

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 #: 1434 NQF Project: End Stage Renal Disease
MEASURE DESCRIPTIVE INFORMATION
De.1 Measure Title: Sodium Profiling Practice for Hemodialysis
De.2 Brief description of measure: Proportion of patients who were not prescribed sodium profiling 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
<p>A. The measure is in the public domain or an intellectual property (measure steward agreement) is signed. <i>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.</i></p> <p>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</p> <p>A.2 Indicate if Proprietary Measure (as defined in measure steward agreement):</p> <p>A.3 Measure Steward Agreement: Government entity and in the public domain - no agreement necessary</p> <p>A.4 Measure Steward Agreement attached:</p>	<p>A</p> <p>Y <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
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	<p>B</p> <p>Y <input type="checkbox"/></p>

every 3 years. Yes, information provided in contact section	N <input type="checkbox"/>
C. The intended use of the measure includes <u>both</u> public reporting <u>and</u> quality improvement. ► Purpose: Public reporting, Internal quality improvement	C Y <input type="checkbox"/> N <input type="checkbox"/>
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 <input type="checkbox"/> N <input type="checkbox"/>
(for NQF staff use) Have all conditions for consideration been met? Staff Notes to Steward (if submission returned):	Met Y <input type="checkbox"/> N <input type="checkbox"/>
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. <i>Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)</i> 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: In the United States, a significant proportion of HD patients are subjected to the practice of sodium profiling in dialysis facilities to ensure stability of the HD session. While the practice tends to achieve this aim, it exposes the patient to a sodium load in the process, even though intent is to lower the serum sodium by the end of the treatment. Elimination of this practice over time in the vast majority of HD patients will prevent this repetitive sodium loading which has the potential for cumulative harm in the form of excessive thirst, interdialytic weight gain, hypertension, with worsening left ventricular hypertrophy, heart failure, etc. The recent European best practice guidelines do not recommend the use of sodium profiling for these reasons. The KDOQI (2006) panel had also cautioned against the potential deleterious effects of this practice. 1a.4 Citations for Evidence of High Impact: Charra B, Chazot C. "The neglect of sodium restriction in dialysis patients: A short review." HemodialInt. 2003; 7:342-347. Flanigan M. "Dialysate composition and hemodialysis hypertension." Semin Dial 2004; 17:279-283. 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. KDOQI. Clinical practice guidelines for hemodialysis adequacy. Am J Kidney Dis. 2006; Jul;48 (1 Suppl 1):	1a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

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).

<p>S13-97.</p> <p>Song JH, Park GH, Lee SY, et al. "Effect of sodium balance and the combination of ultrafiltration profile during sodium profiling hemodialysis on the maintenance of the quality of dialysis and sodium and fluid balances." J Am Soc Nephrol. 2005; 16:237-46.</p> <p>Stiller S, Bonnie-Schorn E, Grassmann A, et al. "A critical review of sodium profiling for hemodialysis." Seminars in dialysis. 2001; 14:337-47.</p> <p>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.</p>	
<p>1b. Opportunity for Improvement</p> <p>1b.1 Benefits (improvements in quality) envisioned by use of this measure: In the United States, a significant proportion of hemodialysis (HD) patients are subjected to the practice of sodium profiling in dialysis facilities to ensure stability of the HD session especially in those prone to intradialytic hypotension. While the practice tends to achieve this aim, it exposes the patient to a sodium load in the process, even though intent is to lower the serum sodium by the end of the treatment. Elimination of this practice over time in the vast majority of HD patients will prevent this repetitive 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.</p> <p>1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers: There are no published nationally representative studies estimating the prevalence of this practice in the United States. A recent investigation of data from the Dialysis Outcomes and Practice Patterns Study presented (DOPPS) at the 2010 European Dialysis and Transplant Association meeting reported on the international prevalence of this practice (highest in United States and Canada) and its long term adverse consequences (Saran et al 2010).</p> <p>1b.3 Citations for data on performance gap: N/A</p> <p>1b.4 Summary of Data on disparities by population group: Disparities for sodium profiling by population group have not been reported in the literature.</p> <p>1b.5 Citations for data on Disparities: N/A</p>	<p>1b</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>1c. Outcome or Evidence to Support Measure Focus</p> <p>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 exposure to sodium by way of dietary intake or exposure to sodium in the dialysate, is likely the most important contributor to excessive interdialytic fluid weight gain and hypertension among dialysis patients with potential for long term adverse outcomes.</p> <p>1c.2-3. Type of Evidence: Observational study, Evidence-based guideline, Expert opinion</p> <p>1c.4 Summary of Evidence (as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome): Excess exposure to sodium by way of dietary intake or exposure to sodium in the dialysate, is likely the most important contributor to excessive interdialytic fluid weight gain and hypertension among dialysis patients with potential for long term adverse outcomes.</p> <p>1c.5 Rating of strength/quality of evidence (also provide narrative description of the rating and by whom):</p>	<p>1c</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>

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])

Observational studies (Level B evidence, as rated by the Fluid Weight Management Clinical Technical Expert Panel using an assessment scale similar to KDOQI).

