Transplant Data Availability Limitations

Dr. McGonigal reminded participants that historically, KCP and KCQA members have supported the development of a "transplant referral" based measure because failure to refer is a persistent barrier to access and referrals are firmly within the facility's realm of control. She noted 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; however, none of those three data elements are currently collected nationally, creating challenges when looking to develop a dialysis-facility centric measure. She informed attendees that the Transplant Workgroup and Steering Committee have agreed that 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.

Referral Measure Strengths and Limitations

Dr. McGonigal next reviewed potential strengths and limitations of a referral-based metric identified by the Workgroup and Steering Committee. 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 attendees that this could theoretically raise issues at NQF in regard 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 and Steering Committee believe 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, Dr. McGonigal noted that the Workgroup

and Steering Committee believe that pairing a referral measure with a well-constructed "counterbalancing" metric would effectively curb this tendency toward "over-referring."

PROPOSED KCQA TRANSPLANT MEASURES

Dr. McGonigal then reminded attendees that of the various options for a paired "counterbalancing" measure set considered by the Workgroup and Steering Committee, 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 reviewed the rationale for this decision: 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 and Steering Committee are 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 CMS's Percentage of Prevalent Patients Waitlisted measure (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.

Overarching Considerations:

- **Data Source:** The Workgroup and Steering Committee 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 through performance measurement. 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, both the Workgroup and Steering Committee agreed KCQA should move forward with what's feasible in the near-term to incentivize high-quality referrals now, sooner than later—and both believe this measure set will do that. Dr. McGonigal noted that the Workgroup will

nevertheless convene for a final call 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 subsequently bring those recommendations to the Steering Committee and the KCQA Voting Body for consideration.

- **Patient Construct:** The Workgroup initially 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.) The Steering Committee, however, 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 noted that both groups believe either construct would serve KCQA well and would produce meaningful, valid, reliable information that can 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 noted that a formal survey vote to gather additional input from Steering Committee members is in progress, after which results would be taken back to the Workgroup for additional consideration.
    - *Discussion:* Lead Representatives were agreeable with the proposed approach to resolution of this issue.

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 and Steering Committee 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 to which the patient was referred and the date of the referral. Dr. McGonigal noted that both the Transplant and Data/Testing Workgroups have confirmed that referral, transplant center, and date of referral should all

be documented in the dialysis facility medical records and should be readily retrievable for measure testing. She also remarked that CMS has confirmed its intent to implement these particular dialysis facility-level data elements in EQRS in near future.

- *Discussion:* Lead Representatives agreed 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. Dr. McGonigal noted that while the Conditions for Coverage *do* require dialysis facilities to track results of each transplant center referral, the Workgroup and Steering Committee acknowledged that these two items may not be as consistently documented by facilities as the three "core" items above; as such, it is recommended that a feasibility assessment be conducted during measure testing. If it's found that these data elements are *not* feasible, the Workgroup and Steering Committee 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 the measure specifications, when feasible.

- *Discussion:* Lead Representatives agreed that these data elements may not be discretely captured and were agreeable with the proposed investigative approach during testing.

- **Exclusions:** The Workgroup and Steering Committee recommend 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.
    - *Discussion:* Dr. McGonigal noted here that, as was a concern with the Home Dialysis measures, the nursing home data element may not be consistently reliable and/or valid across facilities. As such, 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 and Steering Committee have 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. Lead Representatives were agreeable with this approach.

- New patients—e.g., patients admitted to the facility for <30 days.
    - *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. Lead Representatives were similarly divided. Dr. McGonigal indicated that she will 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. Lead Representatives were 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.
    - *Discussion:* Dr. McGonigal informed attendees 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. However, given the complexity of this data element, she indicated it will be confirmed during measure testing that the data are in fact captured and are sufficiently nuanced to support this exclusion. Lead Representatives were agreeable with this approach.
- 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.
    - *Discussion:* While not exhaustive, Dr. McGonigal indicated that these clinical diagnoses were identified by the Workgroup and confirmed by the Steering Committee 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. Lead Representatives agreed that these data elements may not be discretely captured and were agreeable with the proposed investigative approach during testing. One attendee also expressed concern that the identified contraindications will not be completely aligned with all transplant centers and may thus be at odds with survey requirements. Other attendees acknowledged the concern, but agreed the list is not intended to supersede existing requirements by local transplant centers and will not impact the survey process. Rather, the measures are intended specifically for performance measurement and gauging quality in dialysis facilities' approach to transplant referrals.

APPROVAL OF MEASURES FOR TESTING

Upon complement of the preceding discussion, Dr. McGonigal asked the KCQA Lead Representatives for approval to advance the Transplant Measure Set for measure testing. No objections were voiced.

PUBLIC COMMENT

There were no public comments.

NEXT STEPS

Next project steps were summarized as below:

- Measure testing will commence immediately.
- The Steering Committee will reconvene in early-to-mid December to review testing results and make a recommendation to the KCQA Lead Representatives on whether to advance the measures to NQF for endorsement consideration.
- KCQA Lead Representatives will reconvene in mid-December to consider the Steering Committee's recommendations.

