KIDNEY CARE QUALITY ALLIANCE

KCQA-Phase 2 Webinar/Conference Call

October 16, 2014
1-2 pm Eastern Time

Dial-in: 888.453.4221; 569783#
***Webinar link:**
https://meetings.webex.com/collabs/#/meetings/detail?uuid=MESHUZEECPCDPVJOBJGHJJO35P-EW67&rnd=108759.21150

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DRAFT AGENDA

1:00 pm Roll call, Welcome and Opening Remarks, Review of Agenda
Edward Jones, MD – KCQA Co-Chair
Allen Nissenson, MD – KCQA Co-Chair

1:05 pm Update on Progress Since June Webinar/Call

- Background/preparatory work (Call for Fluid Management (FM) concepts; follow-up environmental scan queries; nominations and appointment of Workgroup
- Review of Workgroup progress
  Robyn Y. Nishimi, PhD – KCQA Conultant
  Eduardo Lacson, Jr., MD, MPH – KCQA Steering Committee and Workgroup member
- Q&A from KCQA members

1:55 pm Next Steps and Public Comment

2:00 pm Adjourn

*We recommend you access this link a few minutes prior to the call; depending on your system, some set-up and installation may be required.

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FLUID MANAGEMENT MEASURE FEASIBILITY/TESTING WORKGROUP
Summary of Deliberations and Decisions
September 3-October 8, 2014

Workgroup Members: Scott Beiber, DO; Steven Brunelli, MD; Maggie Carey; Allan Collins, MD; Joseph Flynn, MD; Lori Hartwell; Jeffrey Hymes, MD; Mahesh Krishnan, MD, MPH, MBA; Jay-r Lacson, MD, MPH; Klemens Meyer, MD; Paul Miller, MD; Donald Molony, MD; Tom Parker, MD; Glenda Payne, MS, RN; Daniel Weiner, MD

KCQA Consultants: Lisa McGonigal, MD, MPH; Vincent Mor, PhD; Robyn Nishimi, PhD

BACKGROUND AND WORKGROUP CHARGE

Kidney Care Partners (KCP) reconvened the Kidney Care Quality Alliance (KCQA) reconvened in February 2014 for the purpose of developing facility-level performance measures addressing End-Stage Renal Disease (ESRD) care for endorsement consideration by the National Quality Forum (NQF) and eventual use in the Centers for Medicare and Medicaid Services' (CMS) ESRD Quality Incentive Program (QIP). As its initial task, KCQA prioritized 35 of the (sub)domains for kidney care quality identified in KCP's *A Strategic Blueprint for Advancing Kidney Care Quality* using a modified Delphi process and approved *Fluid Management* as its measure development area for 2014. KCQA then further prioritized topics within *Fluid Management* to the following four areas: **Extracellular Fluid (ECF) Volume Management, Ultrafiltration Rate (UFR), Dialysis Frequency/Duration, and Sodium Management (Dietary and Dialysate).**

Following nominations from KCQA members, the KCQA Steering Committee[1] appointed the *KCQA Measure Feasibility and Testing Workgroup.* The Steering Committee tasked the Workgroup, as follows: *Identify the top 4-5 measure concepts, and from there measure specifications (numerator, denominator, exclusions), from which KCQA can select the 1-2 related measures for testing for the purpose of submitting to NQF for endorsement.*

CURRENT WORKGROUP RECOMMENDATION

The Workgroup recommendation at this time is:

- ***FM2: Post-Dialysis Weight Above Target Weight*** – Percentage of patients with an average post-dialysis weight >1 kg or more above or below the prescribed target in the reporting month. Currently to be paired with a UFR measure (designated ***FM7***), as further described in the section on ***FM1*** below.

The sections that follow summarize the process and decisionmaking leading to this recommendation.

IDENTIFICATION OF CANDIDATE FLUID MANAGEMENT MEASURE CONCEPTS

A list of 63 candidate measures and concepts (Attachment A) among the four measure development areas was identified through an environmental scan of publicly available sources,

1 Edward Jones, MD (Co-Chair); Allen Nissenson, MD, (Co-Chair); Akhtar Ashfaq, MD; Donna Bednarski, RN, MSN; Barbara Fivush, MD; Raymond Hakim, MD, PhD; Eduardo Lacson, Jr, MD, MPH; Chris Lovell, RN, MSN; Shari Ling, MD (CMS Liaison); Thomas Manley, RN, BSN; Gail Wick, MHSA, BSN, RN.

submitted as used for internal quality improvement purposes by KCQA member dialysis organizations, or submitted by KCQA members through a "Call for Concepts." The Workgroup used this list as the starting point for its deliberations, which were conducted with the NQF's endorsement criteria in mind (Importance to Measure and Report; Scientific Acceptability of Measure Properties; Feasibility; Usability and Use; and Comparison to Related or Competing Measures).