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

1c.7 Summary of Controversy/Contradictory Evidence: While short-term studies suggest that sodium profiling is relatively successful at preventing intradialytic hypotensive episodes, it has been associated with increased post-dialysis thirst and higher interdialytic weight gain. No large-scale randomized trials have been conducted to assess long-term benefits or adverse consequences of sodium profiling. There is also non-availability of large observational outcomes studies in this regard.

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

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.

Kooman J, Basci A, Pizzarelli F, Canaud B, Haage P, Fouque D, Konner K, Martin-Malo A, Pedrini L, Tattersall J, Tordoir J, Vennegoor M, Wanner C, ter Wee P, Vanholder R. "EBPG guideline on haemodynamic instability." *Nephrol Dial Transplant* 2007; 22[Suppl 2]: ii22-ii44.

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.

Song JH, Park GH, Lee SY, et al. "Effect of sodium balance and the combination of ultrafiltration profile during sodium profiling hemodialysis on the maintenance of the quality of dialysis and sodium and fluid balances." *J Am Soc Nephrol.* 2005; 16:237-46.

Stiller S, Bonnie-Schorn E, Grassmann A, et al. "A critical review of sodium profiling for hemodialysis." *Seminars in dialysis.* 2001; 14:337-47.

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 2006 KDOQI guideline, which suggests that the practice of sodium profiling should be avoided:

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 sodium profiling in dialysis patients.

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.

TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Importance to Measure and Report</i> ?	1
Steering Committee: Was the threshold criterion, <i>Importance to Measure and Report</i> , met? Rationale:	1 Y <input type="checkbox"/> N <input type="checkbox"/>
2. SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES	
Extent to which the measure, <u>as specified</u> , 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:	
<u>2a. Precisely Specified</u>	
2a.1 Numerator Statement (<i>Brief, text description of the numerator - what is being measured about the target population, e.g. target condition, event, or outcome</i>): Number of patients in denominator who were not prescribed sodium profiling in the reporting month.	
2a.2 Numerator Time Window (<i>The time period in which cases are eligible for inclusion in the numerator</i>): The entire calendar month.	
2a.3 Numerator Details (<i>All information required to collect/calculate the numerator, including all codes, logic, and definitions</i>): A data element recording whether "sodium profiling/modeling was prescribed for any dialysis session in the reporting month" will be included in the 2011 CROWNWeb national roll-out. Note that for the purposes of this measure, sodium profiling is defined as any technique where the dialysate concentration varies over the hemodialysis (HD) session. Typically, the concentration varies from high initial concentration at the start of dialysis to lower concentration at the end. However, sodium profiling resulting in a time-average sodium concentration below the starting value would still be classified as sodium profiling for this measure. The term sodium profiling is synonymous with sodium modeling.	
2a.4 Denominator Statement (<i>Brief, text description of the denominator - target population being measured</i>): Number of patients in an outpatient dialysis facility undergoing chronic maintenance HD.	
2a.5 Target population gender: Female, Male	
2a.6 Target population age range: Adults 18 years or older.	
2a.7 Denominator Time Window (<i>The time period in which cases are eligible for inclusion in the denominator</i>): The entire calendar month.	
2a.8 Denominator Details (<i>All information required to collect/calculate the denominator - the target population being measured - including all codes, logic, and definitions</i>): Denominator includes only in-center HD patients.	
2a.9 Denominator Exclusions (<i>Brief text description of exclusions from the target population</i>): None.	
2a.10 Denominator Exclusion Details (<i>All information required to collect exclusions to the denominator, including all codes, logic, and definitions</i>): N/A	2a-specs C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
2a.11 Stratification Details/Variables (<i>All information required to stratify the measure including the stratification variables, all codes, logic, and definitions</i>): No stratification is required for this measure.	

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.

