NATIONAL QUALITY FORUM

Measure Evaluation 4.1
December 2009

This form contains the measure information submitted by stewards. Blank fields indicate no information was provided. Attachments also may have been submitted and are provided to reviewers. The subcriteria and most of the footnotes from the evaluation criteria are provided in Word comments within the form and will appear if your cursor is over the highlighted area. Hyperlinks to the evaluation criteria and ratings are provided in each section.

TAP/Workgroup (if utilized)**:** Complete all yellow highlighted areas of the form. Evaluate the extent to which each subcriterion is met. Based on your evaluation, summarize the strengths and weaknesses in each section.

Note: *If there is no TAP or workgroup, the SC also evaluates the subcriteria (yellow highlighted areas).*

Steering Committee: Complete all pink highlighted areas of the form. Review the workgroup/TAP assessment of the subcriteria, noting any areas of disagreement; then evaluate the extent to which each major criterion is met; and finally, indicate your recommendation for the endorsement. Provide the rationale for your ratings.

Evaluation ratings of the extent to which the criteria are met
C = Completely (unquestionably demonstrated to meet the criterion)
P = Partially (demonstrated to partially meet the criterion)
M = Minimally (addressed BUT demonstrated to only minimally meet the criterion)
N = Not at all (NOT addressed; OR incorrectly addressed; OR demonstrated to NOT meet the criterion)
NA = Not applicable (only an option for a few subcriteria as indicated)

(for NQF staff use) **NQF Review #:** 1435 **NQF Project:** End Stage Renal Disease
MEASURE DESCRIPTIVE INFORMATION
De.1 **Measure Title:** Restriction of Dialysate Sodium
De.2 **Brief description of measure***:* Proportion of patients who were prescribed a dialysate sodium concentration less than or equal to 138 mEq/L for all sessions in the reporting month
1.1-2 **Type of Measure:** Process De.3 **If included in a composite or paired with another measure, please identify composite or paired measure** N/A
De.4 **National Priority Partners Priority Area:** Population health De.5 **IOM Quality Domain**: Effectiveness De.6 **Consumer Care Need:** Living with illness

CONDITIONS FOR CONSIDERATION BY NQF	
Four conditions must be met before proposed measures may be considered and evaluated for suitability as voluntary consensus standards:	**NQF Staff**
A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. *Public domain only applies to governmental organizations. All non-government organizations must sign a measure steward agreement even if measures are made publicly and freely available.* A.1 **Do you attest that the measure steward holds intellectual property rights to the measure and the right to use aspects of the measure owned by another entity (e.g., risk model, code set)?** Yes A.2 **Indicate if Proprietary Measure** (*as defined in measure steward agreement*)**:** A.3 **Measure Steward Agreement:** Government entity and in the public domain - no agreement necessary A.4 **Measure Steward Agreement attached:**	**A** **Y**☐ **N**☐
B. The measure owner/steward verifies there is an identified responsible entity and process to maintain and update the measure on a schedule that is commensurate with the rate of clinical innovation, but at least	**B** **Y**☐

every 3 years. Yes, information provided in contact section	**N**☐
C. The intended use of the measure includes both public reporting and quality improvement. ►**Purpose:** Public reporting, Internal quality improvement	**C** **Y**☐ **N**☐
D. The requested measure submission information is complete. Generally, measures should be fully developed and tested so that all the evaluation criteria have been addressed and information needed to evaluate the measure is provided. Measures that have not been tested are only potentially eligible for a time-limited endorsement and in that case, measure owners must verify that testing will be completed within 12 months of endorsement. D.1**Testing:** No, testing will be completed within 12 months D.2 **Have NQF-endorsed measures been reviewed to identify if there are similar or related measures?** Yes	**D** **Y**☐ **N**☐
(for NQF staff use) **Have all conditions for consideration been met?** **Staff Notes to Steward** (*if submission returned*)**:**	**Met** **Y**☐ **N**☐
Staff Notes to Reviewers (*issues or questions regarding any criteria*)**:** **Staff Reviewer Name(s):**	