WORKGROUP DELIBERATIONS AND RECOMMENDATIONS

From September 3 through October 8, 2014, the Workgroup has convened for seven 1.5-hour conference calls, which were open to KCQA members and the public. During this process, Workgroup members operated by consensus among discussants, first winnowing the 63 concepts to 4-5 measure concepts before in-depth discussions of the feasibility and evidentiary base for the 6 candidate measures specified at the numerator, denominator, and exclusions levels. The following sections summarize the results of the Workgroup's deliberations for the 6 draft measure specifications; details are provided in the background documents for and summaries of the Workgroup calls.

Concepts Not Advanced to Measure Specification Phase

The following concepts were not advanced to the measure specification phase:

- *Adult Kidney Disease: Adequacy of Volume Management*
- *Periodic Assessment of Post-Dialysis Weight by Nephrologist*
- *Percent Attained Dry Weight vs Prescribed Dry Weight*
- *Post-Dialysis Weight Below Target Weight*
- *Reconciliation of Prescribed and Achieved Post-HD Weight (within 0.5 or 1.0 kg)*
- *Use of Blood Volume Monitoring*
- *Intradialytic Hypotension*
- *Frequency of Cramping*
- *Estimated Dry Weight Assessment Within 1 Week of Discharge*
- *Percent Interdialytic Weight Loss*
- *Excessive Interdialytic Weight Gain*
- *Achieving Dry Weight Post Hospital Discharge*
- *Percent of Crit-Line Differing from Standard of Care*
- *Use of Bioimpedence Analysis*
- *Interdialytic Weight Gain*
- *Frequency of Volume Determinations*
- *Patient Perception of Thirst*
- *Percent Intradialytic Weight Loss*
- *Use of Protocols for Dry Weight Assessment by RN*
- *Dietician Involvement with Dry Weight Assessments*
- *Evaluation of Excessive Fluid Gains by Interdisciplinary Team*
- *Monitoring of Interdialytic Urine Volume*
- *Percent of Patients Requiring >5% Body Weight Volume Removal in a Single Dialysis Session*
- *Percent of Patient with Excessive Interdialytic Fluid Gain as a Percent of Target Weight*
- *UFR Documented in Treatment Log*
- *UFR >10 ml/kg/hour*
- *Maximum UFR Prescribed >13 ml/kg/hour*
- *Distribution of UFRs*
- *UFR <10, 10-13, and >13 ml/kg/hour*
- *Total UF Exceeding 3kg with a UFR >15 ml/kg/hour*

- *Percent Patients Requiring an Average UFR >12 ml/kg/hour*
- *Use of UF Profiles*
- *Pediatric UFRs to be Correlated with Use of Crit-Line*
- *IDWG to UFR Ratio*
- *Percent of Patients Symptomatic to Degree that UFR Must be Decreased During Treatment*
- *Percent Blood Volume Change*
- *Avoidance of Sodium Loading During Dialysis Treatment*
- *Dietary Sodium Reduction Advice Within the Past 90 Days*
- *Dietary Sodium Advice for Patients New to Dialysis*
- *Sodium Profiling Practice for Hemodialysis*
- *Restriction of Dialysate Sodium to ≤138 mEq/L*
- *Dialysate Sodium ≤138 mmol/L*
- *Dialysate Composition*
- *Pre-Dialysis Serum Sodium Level*
- *Percent Patient with Pre-Dialysis Serum Sodium <130 mEq/L*
- *Pediatric – Frequency of Hemodialysis in Children*
- *Number of Additional Treatments Required Per Month*
- *Documented Counseling on URF and Prescribed Time*
- *Offering Alternative Treatment Modalities (e.g., Nocturnal, PD)*
- *Offering Extra Treatments When Possible*
- *Ratio of Prescribed Time Versus Delivered Time (Monthly Average)*
- *Percent Patients Using Both Hemodialysis and Peritoneal Dialysis to Achieve Adequacy*
- *Percent Patients Requiring Longer Dialysis Sessions for Fluid Management*
- *Percent Patients Requiring Lengthened Dialysis Sessions for Volume Removal*
- *Utilization of Dialysis Duration of 4 Hours or Longer for Patients New to Dialysis*
- *Average Prescribed Time on Dialysis*
- *Average Delivered Time on Dialysis*
- *Percent Time on Dialysis >4.0 Hours*
- *Percent Patients with Time on Dialysis <4.0 Hours*
- *Need for >3 Sessions Per Week*

Concepts Advanced to Measure Specification Phase

The Workgroup initially identified five concepts for additional measure specification (numerator, denominator, exclusions). During the course of its discussions, a sixth concept was identified and specified; several measures underwent revisions, as noted in the sections that follow.