<p>2a.12-13 Risk Adjustment Type: No risk adjustment necessary</p> <p>2a.14 Risk Adjustment Methodology/Variables (<i>List risk adjustment variables and describe conceptual models, statistical models, or other aspects of model or method</i>): N/A</p> <p>2a.15-17 Detailed risk model available Web page URL or attachment:</p>	
<p>2a.18-19 Type of Score: Rate/proportion</p> <p>2a.20 Interpretation of Score: Better quality = Higher score</p> <p>2a.21 Calculation Algorithm (<i>Describe the calculation of the measure as a flowchart or series of steps</i>): 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 HDend 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 sodium profiling for any session in the reporting month, as indicated by the corresponding CROWNWeb data element (see numerator details). The measure is calculated by dividing the numerator by the denominator.</p>	
<p>2a.22 Describe the method for discriminating performance (<i>e.g., significance testing</i>): The performance of the facility will be compared to state, Network and national performance.</p>	
<p>2a.23 Sampling (Survey) Methodology <i>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)</i>: N/A</p>	
<p>2a.24 Data Source (<i>Check the source(s) for which the measure is specified and tested</i>) Electronic clinical data</p>	
<p>2a.25 Data source/data collection instrument (<i>Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.</i>): CROWNWeb</p>	
<p>2a.26-28 Data source/data collection instrument reference web page URL or attachment: URL http://www.projectcrownweb.org/crown/index.php</p>	
<p>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</p>	
<p>2a.32-35 Level of Measurement/Analysis (<i>Check the level(s) for which the measure is specified and tested</i>) Facility/Agency</p>	
<p>2a.36-37 Care Settings (<i>Check the setting(s) for which the measure is specified and tested</i>) Dialysis Facility</p>	
<p>2a.38-41 Clinical Services (<i>Healthcare services being measured, check all that apply</i>) Dialysis</p>	
TESTING/ANALYSIS	
<p>2b. Reliability testing</p> <p>2b.1 Data/sample (<i>description of data/sample and size</i>): The measure has not been tested for reliability.</p>	<p>2b</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p>

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.

<p>2b.2 Analytic Method (<i>type of reliability</i> & <i>rationale, method for testing</i>): N/A; see above.</p> <p>2b.3 Testing Results (<i>reliability statistics, assessment of adequacy in the context of norms for the test conducted</i>): N/A; see above.</p>	<p>N <input type="checkbox"/></p>
<p>2c. Validity testing</p> <p>2c.1 Data/sample (<i>description of data/sample and size</i>): Data are not available to test the validity of the measure; however, a clinical technical expert panel (C-TEP) evaluated the measure.</p> <p>2c.2 Analytic Method (<i>type of validity</i> & <i>rationale, method for testing</i>): Face validity is the only validity assessed. The validity was assessed by a vote by the C-TEP.</p> <p>2c.3 Testing Results (<i>statistical results, assessment of adequacy in the context of norms for the test conducted</i>): The measure was unanimously ratified by the C-TEP as a valid measure.</p>	<p>2c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>2d. Exclusions Justified</p> <p>2d.1 Summary of Evidence supporting exclusion(s): There are no exclusions.</p> <p>2d.2 Citations for Evidence: N/A</p> <p>2d.3 Data/sample (<i>description of data/sample and size</i>): N/A</p> <p>2d.4 Analytic Method (<i>type analysis & rationale</i>): N/A</p> <p>2d.5 Testing Results (<i>e.g., frequency, variability, sensitivity analyses</i>): N/A</p>	<p>2d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2e. Risk Adjustment for Outcomes/ Resource Use Measures</p> <p>2e.1 Data/sample (<i>description of data/sample and size</i>): Risk adjustment is not necessary for this measure.</p> <p>2e.2 Analytic Method (<i>type of risk adjustment, analysis, & rationale</i>): N/A</p> <p>2e.3 Testing Results (<i>risk model performance metrics</i>): N/A</p> <p>2e.4 If outcome or resource use measure is not risk adjusted, provide rationale: N/A</p>	<p>2e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2f. Identification of Meaningful Differences in Performance</p> <p>2f.1 Data/sample from Testing or Current Use (<i>description of data/sample and size</i>): The measure is not currently in use; no data were available for testing.</p> <p>2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (<i>type of analysis & rationale</i>): N/A</p> <p>2f.3 Provide Measure Scores from Testing or Current Use (<i>description of scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance</i>): N/A</p>	<p>2f C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

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 is a marker of quality). If face validity is the only validity addressed, it is systematically assessed (e.g., ratings by relevant stakeholders) a... [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 factors that influence the measured out... [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 men with prostate cancer, inequalities in treat... [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 difference of one percentage point in the percentage ... [8]