TAP/Workgroup Reviewer Name:	
Steering Committee Reviewer Name:	
1. IMPORTANCE TO MEASURE AND REPORT	
Extent to which the specific measure focus is important to making significant gains in health care quality (safety, timeliness, effectiveness, efficiency, equity, patient-centeredness) and improving health outcomes for a specific high impact aspect of healthcare where there is variation in or overall poor performance. *Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria.* (evaluation criteria) **1a. High Impact**	**Eval Rating**
(for NQF staff use) **Specific NPP goal**:	
1a.1 **Demonstrated High Impact Aspect of Healthcare:** Leading cause of morbidity/mortality 1a.2 1a.3 **Summary of Evidence of High Impact:** This measure is likely to be high impact because it has the potential to lower sodium gain by dialysis patients during dialysis treatments that can raise blood pressure (with its attendant long term consequences), thirst and interdialytic weight gain which has been associated with higher mortality among HD patients. 1a.4 **Citations for Evidence of High Impact:** Charra B, Chazot C. "The neglect of sodium restriction in dialysis patients: A short review." Hemodial Int. 2003; 7:342-347. Davenport A, Cox C, Thuraisingham R, et al. "The importance of dialysate sodium concentration in determining interdialytic weight gains in chronic hemodialysis patients: the PanThames Renal Audit." The International journal of artificial organs. 2008; 31:411-7. Flanigan M. "Dialysate composition and hemodialysis hypertension." Semin Dial 2004; 17:279-283. KDOQI. Clinical practice guidelines for hemodialysis adequacy. Am J Kidney Dis. 2006; Jul;48 (1 Suppl 1): S13-97. Locatelli F, Di Filippo S, Pontoriero G. "Fluid and electrolyte balance during extracorporeal therapies." in Ronco C, Bellomo R (eds): Critical Care Nephrology. Dordrecht, The Netherlands, Kluwer, 1998, pp 249-259.	**1a** **C**☐ **P**☐ **M**☐ **N**☐

Comment [KP1]: 1a. The measure focus addresses:
•a specific national health goal/priority identified by NQF's National Priorities Partners; OR
•a demonstrated high impact aspect of healthcare (e.g., affects large numbers, leading cause of morbidity/mortality, high resource use (current and/or future), severity of illness, and patient/societal consequences of poor quality).

Thein H, Haloob I, Marshall MR. "Associations of a facility level decrease in dialysate sodium concentration with blood pressure and interdialytic weight gain." Nephrology, dialysis, transplantation : official publication of the European Dialysis and Transplant Association - European Renal Association. 2007; 22:2630-9.

Van Stone JC, Bauer J, Carey J. "The effect of dialysate sodium concentration on body fluid compartment volume, plasma renin activity and plasma aldosterone concentration in chronic hemodialysis patients." Am J Kidney Dis. 1982; 2:58-64.

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: High concentrations of sodium in dialysate reduce the removal of sodium during dialysis and ultrafiltration and therefore such dialysates can aggravate thirst, fluid gain, and hypertension. The reduction of dialysate sodium levels will prevent sodium loading which has the potential for cumulative harm in the form of excessive thirst, interdialytic weight gain, hypertension, worsening left ventricular hypertrophy, and heart failure.

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:
There have been no formal studies on the dialysate sodium concentrations of facilities in the United States, however, historically, most dialysis facilities tend to utilize dialysate sodium concentrations above 138mEq/L.

1b.3 Citations for data on performance gap:
N/A

1b.4 Summary of Data on disparities by population group:
Disparities for dialysate sodium by population group have not been reported in the literature.

1b.5 Citations for data on Disparities:
N/A

1b C☐ P☐ M☐ N☐

1c. Outcome or Evidence to Support Measure Focus

1c.1 Relationship to Outcomes (*For non-outcome measures, briefly describe the relationship to desired outcome. For outcomes, describe why it is relevant to the target population*)**:** Excess sodium exposure (interdialytic and intradialytic) is a primary cause of excessive interdialytic fluid weight gain and poor control of sodium and volume mediated hypertension.

1c.2-3. Type of Evidence: Observational study, Evidence-based guideline, Expert opinion

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*)**:**
Although it has recently been recommended that each patient's dialysate sodium concentration could be titrated to their pre dialysis serum sodium concentration (Levin & Kotanko 2010), in general, in clinical practice, a constant dialysate sodium tends to be utilized at dialysis facilities, except when sodium profiling is being used. It has been concluded that a dialysate sodium concentration greater than 138 mEq/L likely represents excessive exposure to sodium for the majority of hemodialysis patients (Levin 2001; Keen 2007). Research also suggests that "high concentrations of sodium in dialysate reduce the removal of sodium during dialysis and ultrafiltration" (KDOQI 2006; Charra 2003; Flanigan 2004). In particular, the KDOQI panel (2006) argued that "although increasing dialysis sodium concentration can decrease morbidity both during and between treatments, such dialysates can aggravate thirst, fluid gain, and hypertension" (KDOQI 2006; Charra 2003; Flanigan 2004; Locatelli 1998; Van Stone 1982).
Observational studies have shown that patients receiving high dialysate sodium concentrations were receiving an excessive sodium load and that larger sodium gradients were associated with greater interdialytic weight gain, hospitalization rates, and mortality rates (Davenport 2008; Thein 2007).

1c.5 Rating of strength/quality of evidence (*also provide narrative description of the rating and by*

1c C☐ P☐ M☐ N☐

Comment [KP2]: 1b. Demonstration of quality problems and opportunity for improvement, i.e., data demonstrating considerable variation, or overall poor performance, in the quality of care across providers and/or population groups (disparities in care).