FM1: Avoidance of Utilization of High UFR (<15 ml/kg/hour or >800 ml/hour)

Initial proposed draft specifications:

DESCRIPTION	NUMERATOR	DENOMINATOR	EXLUSIONS
Percentage of adult in-center hemodialysis patients in the facility who were not prescribed a UFR ≥15 ml/kg/hour in the reporting month AND whose average monthly calculated UFR is not ≥800 ml/hr. *Based on CMS's Utilization of High UFR (previously #26) and FMC's UFR ≥800*	Number of patients from the denominator who were not prescribed a UFR ≥15 ml/kg/hour in the reporting month AND whose average monthly calculated UFR is not ≥800 ml/hour. **Interpretation of Score:** Higher score = better quality **Additional Information:** Average monthly UFR is calculated for all dialysis sessions from the denominator at each treatment as:	Number of adult in-center hemodialysis patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis in the reporting month.	1. Age <18 years. 2. Patients in a facility <30 days. 3. Acute renal failure patients. 4. Home dialysis patients. 5. <7 hemodialysis treatments in the facility during the month. 6. Facilities treating <XX adult in-center hemodialysis patients during the reporting month.

DESCRIPTION	NUMERATOR	DENOMINATOR	EXLUSIONS
ml/hour (previously 30a) measures.	([Pre-Dialysis Wt – Post-Dialysis Wt {in kg}] ×1000 kg/ml) ÷ Delivered Treatment Time (in hours)		

- Results from a recent (as-of-yet unpublished) study on the universal association between a non-normalized UFR >800 ml/hour and mortality were reviewed.
- Workgroup members noted that a weight gain in excess of 3 kg occurs not infrequently, and that the most fluid that could be removed in 4 hours using a maximum rate of 800 ml/hour is 3,200 ml.
- The Workgroup agreed with the proposed denominator construction and reporting timeframe.
- The Workgroup agreed with the proposed exclusions, with the exception of #3 and #4. The Workgroup noted there is no mechanism for accurately defining patients with acute renal failure, but that the <30 day exclusion would effectively capture these patients. Additionally, high UFRs are problematic whether at home or in the clinic and so the Workgroup opted to include home hemodialysis (HD) patients in the denominator. Since there is insufficient data on this topic for peritoneal dialysis (PD) patients, the Workgroup agreed that PD patients should still be excluded. The Workgroup also recommended that patients without a completed CMS Form 2728 be excluded from the denominator population. Finally, it was noted that KCP has historically argued for a small numbers facility exclusion (#7) of 26, but that CMS varies its small numbers exclusion from 1 to 11 patients. The Workgroup decided that threshold should be determined during testing.
- The Workgroup agreed with the proposed numerator construction, with the exception of the term "prescribed UFR." Workgroup members noted that UFRs are not actually prescribed...rather, target weights are set and the dialysis machine calculates the necessary UFR. It also was noted that use of the word "prescribed" creates a potential for gaming; the Workgroup opted to change the verbiage to instead target delivered UFR.
- The Workgroup noted the potential for the measure to create a perverse incentive to not remove enough fluid so as to "pass" the measure criteria, but ultimately agreed that the risk:benefit profile is positive. It was noted that the average interdialytic weight gain is approximately 2.4 L (well below the maximum fluid that could be removed with the proposed thresholds), and that the measure would change how UFRs are approached within dialysis facilities and could consequently substantially impact how care is delivered.
- The Workgroup considered what data would be required for the measure and determined that total minutes dialyzed and total UFR per treatment would be necessary; the average calculation could be performed subsequent to data collection.
- One Workgroup member noted that the impact of the measure will be that treatment times will increase, and questioned what would happen if patients sign off early; another noted that the measure would move practice toward the desired goal of increasing session time and/or number of treatments per week.
- Some Workgroup members noted that some patients might benefit from even greater fluid removal, and expressed concern that the measure is attempting to be "one size fits all."
- It was noted that KCP has historically opposed UFR measures because the literature did not rise to the level of evidence to support a performance measure and because of the confounding linear relationship between body size and UFR; while new evidence has since been published and use of the non-normalized UFR would address the latter issue,

it was suggested that focusing on a different priority area might be prudent; others disagreed, noting that the concept has solid face validity and should be retained for further discussion.

- The Workgroup agreed that the measure should be retained and further discussed, but with the numerator revised to focus solely on the delivered non-normalized UFR.
- ***Decision: Retain and redraft specifications as discussed; pair with FM2.***[2]

FM1 revised draft specifications: Avoidance of Utilization of High UFR (>800 ml/hour)

DESCRIPTION	NUMERATOR	DENOMINATOR	EXLUSIONS
Percentage of adult in-center hemodialysis patients in the facility whose average monthly calculated UFR is not ≥800 ml/hr. *Based on FMC's UFR ≥800 ml/hour (previously 30a) measure.* To be linked/paired with FM2.	Number of patients from the denominator whose average monthly calculated UFR is not ≥800 ml/hour. **Interpretation of Score:** Higher score = better quality **Additional Information:** Average monthly UFR is calculated for all dialysis sessions from the denominator at each treatment as: ([Pre-Dialysis Wt – Post-Dialysis Wt {in kg}] ×1000 kg/ml) ÷ Delivered Treatment Time (in hours)	Number of adult in-center hemodialysis patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis in the reporting month.	1. Age <18 years. 2. Patients in a facility <30 days. 3. Home dialysis patients. 4. <7 hemodialysis treatments in the facility during the month. 5. Facilities treating <XX adult in-center hemodialysis patients during the reporting month. 7. Patients without a completed CMS Medical Evidence Form (Form CMS-2728).