KIDNEY CARE QUALITY ALLIANCE

ALL-KCQA MEETING 5 SUMMARY
DECEMBER 16, 2021

Attending Organizations: Akebia; American Kidney Fund; American Nephrology Nurses Association; AstraZeneca; Atlantic Dialysis; CorMedix; DaVita, Inc; NNCC; Otsuka; Renal Healthcare Association; Renal Physicians Association; Rogosin Institute; Lisa McGonigal (KCQA Staff); Kathy Lester (KCQA Staff), Craig Solid (KCQA Staff)

AGENDA

- Welcome and Opening Remarks, Roll Call, Review of Agenda
- Update on Transplant Measure Set Disposition
- Review of Home Dialysis Measure Set Testing Results
- Discussion and Vote on NQF Submission
- Next Steps
- Public Comment
- Adjourn

TRANSPLANT MEASURE SET UPDATE

After welcoming remarks from Steering Committee Co-Chairs Drs. George Aronoff and Keith Bellovich, Dr. McGonigal provided an update on the disposition of the Transplant Measure Set. She reminded attendees that since September, the KCQA Consulting Team has been working with KCQA Member LDOs to test the Home Dialysis and Transplant Measure Set specifications. She indicated that the final transplant data pulls were received last week, and after reviewing the data with the Steering Committee, there were some concerns around the waitlisting data element, in particular. Specifically, the waitlisting data that providers have access to may not be sufficiently reliable or valid to support a performance measure. She noted that this does not mean KCQA is abandoning the measure set; rather one of our data points is proving problematic, and the Consulting Team and Steering Committee will pause to investigate the issue in more depth and, if needed, explore alternatives to get at that data. She remarked, however, that this does mean there will be a delay in the NQF submission, as the team will be unable to complete the analyses in time for the January 5 deadline. Immediately following the holidays, the KCQA Consulting Team will be meeting with the transplant data team within the LDO to determine the underlying issue and potential solutions. Ms. Lester added that these findings can also serve as a clarion cry to CMS that we need better data and better alignment are the data that are shared. She noted that the "bump in the road" gives us a really good opportunity for dialogue with the Administration around data sharing and the health equity issues that surround that process. Dr. McGonigal concluded by noting that the Team will keep the Lead Representatives apprised of the process as it unfolds over the next couple of months. The Lead Representatives were agreeable with this approach.

HOME DIALYSIS MEASURE SET TESTING RESULTS

Dr. McGonigal next 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 measures 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 each of the Home Dialysis Measures today.

Home Dialysis Measure Set
Dr. McGonigal reminded attendees that the Home Dialysis Measure Set pairs a "core" Home Dialysis Rate Measure (Measure A) 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 (see detailed specifications **here**):

- **Home Dialysis Rate:** 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:** 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

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.

[1] Patient counts vary across months.

Discussion: There were no questions; Lead Representatives agreed with the approach and conclusions.

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 a "gold standard measure" or 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, to be identified by staff and the Steering Committee.

Discussion: There were no questions; Lead Representatives 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 and calculated the 95% confidence interval for mean performance were 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

[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.

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: Lead Representatives agreed with the approach and conclusions.

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 attendees 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

[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.

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: Lead Representatives 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.
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 participants 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 attendees 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%
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 indicated that the Steering Committee believes 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.

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

- **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, the Steering Committee recommends two exclusions be removed:

- **Discharge to another facility (0.7%):** Despite the low occurrence of this exclusion, the KCQA Steering Committee agreed that 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.

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

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%

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

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 noted that the Steering Committee recommends 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: Lead Representatives agreed with the approach and conclusions.

Risk Adjustment Analysis

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

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

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

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

[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.

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 reported that the Steering Committee believes 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. As such, the Committee recommends that performance scores for the Home Dialysis Measures be stratified by age, gender, race, ethnicity,[10] and dual-eligibility.

Discussion: Lead Representatives agreed with the approach and conclusions.

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

[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."

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. McGonigal 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. McGonigal postulated that more facilities will be included in the Retention Measure and reliability could be expected to increase.

Second, she reported that a large number of facilities scored at 100% for the Retention Measure, reducing between-facility variability and lowering reliability estimates. She 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, she reminded the Lead Representatives that the Retention Measure was explicitly designed to function as a "guardrail" metric, to ensure that sufficient efforts and resources are focused on patient education, training, and support in the transition home. She 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, the Steering Committee recommended that it 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 questioned if KCQA were to be 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. It 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 include collaboration with CMS to implement the Retention Measure as a "reporting-only measure" for or year, or retesting the measure within KCP Member Organizations using more contemporary (post-ETC) data.

Discussion: Lead Representatives agreed with the approach and conclusions.

APPROVAL OF MEASURES FOR NQF SUBMISSION
Upon complement of the preceding discussion, Dr. McGonigal asked the KCQA Lead Representatives for approval to advance the Home Dialysis Measure Set to NQF for endorsement consideration. There were no objections.

PUBLIC COMMENT
There were no public comments.

NEXT STEPS
Next project steps were summarized as below:

- Staff will proceed with the SurveyMonkey face validity assessments and with completion of the NQF forms.
- Final "Intent to Submit" documents, including measure testing data, will be submitted to NQF by January 5.