Comment [k3]: 1 Examples of data on opportunity for improvement include, but are not limited to: prior studies, epidemiologic data, measure data from pilot testing or implementation. If data are not available, the measure focus is systematically assessed (e.g., expert panel rating) and judged to be a quality problem.

Comment [k4]: 1c. The measure focus is:
•an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;
OR
•if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
oIntermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
oProcess – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
oStructure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
oPatient experience – evidence that an association exists between the measure ... [1]

Comment [k5]: 4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve ... [2]

Comment [k6]: 3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system ... [3]

whom):
Observational studies and small pilot clinical trials (Level B evidence, as rated by the Fluid Weight Management Clinical Technical Expert Panel (C-TEP) using an assessment scale similar to KDOQI).

1c.6 **Method for rating evidence:** The C-TEP followed similar methods of evidence assessment as that used by the KDOQI clinical practice guidelines.

1c.7 **Summary of Controversy/Contradictory Evidence:** Historically, lower dialysate serum sodium concentrations were associated with high incidence of dialysis disequilibrium syndrome and one way to deal with the latter was to raise the dialysate sodium concentration. Thus, the dialysis community continued using somewhat higher dialysate sodium concentrations. While the incidence of dialysis disequilibrium has decreased over time, hypertension and volume overload in dialysis patients with its associated complications have emerged as major risk factors for cardiovascular disease. It has therefore become imperative that any unnecessary salt loading of dialysis patients be curtailed. While short-term, single-center studies have shown the feasibility and benefits of lowering dialysate sodium concentrations, large-scale randomized trials and outcome studies have not been performed.

1c.8 **Citations for Evidence (***other than guidelines***):** Charra B, Chazot C. "The neglect of sodium restriction in dialysis patients: A short review." Hemodial Int. 2003; 7:342–347.

Davenport A, Cox C, Thuraisingham R, et al. "The importance of dialysate sodium concentration in determining interdialytic weight gains in chronic hemodialysis patients: the PanThames Renal Audit." The International journal of artificial organs. 2008; 31:411-7.

Flanigan M. "Dialysate composition and hemodialysis hypertension." Semin Dial 2004; 17:279–283.

KDOQI. Clinical practice guidelines for hemodialysis adequacy. Am J Kidney Dis. 2006; Jul;48 (1 Suppl 1): S13-97.

Keen ML, Gotch FA: The association of the sodium 'setpoint' to interdialytic weight gain and blood pressure in hemodialysis patients. Int J Artif Organs 2007; 30: 971 979.

Levin NW, Zhu F, Keen M: Interdialytic weight gain and dry weight. Blood Purif 2001; 19: 217–221

Levin NW, Kotanko P, Eckardt KU, Kasiske BL, Chazot C, Cheung AK, Redon J, Wheeler DC, Zoccali C, London GM. "Blood pressure in chronic kidney disease stage 5D-report from a Kidney Disease: Improving Global Outcomes controversies conference." Kidney Int. 2010; 77(4):273-84.

Locatelli F, Di Filippo S, Pontoriero G. "Fluid and electrolyte balance during extracorporeal therapies." in Ronco C, Bellomo R (eds): Critical Care Nephrology. Dordrecht, The Netherlands, Kluwer, 1998, pp 249–259.

Thein H, Haloob I, Marshall MR. "Associations of a facility level decrease in dialysate sodium concentration with blood pressure and interdialytic weight gain." Nephrology, dialysis, transplantation : official publication of the European Dialysis and Transplant Association - European Renal Association. 2007; 22:2630-9.

Van Stone JC, Bauer J, Carey J. "The effect of dialysate sodium concentration on body fluid compartment volume, plasma renin activity and plasma aldosterone concentration in chronic hemodialysis patients." Am J Kidney Dis. 1982; 2:58–64.

1c.9 **Quote the Specific guideline recommendation (***including guideline number and/or page number***):**
This measure is related to the following 2006 KDOQI volume and blood pressure guideline:
5.3 - Increasing positive sodium balance by "sodium profiling" or using a high dialysate sodium concentration should be avoided. (Evidence Level B)

1c.10 **Clinical Practice Guideline Citation:** KDOQI. Clinical practice guidelines for hemodialysis adequacy. Am J Kidney Dis. 2006; Jul;48 (1 Suppl 1): S13-97.
1c.11 **National Guideline Clearinghouse or other URL:** N/A