- The Workgroup was informed that a feasibility assessment of the measure's required data elements as compared to what is currently available in CROWNWeb incidates that all necessary data elements appear to be available in CROWNWeb. The Workgroup was asked if the identified elements appeared to be correct and complete; the Workgroup responded yes.
- One Workgroup member lamented moving away from the normalized UFR, noting that there appears to be more supporting evidence for that than for the non-normalized value. Another concurred that use of a "flat ceiling" is problematic, as it sets a more difficult bar to reach for heavier patients; however, use of the normalized value is risky for lighter patients, who are known to be particularly vulnerable to UFR variations. Another noted that the normalized values have more face validity.
- Another Workgroup member suggested that perhaps enough data has emerged over the 24 months since NQF has last reviewed a UFR (normalized) measure to justify revisiting use of the normalized rate. Another noted that the newer data addresses the premise that a high UFR is harmful, but has not addressed a specific benchmark value.
- Another noted that there is not a general acceptance of normalization. The question centers on the speed with which the vascular space is drained and how quickly it is refilled during dialysis. If comparing lean people, a larger person has more blood volume, but it's not clear that this is a linear relationship.

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2 "Pairing" of measures refers to an NQF approach whereby the developer recommends the NQF Standing Committee (and any implementers) consider the measures as complements. Each is evaluated on its own, but one may, for example, be a measure of unintended consequences of the other. For example, a "% of patients assessed pain weekly" in a nursing home measure has in the past been paired with a "% of patients on [listed] pain medications." Creating a single, composite measure would be confusing and cumbersome, so the developer has signaled the importance of results from both "paired" as a more accurate representation of quality.

- One Workgroup member suggested that the numerator could be revised to the following to address these concerns: Patients whose UFR does not exceed 15 ml/kg/hour OR 800 ml/hour. It was noted that the Workgroup had previously rejected this construction in favor of simplicity, but that the construct would be acceptable within NQF. Moreover, a close review of the literature suggests that the addition of the normalized rate would place the measure on firmer evidentiary ground. Others agreed that this approach would address their concerns, noting that the normalized UFR would set a maximum, while the non-normalized UFR would set a safety ceiling.
- One Workgroup member disagreed and advocated for use of the absolute non-normalized level only, noting that the combined measure would capture a smaller portion of the target population and would thus have less impact. He noted that the average patient weight at his LDO is 75-80 kg, and that the combined measure will drive down the eligible denominator population.
- Others reiterated their safety concerns with use of the non-normalized UFR in smaller patients, noting that while the non-normalized value would be stricter in heavier patients, but the normalized would be stricter in slighter patients. One noted that approximately 15% of treatments over a 3-month period exceeded 13 ml/kg/hour at one LDO; the measure would be applicable to this sizeable group.
- One suggested that a weight limit could be set in the denominator or exclusions to address this concern, but another disagreed, noting that this would be too lax for larger patients. He reiterated that vascular volume does not increase as a linear function of body weight, and advocated for the 800 ml/hour ceiling.
- One suggested that the normalized UFR could be set lower, and suggested that the final specifications be revisited after there is evidence on a performance gap from field testing.
- One Workgroup member noted the potential for removing too much fluid in the first two hours of a treatment is still a concern with either construction, and again stressed the need for proper provider and patient education.
- The Workgroup revisited the current evidence for normalized rate and determined that the evidence is sufficiently strong to support a rate of 13 ml/kg/hour; they concluded that 15 ml/kg/hour is too high and will not be as effective in driving improvement in care and outcomes.
- The Workgroup concluded that the measure would be revised to target patients with a maximum UFR ≥13 ml/kg/hour (normalized) AND not to exceed >800 ml/hour (non-normalized).
- ***Decision: Retain and redraft specifications as discussed; pair with FM2.***

FM1 revised draft specifications #2: Avoidance of Utilization of High UFR (≥13 ml/kg/hour AND >800 ml/hour)

MEASURE	DESCRIPTION	NUMERATOR	DENOMINATOR	EXLUSIONS
FM1 **Avoidance of Utilization of High UFR (≥13 ml/kg/hour AND >800 ml/hour)** To be linked/paired with FM2.	Percentage of adult in-center hemodialysis patients in the facility whose UFR ≤13 ml/kg/hour AND ≤800 ml/hour for all dialysis sessions in the reporting month. **OR DO YOU WANT THE FOLLOWING**	Number of patients from the denominator whose UFR ≤13 ml/kg/hour AND ≤800 ml/hour for all dialysis sessions in the reporting month. **Interpretation of Score:** Higher score = better quality	Number of adult in-center hemodialysis patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis in the reporting month.	1. Age <18 years. 2. Patients in a facility <30 days. 3. Peritoneal dialysis patients. 4. <7 hemodialysis treatments in the facility during the month. 5. Facilities treating <XX adult in-center hemodialysis patients during the reporting month. 6. Patients without a completed CMS Medical Evidence Form (Form CMS-2728).