<p>2g. Comparability of Multiple Data Sources/Methods</p> <p>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.</p> <p>2g.2 Analytic Method (type of analysis & rationale): N/A</p> <p>2g.3 Testing Results (e.g., correlation statistics, comparison of rankings): N/A</p>	<p>2g</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>2h. Disparities in Care</p> <p>2h.1 If measure is stratified, provide stratified results (scores by stratified categories/cohorts): N/A</p> <p>2h.2 If disparities have been reported/identified, but measure is not specified to detect disparities, provide follow-up plans: N/A</p>	<p>2h</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p> <p>NA <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Scientific Acceptability of Measure Properties</i>?</p>	<p>2</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Scientific Acceptability of Measure Properties</i>, met? Rationale:</p>	<p>2</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p style="text-align: center;">3. USABILITY</p>	
<p>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)</p>	<p>Eval Rating</p>
<p>3a. Meaningful, Understandable, and Useful Information</p> <p>3a.1 Current Use: Testing not yet completed</p> <p>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.</p> <p>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.</p> <p>Testing of Interpretability (Testing that demonstrates the results are understood by the potential users for public reporting and quality improvement)</p> <p>3a.4 Data/sample (description of data/sample and size): Testing of interpretability has not been performed.</p> <p>3a.5 Methods (e.g., focus group, survey, QI project): N/A</p> <p>3a.6 Results (qualitative and/or quantitative results and conclusions): N/A</p>	<p>3a</p> <p>C <input type="checkbox"/></p> <p>P <input type="checkbox"/></p> <p>M <input type="checkbox"/></p> <p>N <input type="checkbox"/></p>
<p>3b/3c. Relation to other NQF-endorsed measures</p> <p>3b.1 NQF # and Title of similar or related measures:</p>	

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.

(for NQF staff use) Notes on similar/related endorsed or submitted measures:	
3b. Harmonization If this measure is related to measure(s) already <u>endorsed by NQF</u> (e.g., same topic, but different target population/setting/data source <u>or</u> different topic but same target population): 3b.2 Are the measure specifications <u>harmonized</u> ? If not, why?	3b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
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 <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
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 <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4. FEASIBILITY	
Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (<u>evaluation criteria</u>)	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? <u>Coding/abstraction performed by someone other than person obtaining original information (E.g., DRG, ICD-9 codes on claims, chart abstraction for quality measure or registry)</u>	4a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
4b. Electronic Sources 4b.1 Are all the data elements available electronically? (<i>elements that are needed to compute measure scores are in defined, computer-readable fields, e.g., electronic health record, electronic claims</i>) Yes 4b.2 If not, specify the near-term path to achieve electronic capture by most providers.	4b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
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 <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/>
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 D-TEP suggested that for true quantification of sodium profiling, data elements for minimum/maximum sodium concentration, profile type (step change, linear, or exponential), and the time over which modeling is performed would be required. Because these data are not collected, the use of sodium profiling must be abstracted from patient treatment records.	4d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

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.

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	
<p>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 D-TEP with representatives from both large and small dialysis organizations. Although the D-TEP suggested that facilities entering data manually into CROWNWeb may be subjected to data entry burden for this measure, the C-TEP felt that the importance of the measure justified the increased data burden.</p> <p>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</p> <p>4e.3 Evidence for costs: See above reference to Federal Register.</p> <p>4e.4 Business case documentation: The gradual elimination of the practice of sodium profiling on the dialysis units will likely not result in significant increase in cost to the dialysis facilities, and in fact could turn out to be a cost effective intervention in view of its potential longer term benefits. In the short term, however, patients who would otherwise qualify for sodium profiling, may require longer dialysis sessions with slower ultrafiltration to ensure stability during the dialysis procedure and this could increase cost for the facility. This topic has not been subjected to formal cost effectiveness analysis.</p>	4e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i>?	4
Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i>, met? Rationale:	4 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>
RECOMMENDATION	
(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.	Time-limited <input type="checkbox"/>
Steering Committee: Do you recommend for endorsement? Comments:	Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/>
CONTACT INFORMATION	
<p>Co.1 Measure Steward (Intellectual Property Owner) Co.1 Organization Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland, 21244</p> <p>Co.2 Point of Contact Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-</p> <p>Measure Developer If different from Measure Steward Co.3 Organization Arbor Research/UM-KECC, 315 W. Huron Street, Ann Arbor, Michigan, 48103</p> <p>Co.4 Point of Contact Adrienne, Janney, adrienne.janney@arborresearch.org, 734-665-4108-</p>	

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).

<p>Co.5 Submitter If different from Measure Steward POC Thomas, Dudley, Thomas.Dudley@cms.hhs.gov, 410-786-1442-, Centers for Medicare & Medicaid Services</p>
<p>Co.6 Additional organizations that sponsored/participated in measure development</p>
<p>ADDITIONAL INFORMATION</p>
<p>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)</p>
<p>Ad.2 If adapted, provide name of original measure: Ad.3-5 If adapted, provide original specifications URL or attachment</p>
<p>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</p>
<p>Ad.10 Copyright statement/disclaimers:</p>
<p>Ad.11 -13 Additional Information web page URL or attachment:</p>
<p>Date of Submission (MM/DD/YY): 12/09/2010</p>

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:
 - o Intermediate outcome - evidence that the measured intermediate outcome (e.g., blood pressure, Hba1c) leads to improved health/avoidance of harm or cost/benefit.
 - o 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).
 - o 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.
 - o 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.
 - o Access - evidence that an association exists between access to a health service and the outcomes of, or experience with, care.
 - o 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.