1c.12 Rating of strength of recommendation (*also provide narrative description of the rating and by whom*)**:** The 2006 KDOQI guidelines were based on Work Group consensus. **1c.13 Method for rating strength of recommendation** (*If different from USPSTF system, also describe rating and how it relates to USPSTF*)**:** N/A **1c.14 Rationale for using this guideline over others:** There are no other known guidelines pertaining to dialysate sodium restriction in dialysis patients.	
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Importance to Measure and Report?*	**1**
Steering Committee: Was the threshold criterion, *Importance to Measure and Report*, **met?** **Rationale:**	**1** **Y☐** **N☐**
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)	**Eval Rating**
2a. MEASURE SPECIFICATIONS	
S.1 Do you have a web page where current detailed measure specifications can be obtained? **S.2 If yes, provide web page URL:** **2a. Precisely Specified**	
2a.1 Numerator Statement (*Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome*)**:** Number of patients in denominator who were prescribed a dialysate sodium concentration less than or equal to 138 mEq/L in the reporting month. **2a.2 Numerator Time Window** (*The time period in which cases are eligible for inclusion in the numerator*)**:** The entire reporting calendar month. **2a.3 Numerator Details** (*All information required to collect/calculate the numerator, including all codes, logic, and definitions*)**:** A data element indicating whether a "dialysate sodium concentration greater than 138 mEq/L was used for any session in the reporting month" will be included in the 2011 CROWNWeb national roll-out.	
2a.4 Denominator Statement (*Brief, text description of the denominator - target population being measured*)**:** Number of patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis (HD). **2a.5 Target population gender:** Female, Male **2a.6 Target population age range:** Adults 18 years or older. **2a.7 Denominator Time Window** (*The time period in which cases are eligible for inclusion in the denominator*)**:** The entire calendar month. **2a.8 Denominator Details** (*All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions*)**:** Denominator includes only in-center HD patients.	**2a-specs** **C☐** **P☐** **M☐** **N☐**
2a.9 Denominator Exclusions (*Brief text description of exclusions from the target population*)**:** None.	

Comment [k7]: USPSTF grading system **http://www.ahrq.gov/clinic/uspstf/grades.htm**: **A -** The USPSTF recommends the service. There is high certainty that the net benefit is substantial. **B -** The USPSTF recommends the service. There is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. **C -** The USPSTF recommends against routinely providing the service. There may be considerations that support providing the service in an individual patient. There is at least moderate certainty that the net benefit is small. Offer or provide this service only if other considerations support the offering or providing the service in an individual patient. **D -** The USPSTF recommends against the service. There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. **I -** The USPSTF concludes that the current evidence is insufficient to assess the balance of benefits and harms of the service. Evidence is lacking, of poor quality, or conflicting, and the balance of benefits and harms cannot be determined.

Comment [KP8]: 2a. The measure is well defined and precisely specified so that it can be implemented consistently within and across organizations and allow for comparability. The required data elements are of high quality as defined by NQF's Health Information Technology Expert Panel (HITEP) .

Comment [k9]: 11 Risk factors that influence outcomes should not be specified as exclusions.
12 Patient preference is not a clinical exception to eligibility and can be influenced by provider interventions.

2a.10 Denominator Exclusion Details (*All information required to collect exclusions to the denominator, including all codes, logic, and definitions***):**
N/A

2a.11 Stratification Details/Variables (*All information required to stratify the measure including the stratification variables, all codes, logic, and definitions***):**
No stratification is required for this measure.

2a.12-13 Risk Adjustment Type: No risk adjustment necessary

2a.14 Risk Adjustment Methodology/Variables (*List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method***):**
N/A

2a.15-17 Detailed risk model available Web page URL or attachment:

2a.18-19 Type of Score: Rate/proportion
2a.20 Interpretation of Score: Better quality = Higher score
2a.21 Calculation Algorithm (*Describe the calculation of the measure as a flowchart or series of steps***):**
A patient's age is determined as of the start of the reporting month. Patients are counted as being in the facility for the entire reporting month if "Admit Date" to the specified facility is prior or equal to the first day of the reporting month, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the reporting month. Patients are counted as in-center HD patients if their in-center HD start date is less than or equal to the first day of the reporting month and their in-center HD end date is greater than or equal to the last day of the reporting month (or blank/null in the case the patient has not ended in-center HD).
Patients are included in the denominator if they are at least 18 years old and were continuously enrolled in the dialysis facility as an in-center HD patient for the entire reporting month.
Patients are included in the numerator if they are in the denominator and the facility reports that the patient was not prescribed a dialysate sodium of greater than 138 mEq/L for any session in the reporting month, as indicated by the corresponding CROWNWeb variable (see numerator details).
The measure is calculated by dividing the numerator by the denominator.

2a.22 Describe the method for discriminating performance *(e.g., significance testing)***:**
The performance of the facility will be compared to state, Network and national performance.