MEASURE	DESCRIPTION	NUMERATOR	DENOMINATOR	EXLUSIONS
	CONSTRUCTION? Percentage of adult in-center hemodialysis patients in the facility whose UFR ≤13 ml/kg/hour AND whose **average rate** ≤800 ml/hour for all dialysis sessions in the reporting month.	**OR DO YOU WANT THE FOLLOWING CONSTRUCTION?** Number of patients from the denominator whose UFR ≤13 ml/kg/hour AND whose **average rate** ≤800 ml/hour for all dialysis sessions in the reporting month. **Additional Information:** The average non-normalized UFR is calculated at each treatment for all patients in the denominator as: ([Pre-Dialysis Wt – Post-Dialysis Wt {in kg}] ×1000ml / 1 kg) ÷ Delivered Treatment Time (in hours) **Interpretation of Score:** Higher score = better quality		

In the course of drafting the Revision #2, we realized there was ambiguity in the Workgroup's guidance and so inquired via e-mail as to members' intentions. Because it was clear members' assumptions about what had been concluded were different, the call on October 8 was held.

Additionally, some Workgroup members voiced new concerns about the feasibility of FM1 from a data collection perspective. Although the Workgroup had previously acknowledged and not objected to per treatment per patient data collection specifications in the prior two calls, the following new issues were raised:

- Most providers have a two-step data entry for weights (patient weighs in, writes on paper and then that is entered into a computer system) that will require data validation, though it was acknowledged that this is inherent to any measure in this area.
- UFR itself is the data challenge. Those who batch transfer would need to transfer either the total UF for the treatment (dated) and the actual treatment time (dated) to do the average hourly UFR for a given treatment, which equates to two data points per treatment plus the date. To do a UFR hourly calculation requires recording the UF removed per hour for each treatment and additional adjustment for the UF during partial hours at the end of treatment, which equates to eight data points per treatment for a 4-hour session. Ideally, data would be transferred directly from a dialysis machine to a dialysis information system rather than manually, but this is not universally the case. Further, with regard to the UFR, the only way practically to capture this in the absence of universal real-time data capture at the level of the dialysis machine is to look at the average UFR for a session. If you want to take 1.5 L in hour 1 and 0.5 L in hours 2 through 4, that is the same as removing 0.75 L/hour.

- Although previously discussed, it was again noted that for single user interface users (13% of the country), the data entry burden will be high from flow sheet to CROWNWeb.
- The nuances of doing "per hour" data reporting and the fidelity of the data elements required are not trivial. Again, ideally this data would flow directly from a machine to a computer system, but this is not universally the case.
- ***Decision: Feasibility issues with current approach are likely insurmountable. Define new specifications (FM7) that focus on more than the current monthly transmission of treatment session data (currently the case to calculate the Kt/V measure) to avoid gaming, but that do not rely on the per treatment per patient construction in the FM1 iterations and account for time element.***

FM2: Post-Dialysis Weight Above Target Weight

Initial proposed specifications:

DESCRIPTION	NUMERATOR	DENOMINATOR	EXLUSIONS
Percentage of patients with post-dialysis weight ≥1 kg above the prescribed target weight in >20% of treatments in the last 91 days (from month-end). *Based on DaVita's IQI measure of like name (previously #7).*	Number of patients from the denominator with post-dialysis weight ≥1 kg above the prescribed target weight in >20% of treatments in the last 91 days (from month-end). **Interpretation of Score:** Lower score = better quality	Number of adult in-center hemodialysis patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis in the reporting period.	1. Age <18 years. 2. Patients in a facility <30 days. 3. Acute renal failure patients. 4. Home dialysis patients. 5. <7 hemodialysis treatments in the facility during the month. 6. Patients on hemodialysis <90 days. 7. Facilities treating <XX adult in-center hemodialysis patients during the reporting period.

- The Workgroup agreed with the proposed denominator construction and reporting timeframe.
- The Workgroup agreed with the proposed exclusions, with the exception of #3 and #6. The Workgroup noted there is no mechanism for accurately defining patients with acute renal failure, but that the <30 day exclusion would effectively capture these patients. Additionally, the Workgroup agreed that 30 days is a sufficient amount of time to define a target weight for a new patient. The Workgroup also suggested that patients without a completed CMS Form 2728 be excluded from the denominator population. Finally, the Workgroup decided that threshold for the small numbers facility exclusion (#7) should be determined during testing.
- Most Workgroup members agreed that 1 kg as a weight range is a good starting place that would improve current practices, and that the threshold can be tightened as performance improves; others believed the target should be lowered to 0.5 kg. The Workgroup agreed to review the threshold once the more in-depth literature review was provided.
- The Workgroup agreed there are no obvious unintended consequences to the measure as constructed.
- The Workgroup was concerned about how data pertaining to the 20% and 91 days required in the numerator could be collected; Dr. Krishnan responded that DaVita has per treatment data within its centralized database that can be used in the calculations. If using CROWNWeb, the individual treatment data would have to be uploaded, or the composite calculated and submitted. One Workgroup member noted that it would be advisable to submit the individual treatment data and have the calculation done post hoc by CMS, which would allow for future changes in the target without having to revise the entire data system.

- The Workgroup acknowledged that the measure would be burdensome for the 13% of facilities that are not submitting data through a batch electronic system. It was noted, however, that the National Renal Administrators Association (NRAA) now offers a Health Information Exchange (HIE) that interfaces to such facilities. It was the Workgroup's view all facilities will soon be required to implement EMRs, so this issue should not prevent the measure from being pursued.
- It was noted that prescribed target weight is a robust and accurate data element in the LDOs.
- One Workgroup member expressed concern that the measure could be "gamed" by revising the target weight; others noted that gaming is a potential issue for almost all performance measures, and that linking the measure to FM3 alleviates some of this risk.
- The Workgroup ultimately agreed to retain measure and revise the specifications as indicated.

FM2 revised draft specifications: Post-Dialysis Weight Above Target Weight

DESCRIPTION	NUMERATOR	DENOMINATOR	EXLUSIONS
Percentage of patients with an average post-dialysis weight >1 kg or more above or below the prescribed target in the reporting month. *Based on DaVita's IQI measure of like name (previously #7).* To be linked/paired with FM1.	Number of patients from the denominator with an average post-dialysis weight 1 kg or more above or below the prescribed target weight in the reporting month. **Interpretation of Score:** Lower score = better quality	Number of adult in-center hemodialysis patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis in the reporting period.	1. Age <18 years. 2. Patients in a facility <30 days. 3. Home dialysis patients. 4. <7 hemodialysis treatments in the facility during the month. 5. Facilities treating <XX adult in-center hemodialysis patients during the reporting period. 6. Patients without a completed CMS Medical Evidence Form (Form CMS-2728),

- The Workgroup was reminded that FM2 would be paired with FM1, as per its prior discussion.
- It was noted that the feasibility assessment indicated that all necessary data elements appear to be available in CROWNWeb, and the Workgroup was asked if the identified elements appeared to be correct and complete. The Workgroup responded yes.
- The Workgroup expressed its preference for FM1 over this measure, should KCQA for some reason be limited to advancing a single measure.
- The Workgroup was again asked to consider if it is a feasibility/burden issue that both measures require data input on a per treatment basis for each all patients. The Workgroup was informed that these data elements are not submitted to CROWNWeb for every treatment right now. The Workgroup continued to indicate that the data could be batched prior to transfer, but that the approximately 13% of facilities that cannot batch and do not participate in a HIE would not be able to do this. The Workgroup again noted that EMRs will soon be a requirement for all providers and that this issue should not preclude pursuit of an otherwise valuable measure. The Workgroup was assured that the affected organizations would have an opportunity to provide their input prior to finalization.
- Based on the evidence review provided, the Workgroup was asked about whether it wished to revise the 1 kg weight threshold. Some noted that the variance in their scales is 0.5 kg; others supported the 1 kg target, and suggested that the measure could be tightened when the data are more precise. All concurred that the evidence supporting a narrower variance is not robust, and so given this and weight measurement variance, agreed to retain the 1 kg value.
- ***Decision: Retain and pair with FM1.***

FM3: Post-Dialysis Weight Above Target Weight Without Documented Plan of Care for Reconciliation

Initial proposed draft specifications:

DESCRIPTION	NUMERATOR	DENOMINATOR	EXLUSIONS
Percentage of patients with post-dialysis weight ≥1 kg above the prescribed target weight in >20% of treatments in the last 91 days (from month-end) who do not have a documented plan of care in the medical record on how to achieve the prescribed target weight in future treatments. *Suggested by Workgroup as a process measure to be paired with FM2.*	Number of patients from the denominator who do not have a documented plan of care in the medical record on how to achieve the prescribed target weight in future treatments within XX days. **Interpretation of Score:** Lower score = better quality	Number of adult in-center hemodialysis patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis with post-dialysis weight ≥1 kg above the prescribed target weight in >20% of treatments in the last 91 days (from month-end). **Note:** FM3 denominator = FM2 numerator	1. Age <18 years. 2. Patients in a facility <30 days. 3. Acute renal failure patients. 4. Home dialysis patients. 5. <7 hemodialysis treatments in the facility during the month. 6. Patients on hemodialysis <90 days. 7. Facilities treating <XX adult in-center hemodialysis patients during the reporting period.