2a.23 Sampling (Survey) Methodology *If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate)*:
N/A

2a.24 Data Source (*Check the source(s) for which the measure is specified and tested)*
Electronic clinical data

2a.25 Data source/data collection instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.***):**
CROWNWeb

2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL
http://www.projectcrownweb.org/crown/index.php

2a.29-31 Data dictionary/code table web page URL or attachment: URL
http://www.projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents

2a.32-35 Level of Measurement/Analysis (*Check the level(s) for which the measure is specified and tested)*
Facility/Agency

2a.36-37 Care Settings (*Check the setting(s) for which the measure is specified and tested)*
Dialysis Facility

2a.38-41 Clinical Services (*Healthcare services being measured, check all that apply*)

Dialysis

TESTING/ANALYSIS

2b. Reliability testing

2b.1 **Data/sample** *(description of data/sample and size)*: The measure has not been tested for reliability.

2b.2 **Analytic Method** *(type of reliability & rationale, method for testing)*:
N/A; see above.

2b.3 **Testing Results** *(reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
N/A; see above.

2b C☐ P☐ M☐ N☐

2c. Validity testing

2c.1 **Data/sample** *(description of data/sample and size)*: Data is not available to test the validity of the measure; however, a C-TEP evaluated the measure.

2c.2 **Analytic Method** *(type of validity & rationale, method for testing)*:
Face validity is the only validity assessed. The validity was assessed by a vote by the C-TEP.

2c.3 **Testing Results** *(statistical results, assessment of adequacy in the context of norms for the test conducted)*:
The measure was unanimously ratified by the C-TEP as a valid measure.

2c C☐ P☐ M☐ N☐

2d. Exclusions Justified

2d.1 **Summary of Evidence supporting exclusion(s):**
There are no exclusions.

2d.2 **Citations for Evidence:**
N/A

2d.3 **Data/sample** *(description of data/sample and size)*: N/A

2d.4 **Analytic Method** *(type analysis & rationale)*:
N/A

2d.5 **Testing Results** *(e.g., frequency, variability, sensitivity analyses)*:
N/A

2d C☐ P☐ M☐ N☐ NA☐

2e. Risk Adjustment for Outcomes/ Resource Use Measures

2e.1 **Data/sample** *(description of data/sample and size)*: Risk adjustment is not necessary for this measure.

2e.2 **Analytic Method** *(type of risk adjustment, analysis, & rationale)*:
N/A

2e.3 **Testing Results** *(risk model performance metrics)*:
N/A

2e.4 **If outcome or resource use measure is not risk adjusted, provide rationale:** N/A

2e C☐ P☐ M☐ N☐ NA☐

2f. Identification of Meaningful Differences in Performance

2f.1 **Data/sample from Testing or Current Use** *(description of data/sample and size)*: The measure is not currently in use; no data was available for testing.

2f.2 **Methods to identify statistically significant and practically/meaningfully differences in performance**

2f C☐ P☐ M☐ N☐

Comment [KP10]: 2b. Reliability testing demonstrates the measure results are repeatable, producing the same results a high proportion of the time when assessed in the same population in the same time period.

Comment [k11]: 8 Examples of reliability testing include, but are not limited to: inter-rater/abstractor or intra-rater/abstractor studies; internal consistency for multi-item scales; test-retest for survey items. Reliability testing may address the data items or final measure score.

Comment [KP12]: 2c. Validity testing demonstrates that the measure reflects the quality of care provided, adequately distinguishing good and poor quality. If face validity is the only validity addressed, it is systematically assessed.

Comment [k13]: 9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 ... [4]

Comment [KP14]: 2d. Clinically necessary measure exclusions are identified and must be:
•supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;
AND ... [5]

Comment [k15]: 10 Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, sensitivity analyses with and without the exclusion, and variability of exclusions across providers.

Comment [KP16]: 2e. For outcome measures and other measures (e.g., resource use) when indicated:
•an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical ... [6]

Comment [k17]: 13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American ... [7]

Comment [KP18]: 2f. Data analysis demonstrates that methods for scoring and analysis of the specified measure allow for identification of statistically significant and practically/clinically meaningful differences in performance.

Comment [k19]: 14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant differe ... [8]