- The Workgroup had initially proposed that this process measure be paired with FM2 (*Post-Dialysis Weight Above Target Weight),* but later noted that the plan of care is not necessarily recorded in the treatment record and concluded that necessary data elements could not be effectively captured.
- The Workgroup agreed that the measure as specified would ultimately be a checkbox attestation that would be unlikely to significantly drive improvement in care or outcomes.
- Several Workgroup members expressed concern that the measure is too subjective and that there is the potential for untoward consequences to patients.
- ***Decision: Abandon measure.***

FM4: Restriction of Use of Sodium Profiling

Initial proposed draft specifications:

DESCRIPTION	NUMERATOR	DENOMINATOR	EXLUSIONS
Percentage of patients who were not prescribed sodium profiling in the reporting month. Based on CMS's *Sodium Profiling Practice for Hemodialysis* measure and the measure concept of like name submitted to KCQA (previously #46).	Number of patients from the denominator who were not prescribed sodium profiling in the reporting month. **Interpretation of Score:** Higher score = better quality	Number of adult in-center hemodialysis patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis in the reporting month.	1. Age <18 years. 2. Patients in a facility <30 days. 3. Acute renal failure patients. 4. Home dialysis patients. 5. <7 hemodialysis treatments in the facility during the month. 6. Facilities treating <XX adult in-center hemodialysis patients during the reporting month.

- It was noted that CMS's sodium profiling measure did not pass NQF's *Importance to Measure and Report* endorsement criterion 2010, but that data on a performance gap—a vital component of the criterion—was not presented.
- The Workgroup agreed with the proposed denominator construction and reporting timeframe, including limiting the target population to adults since profiling is not routinely used in children.
- The Workgroup agreed with the proposed exclusions, with the exception of #3. The Workgroup noted that there is no mechanism for accurately defining patients with acute renal failure, but that the <30 day exclusion would effectively capture these patients. The Workgroup also suggested that patients without a completed CMS Form 2728 be excluded from the denominator population. Finally, the Workgroup decided that

threshold for the small numbers facility exclusion (#6) should be determined during testing.

- One Workgroup member remarked that sodium profiling is only still used in <8% of patients and that some providers have entirely deactivated the profiling option on their dialysis machines. Others suggested that the practice is still being used in up to 15% of patients and remains a significant concern. It was noted that a performance gap analysis would be performed if the measure is advanced to the testing phase.
- It was noted that CROWNWeb does not currently contain any sodium management data elements and the Workgroup was asked to consider if this raised concerns about measure feasibility. No concerns were raised.
- It was noted that this measure would potentially be used in the QIP, and the Workgroup was asked to provide input on how to construct the measure such that facilities are not penalized when their actions are clinically appropriate. The Workgroup was specifically asked to consider whether this is a measure for which providers would not be expected to reach 0 percent. The Workgroup agreed that, in some instances, the practice is appropriate and desirable, but acknowledged that justifying a specific target number would be difficult. The Workgroup opined that another tactic would be to explicitly define situations in which the practice is appropriate and exclude these patients from the denominator, but the members ultimately agreed this would be complicated and there is little evidence defining such scenarios.
- Workgroup members noted that much profiling is prescribed by nursing staff without standing orders. Some suggested that the measure would provide impetus to eliminate profiling and to remove the option from the machines, but others pointed out that this would interfere with judicial use of the practice when clinically warranted.
- The majority of the Workgroup greed that regardless of how the numerator is constructed, there is significant variability and discrepancy in this aspect of care and that unintended consequences would be a serious concern with this as an accountability measure.
- Others felt strongly that minimizing this practice would be beneficial to patients and suggested that defining a low performance target rate, informed by the performance gap analysis that would occur during testing, is the appropriate path.
- ***Decision: Retain measure and pair with FM5; revise numerator focus as indicated. Follow-up: Abandon measure in favor of FM2 and UFR measures.***

FM5: Restriction of Use of Hypertonic Saline During Dialysis Treatments

Initial proposed draft specifications:

DESCRIPTION	NUMERATOR	DENOMINATOR	EXLUSIONS
Percentage of patients who were not administered hypertonic saline during any dialysis treatment in the reporting month. *Submitted concept.*	Number of patients from the denominator who were not administered hypertonic saline during any dialysis treatment in the reporting month. **Interpretation of Score:** Higher score = better quality	Number of adult in-center hemodialysis patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis in the reporting month.	1. Age <18 years. 2. Patients in a facility <30 days. 3. Acute renal failure patients. 4. Home dialysis patients. 5. <7 hemodialysis treatments in the facility during the month. 6. Facilities treating <XX adult in-center hemodialysis patients during the reporting month.

- The Workgroup was asked whether the feasibility issues with this measure were similar to those for FM4. The Workgroup agreed that as hypertonic saline requires an order prior to administration, the necessary data would be more easily captured.

- The Workgroup noted that performance should not be zero for this measure, and suggested that a target percentage be defined.
- The Workgroup was asked whether there are potential unintended consequences with this measure, such as withholding hypertonic saline when clinically indicated. The Workgroup agreed with this possibility, and one Workgroup member noted that providers could simply increase dialysate sodium to get around the measure. It was noted that the Workgroup had intended that the measure be paired with FM4 to address this potentiality, and the Workgroup confirmed that the measure cannot stand alone and should still be paired with FM4.
- One Workgroup member pointed out that the measure might inappropriately limit the clinical armamentarium.
- A Workgroup member suggested that the measure be revised into a sodium load measure, using the following specifications: Denominator = all treatments during the month; Numerator = patients with a dialysate sodium >3 mEq more than the 3-month average serum sodium. Others agreed that this revised construct would drive clinicians to look closely at intradialytic sodium, which is where most of the sodium issues are arising now that profiling is in decline. All agreed the measure would be feasible in terms of data collection, but one cautioned that they should avoid being overly prescriptive and would have to educate both providers and patients on what to expect in terms of symptoms when sodium is reduces so as to avoid a knee-jerk reaction against the measure.
- The Workgroup was asked for evidence supporting the use of the 3mEq target; Dr. Lacson responded that the standard deviation of serum sodium is approximately 2.6, and that setting a target over 1 SD will minimize some of the noise.
- ***Decision: Draft specifications for new measure, as discussed. Follow-up: Abandon measure in favor of FM2 and UFR measures.***

FM6: Dialysate Sodium Prescription >3 mEq/L More Than the 3-Month Rolling Average Serum/Plasma Sodium

Initial proposed draft specifications:

DESCRIPTION	NUMERATOR	DENOMINATOR	EXLUSIONS
Percentage of patients whose dialysate sodium prescription on the last treatment of the reporting month was >3 mEq/L more than the 3-month rolling average serum/plasma sodium. **Threshold:** TBD *(Loosely) based on CMS's and DaVita's measures of like name (previously #42 and 42a, respectively), modified according to the Workgroup's discussion on 9/24/14 and subsequent communications with Dr. Lacson.*	Number of patient-months from the denominator in which the dialysate sodium prescription on the last treatment of the reporting month >3 mEq/L more than the 3-month rolling average serum/plasma sodium. **Interpretation of Score:** Lower score = better quality **Calculation of Difference:** Prescribed Dialysate Sodium − ([sum of the monthly Serum/ Plasma Sodium for the last 3 months] ÷ [the number of contributing sodium values])	Number of patient-months for all adult in-center hemodialysis patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis in the reporting month.	1. Age <18 years. 2. Patients in a facility <30 days. 3. Serum/plasma sodium <135 mEq/L. 4. Patients with no serum/plasma sodium drawn during the reporting month. 5. Home dialysis patients. 6. <7 hemodialysis treatments in the facility during the month. 7. Facilities treating <XX adult in-center hemodialysis patients during the reporting month. 8. Patients without a completed CMS Medical Evidence Form (Form CMS-2728). 9. Incident Patients (<90 days of dialysis).

- The Workgroup was asked if they agreed with the proposed 3mEq threshold; it was again noted that the rationale for this value is based on the fact that the standard deviation of serum sodium is approximately 2.6, and that setting a target over 1 SD will minimize some of the noise. Workgroup members did not object.

- One Workgroup member asked whether, given KCP's historical position against sodium measures and NQF's past history of rejecting a dialysate sodium measure set at 138 mEq, the measure has a better chance of being endorsed and adopted than prior measures. He noted that the strength of this measure lies in the fact that it does not prescribe an absolute sodium level—it is tied specifically to patients rather than to facility-level dialysate concentrations.
- Other Workgroup members noted that in selecting the measures they wish to pursue, they must be cognizant of not only what would have the greatest impact on patient care and outcomes, but also what would have a good chance of passing NQF's criteria. At this, several members voiced their general preference for a measure addressing UFR, noting that while more challenging to construct, it would have a greater potential to impact patient care and outcomes. It was noted that many providers are already trying to reduce dialysate sodium, but that as little is being done to address UFRs, a measure in that realm would be more impactful. The HEMO study was mentioned, wherein the notion of giving more sodium was put forth. Workgroup members noted, however, that the study is over a decade old and agreed that this tactic has since been refuted and has fallen out of favor.
- Workgroup members noted that there is significant variability when assessing sodium measurements; for instance, one Workgroup member indicated that a variability of +/- 4 mEq was found in one facility with 30 machines. The Workgroup concluded this is a significant threat to this measure's validity, and that the measure might ultimately not yield what is intended.
- It was agreed that this threat to validity is substantial and that the measure should consequently be abandoned.
- ***Decision: Abandon measure.***

NEXT STEPS

The Workgroup's final recommendations are pending. Additional calls are scheduled on October 15 and 22. The Workgroup has agreed that FM2 should advance to measure testing. FM1 has been removed from consideration due to data feasibility issues. The Workgroup is in the process of drafting a new UFR measure, which to avoid confusion will be cast as FM7.