(type of analysis & rationale): N/A 2f.3 **Provide Measure Scores from Testing or Current Use** *(description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*: N/A	
2g. Comparability of Multiple Data Sources/Methods 2g.1 **Data/sample** *(description of data/sample and size)*: Multiple data sources are not allowed for this measure and therefore testing is not applicable. 2g.2 **Analytic Method** *(type of analysis & rationale)*: N/A 2g.3 **Testing Results** *(e.g., correlation statistics, comparison of rankings)*: N/A	**2g** C☐ P☐ M☐ N☐ NA☐
2h. Disparities in Care 2h.**1 If measure is stratified, provide stratified results** *(scores by stratified categories/cohorts)*: N/A 2h.2 **If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans:** N/A	**2h** C☐ P☐ M☐ N☐ NA☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Scientific Acceptability of Measure Properties?*	**2**
Steering Committee: Overall, to what extent was the criterion, *Scientific Acceptability of Measure Properties*, **met?** **Rationale:**	*2* C☐ P☐ M☐ N☐
3. USABILITY	
Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)	**Eval Rating**
3a. Meaningful, Understandable, and Useful Information 3a.1 **Current Use:** Testing not yet completed 3a.2 **Use in a public reporting initiative (disclosure of performance results to the public at large)** (*If used in a public reporting initiative, provide name of initiative(s), locations, Web page URL(s). If not publicly reported, state the plans to achieve public reporting within 3 years*): This measure is currently not publically reported. This measure could be considered for public reporting on Medicare's Dialysis Facility Compare (DFC) website in the future. 3a.3 **If used in other programs/initiatives (***If used in quality improvement or other programs/initiatives, name of initiative(s), locations, Web page URL(s). If not used for QI, state the plans to achieve use for QI within 3 years***):** None. **Testing of Interpretability** (*Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement*) 3a.4 **Data/sample** *(description of data/sample and size)*: Testing of interpretability has not been performed. 3a.5 **Methods** *(e.g., focus group, survey, QI project)*: N/A	**3a** C☐ P☐ M☐ N☐

Rating: C=Completely; P=Partially; M=Minimally; N=Not at all; NA=Not applicable

Comment [KP20]: 2g. If multiple data sources/methods are allowed, there is demonstration they produce comparable results.

Comment [KP21]: 2h. If disparities in care have been identified, measure specifications, scoring, and analysis allow for identification of disparities through stratification of results (e.g., by race, ethnicity, socioeconomic status, gender);OR rationale/data justifies why stratification is not necessary or not feasible.

Comment [KP22]: 3a. Demonstration that information produced by the measure is meaningful, understandable, and useful to the intended audience(s) for both public reporting (e.g., focus group, cognitive testing) and informing quality improvement (e.g., quality improvement initiatives). An important outcome that may not have an identified improvement strategy still can be useful for informing quality improvement by identifying the need for and stimulating new approaches to improvement.

3a.6 Results *(qualitative and/or quantitative results and conclusions)*: N/A	
3b/3c. Relation to other NQF-endorsed measures **3b.1 NQF # and Title of similar or related measures:**	
(for NQF staff use) **Notes on similar/related endorsed or submitted measures:**	
3b. Harmonization If this measure is related to measure(s) already endorsed by NQF (e.g., same topic, but different target population/setting/data source or different topic but same target population): **3b.2 Are the measure specifications harmonized? If not, why?**	**3b** C☐ P☐ M☐ N☐ NA☐
3c. Distinctive or Additive Value **3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:** **5.1 If this measure is similar to measure(s) already endorsed by NQF (i.e., on the same topic and the same target population), Describe why it is a more valid or efficient way to measure quality:** N/A	**3c** C☐ P☐ M☐ N☐ NA☐
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Usability?*	**3**
Steering Committee: Overall, to what extent was the criterion, *Usability*, **met?** **Rationale:**	**3** C☐ P☐ M☐ N☐
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)	**Eval Rating**
4a. Data Generated as a Byproduct of Care Processes **4a.1-2 How are the data elements that are needed to compute measure scores generated?** Data generated as byproduct of care processes during care delivery (Data are generated and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition)	**4a** C☐ P☐ M☐ N☐
4b. Electronic Sources **4b.1 Are all the data elements available electronically?** (*elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims*) Yes **4b.2 If not, specify the near-term path to achieve electronic capture by most providers.**	**4b** C☐ P☐ M☐ N☐
4c. Exclusions **4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications?** No **4c.2 If yes, provide justification.**	**4c** C☐ P☐ M☐ N☐ NA☐

Comment [KP23]: 3b. The measure specifications are harmonized with other measures, and are applicable to multiple levels and settings.

Comment [k24]: 16 Measure harmonization refers to the standardization of specifications for similar measures on the same topic (e.g., *influenza immunization* of patients in hospitals or nursing homes), or related measures for the same target population (e.g., eye exam and HbA1c for *patients with diabetes*), or definitions applicable to many measures (e.g., age designation for children) so that they are uniform or compatible, unless differences are dictated by the evidence. The dimensions of harmonization can include numerator, denominator, exclusions, and data source and collection instructions. The extent of harmonization depends on the relationship of the measures, the evidence for the specific measure focus, and differences in data sources.

Comment [KP25]: 3c. Review of existing endorsed measures and measure sets demonstrates that the measure provides a distinctive or additive value to existing NQF-endorsed measures (e.g., provides a more complete picture of quality for a particular condition or aspect of healthcare, is a more valid or efficient way to measure).

Comment [KP26]: 4a. For clinical measures, required data elements are routinely generated concurrent with and as a byproduct of care processes during care delivery. (e.g., BP recorded in the electronic record, not abstracted from the record later by other personnel; patient self-assessment tools, e.g., depression scale; lab values, meds, etc.)

Comment [KP27]: 4b. The required data elements are available in electronic sources. If the required data are not in existing electronic sources, a credible, near-term path to electronic collection by most providers is specified and clinical data elements are specified for transition to the electronic health record.

Comment [KP28]: 4c. Exclusions should not require additional data sources beyond what is required for scoring the measure (e.g., numerator and denominator) unless justified as supporting measure validity.

4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences

4d.1 **Identify susceptibility to inaccuracies, errors, or unintended consequences of the measure and describe how these potential problems could be audited. If audited, provide results.**
The prescribed dialysate sodium concentration should be easily obtained from patient treatment records as prescribed sodium concentration in the dialysate is typically a routinely monitored and documented data element for every dialysis session.

4d C☐ P☐ M☐ N☐

Comment [KP29]: 4d. Susceptibility to inaccuracies, errors, or unintended consequences and the ability to audit the data items to detect such problems are identified.

4e. Data Collection Strategy/Implementation

4e.1 **Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data/missing data, timing/frequency of data collection, patient confidentiality, time/cost of data collection, other feasibility/ implementation issues:**
The measure was evaluated by a C-TEP and data technical expert panel (D-TEP) with representatives from both large and small dialysis organizations. Both panels agreed that the data elements would be easy to collect.

4e.2 **Costs to implement the measure** (*costs of data collection, fees associated with proprietary measures*)**:**
The estimated data collection burden and associated cost estimates for comparable measures are presented in Tables 1-3 in the Federal Register. Vol. 73, No. 73 page 20469. URL: http://www.cms.gov/CFCsAndCoPs/downloads/ESRDfinalrule0415.pdf

4e.3 **Evidence for costs:**
See above reference to Federal Register.

4e.4 **Business case documentation:** Reducing the dialysate sodium concentration to <= 138mEq/L, should not result in any additional cost to dialysis facilities, whilst retaining the potential to be an effective intervention.

4e C☐ P☐ M☐ N☐

Comment [KP30]: 4e. Demonstration that the data collection strategy (e.g., source, timing, frequency, sampling, patient confidentiality, etc.) can be implemented (e.g., already in operational use, or testing demonstrates that it is ready to put into operational use).

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for *Feasibility*?

4

Steering Committee: Overall, to what extent was the criterion, *Feasibility*, met?
Rationale:

4 C☐ P☐ M☐ N☐

RECOMMENDATION

(for NQF staff use) **Check if measure is untested and only eligible for time-limited endorsement.**

Time-limited ☐

Steering Committee: Do you recommend for endorsement?
Comments:

Y☐ N☐ A☐

CONTACT INFORMATION

Co.1 **Measure Steward (Intellectual Property Owner)**
Co.1 **Organization**
Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, 21244

Co.2 **Point of Contact**
Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-

Measure Developer If different from Measure Steward
Co.3 **Organization**
Arbor Research/UM-KECC, 315 W. Huron Street, Ann Arbor, Michigan, 48103

Co.4 **Point of Contact**
Adrienne, Janney, adrienne.janney@arborresearch.org, 734-665-4108-

Co.5 **Submitter If different from Measure Steward POC**
Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-, Centers for Medicare & Medicaid Services

Co.6 **Additional organizations that sponsored/participated in measure development**

ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 **Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.**
Dr. Rajiv Agarwal, panel chair (University of Indiana, School of Medicine, Indianapolis, IN)
Dr. Nathan Levin (Renal Research Institute, New York, NY)
Dr. John Daugirdas (University of Chicago, Chicago, IL)
William Peckham (http://www.billpeckham.com)
Dr. Raymond Hakim (Fresenius Medical Care NA, Brentwood, TN)
Dr. Thomas Parker III (Renal Ventures Management, Lakewood, CO)
Dr. Allen Nissenson (DaVita, El Segundo, CA)
Dr. Rajiv Saran, Moderator (University of Michigan – Kidney Epidemiology and Cost Center, Ann Arbor, MI)
Brett Lantz, Analyst (Arbor Research Collaborative for Health, Ann Arbor, MI)

Ad.2 **If adapted, provide name of original measure:**
Ad.3-5 **If adapted, provide original specifications URL or attachment**

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.6 **Year the measure was first released:**
Ad.7 **Month and Year of most recent revision:**
Ad.8 **What is your frequency for review/update of this measure?** Three years
Ad.9 **When is the next scheduled review/update for this measure?** 2013

Ad.10 **Copyright statement/disclaimers:**

Ad.11 -13 **Additional Information web page URL or attachment:**

Date of Submission (*MM/DD/YY*)**:** 12/09/2010

Page 3: [1] Comment [k4] **Karen Pace** **10/5/2009 8:59:00 AM**

1c. The measure focus is:

- an outcome (e.g., morbidity, mortality, function, health-related quality of life) that is relevant to, or associated with, a national health goal/priority, the condition, population, and/or care being addressed;

OR

- if an intermediate outcome, process, structure, etc., there is **evidence** that supports the specific measure focus as follows:
  - Intermediate outcome – evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
  - Process – evidence that the measured clinical or administrative process leads to improved health/avoidance of harm and
    if the measure focus is on one step in a multi-step care process, it measures the step that has the greatest effect on improving the specified desired outcome(s).
  - Structure – evidence that the measured structure supports the consistent delivery of effective processes or access that lead to improved health/avoidance of harm or cost/benefit.
  - Patient experience – evidence that an association exists between the measure of patient experience of health care and the outcomes, values and preferences of individuals/ the public.
  - Access – evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
  - Efficiency – demonstration of an association between the measured resource use and level of performance with respect to one or more of the other five IOM aims of quality.

Page 3: [2] Comment [k5] **Karen Pace** **10/5/2009 8:59:00 AM**

4 Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multi-step process, the step with the greatest effect on the desired outcome should be selected as the focus of measurement. For example, although assessment of immunization status and recommending immunization are necessary steps, they are not sufficient to achieve the desired impact on health status – patients must be vaccinated to achieve immunity. This does not preclude consideration of measures of preventive screening interventions where there is a strong link with desired outcomes (e.g., mammography) or measures for multiple care processes that affect a single outcome.

Page 3: [3] Comment [k6] **Karen Pace** **10/5/2009 8:59:00 AM**

3 The strength of the body of evidence for the specific measure focus should be systematically assessed and rated (e.g., USPSTF grading system http://www.ahrq.gov/clinic/uspstf07/methods/benefit.htm). If the USPSTF grading system was not used, the grading system is explained including how it relates to the USPSTF grades or why it does not. However, evidence is not limited to quantitative studies and the best type of evidence depends upon the question being studied (e.g., randomized controlled trials appropriate for studying drug efficacy are not well suited for complex system changes). When qualitative studies are used, appropriate qualitative research criteria are used to judge the strength of the evidence.

Page 7: [4] Comment [k13] **Karen Pace** **10/5/2009 8:59:00 AM**

9 Examples of validity testing include, but are not limited to: determining if measure scores adequately distinguish between providers known to have good or poor quality assessed by another valid method; correlation of measure scores with another valid indicator of quality for the specific topic; ability of measure scores to predict scores on some other related valid measure; content validity for multi-item scales/tests. Face validity is a subjective assessment by experts of whether the measure reflects the quality of care (e.g., whether the proportion of patients with BP < 140/90 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) and the measure is judged to represent quality care for the specific topic and that the measure focus is the most important aspect of quality for the specific topic.

Page 7: [5] Comment [KP14] **Karen Pace** **10/5/2009 8:59:00 AM**

2d. Clinically necessary measure exclusions are identified and must be:

- supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion;

AND

- a clinically appropriate exception (e.g., contraindication) to eligibility for the measure focus;

AND

if patient preference (e.g., informed decision-making) is a basis for exclusion, there must be evidence that it strongly impacts performance on the measure and the measure must be specified so that the information about patient preference and the effect on the measure is transparent (e.g., numerator category computed separately, denominator exclusion category computed separately).

Page 7: [6] Comment [KP16] **Karen Pace** **10/5/2009 8:59:00 AM**

2e. For outcome measures and other measures (e.g., resource use) when indicated:

- an evidence-based risk-adjustment strategy (e.g., risk models, risk stratification) is specified and is based on patient clinical factors that influence the measured outcome (but not disparities in care) and are present at start of care;**Error! Bookmark not defined.** OR

rationale/data support no risk adjustment.

Page 7: [7] Comment [k17] **Karen Pace** **10/5/2009 8:59:00 AM**

13 Risk models should not obscure disparities in care for populations by including factors that are associated with differences/inequalities in care such as race, socioeconomic status, gender (e.g., poorer treatment outcomes of African American men with prostate cancer, inequalities in treatment for CVD risk factors between men and women). It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences.

Page 7: [8] Comment [k19] **Karen Pace** **10/5/2009 8:59:00 AM**

14 With large enough sample sizes, small differences that are statistically significant may or may not be practically or clinically meaningful. The substantive question may be, for example, whether a statistically significant difference of one percentage point in the percentage of patients who received smoking cessation counseling (e.g., 74% v. 75%) is clinically meaningful; or whether a statistically significant difference of $25 in cost for an episode of care (e.g., $5,000 v. $5,025) is practically meaningful. Measures with overall poor performance may not demonstrate much variability across providers.