

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 #: 1454	NQF Project: End Stage Renal Disease
MEASURE DESCRIPTIVE INFORMATION	
De.1 Measure Title: Proportion of patients with hypercalcemia	
De.2 Brief description of measure: Proportion of patients with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL	
1.1-2 Type of Measure: Outcome	
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: Yes, fully developed and tested 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 (<i>if submission returned</i>):	Met Y <input type="checkbox"/> N <input type="checkbox"/>
Staff Notes to Reviewers (<i>issues or questions regarding any criteria</i>):	
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.</i> (evaluation criteria) 1a. High Impact	Eval Rating
(for NQF staff use) Specific NPP goal :	
1a.1 Demonstrated High Impact Aspect of Healthcare: Severity of illness 1a.2 1a.3 Summary of Evidence of High Impact: In 2007, total Medicare costs for the ESRD program were \$23.9 billion, a 6.1% increase from 2006 (USRDS, 2009). Abnormalities in serum levels of calcium and phosphorus, which are markers of mineral and bone disorder, are common among ESRD patients. Numerous studies have demonstrated the association of prolonged calcium and phosphorus dysregulation on patient morbidity and mortality (KDIGO 2009; KDOQI 2003). In March 2010, the C- TEP recommended that a clinical performance measure (CPM) for the upper limit of total serum calcium be calculated as the proportion of patients with 3-month rolling average of total serum calcium greater than 10.2 mg/dL. This recommendation is consistent with the value indicated by a TEP held in 2006 and with the 2003 KDOQI guidelines [1]. Since 10.2 mg/dl is the considered the upper limit of the normal range in the majority of clinical laboratories, this CPM is also consistent with the recently published KDIGO guidelines [2]. Review of the currently available literature indicates that observational cohort studies show a consistent adverse association of hypercalcemia with cardiovascular events and all-cause mortality [3-7]. Clinical data demonstrate the association of increased serum calcium with vascular [8,9] and valvular calcifications [10]. The basic science also supports a pathological role of high calcium in promoting soft tissue and vascular calcification [11-13]. Although there are no interventional studies demonstrating the benefit of correcting hypercalcemia, there was unanimous agreement among the C-TEP members that calcium concentrations	1a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/>

>10.2 mg/dL place the patient at increased risk of poor outcomes. Current guidelines indicate that clinical decision should be based on trends rather than single laboratory values [2]. Therefore, it was unanimously agreed to use a three-month rolling average for reporting.

1a.4 Citations for Evidence of High Impact: 1) National Kidney Foundation: K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. American Journal of Kidney Disease 2003 42:S1-S202 (suppl 3).

2) Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group: KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). Kidney International 2009 76 (Suppl 113): S1-S130.

3) Block GA, Klassen PS, Lazarus JM, et al. Mineral metabolism, mortality, and morbidity in maintenance hemodialysis. Journal of the American Society of Nephrology : JASN 2004 15:2208-18.

4) Young EW, Albert JM, Satayathum S, et al. Predictors and consequences of altered mineral metabolism: the Dialysis Outcomes and Practice Patterns Study. Kidney international 2005 67:1179-87.

5) Kalantar-Zadeh K, Kuwae N, Regidor DL, et al. Survival predictability of time-varying indicators of bone disease in maintenance hemodialysis patients. Kidney international 2006 70:771-80.

6) Kimata N, Albert JM, Akiba T, et al. Association of mineral metabolism factors with all-cause and cardiovascular mortality in hemodialysis patients: the Japan dialysis outcomes and practice patterns study. Hemodialysis international. International Symposium on Home Hemodialysis 2007 11:340-8.

7) Tentori F, Blayney MJ, Albert JM, et al. Mortality risk for dialysis patients with different levels of serum calcium, phosphorus, and PTH: the Dialysis Outcomes and Practice Patterns Study (DOPPS). American journal of kidney diseases : the official journal of the National Kidney Foundation 2008 52:519-30.

8) Chertow G.M., Raggi P., Chasan-Taber S., Bommer J., Holzer H., Burke S.K. Determinants of progressive vascular calcification in haemodialysis patients. Nephrology Dialysis Transplantation 2004 19 (6), pp. 1489-1496.

9) Dhingra R, Sullivan LM, Fox CS, Wang TJ, D'Agostino RB Sr, Gaziano JM, Vasan RS: Relations of serum phosphorus and calcium levels to the incidence of cardiovascular disease in the community. Arch Intern Med 2007 167: 879-885.

10) Wang AY, Lam CW, Wang M, Chan IH, Lui SF, Sanderson JE. Is valvular calcification a part of the missing link between residual kidney function and cardiac hypertrophy in peritoneal dialysis patients? Clinical journal of the American Society of Nephrology 2009 4:1629-36.

11) Ketteler M, Schlieper G, Floege J. Calcification and cardiovascular health: new insights into an old phenomenon. Hypertension 2006 47:1027-1034.

12) Giachelli CM. Vascular calcification mechanisms. Journal of the American Society of Nephrology : JASN 2004 15:2959-2964.

13) Yang H, Curinga G, Giachelli CM. Elevated extracellular calcium levels induce smooth muscle cell matrix mineralization in vitro. Kidney Int. 2004;66(6):2293-2299.

1b. Opportunity for Improvement

1b.1 Benefits (improvements in quality) envisioned by use of this measure: Review of the currently available literature indicates that observational cohort studies show a consistent adverse association of hypercalcemia with cardiovascular events and all-cause mortality. Calcium concentrations >10.2 mg/dL place the patient at increased risk of poor outcomes

1b.2 Summary of data demonstrating performance gap (variation or overall poor performance) across providers:

1b
C
P
M
N

Overall, hypercalcemia may not be common in the ESRD population. However, the published literature indicates that large numbers of ESRD patients are affected by this abnormality [1-5]. Patient-level analysis of data collected from March 2010 through May 2010 as part of the CROWNWeb Project show that 13,690 patients (4.5%) met the requirements for this proposed measure. Furthermore, facility level analyses indicate that in 95% (n = 3,318) of the 3,493 facilities, 13% of patients met the criteria for this measure.

1b.3 Citations for data on performance gap:

- 1) Block GA, Klassen PS, Lazarus JM, et al. Mineral metabolism, mortality, and morbidity in maintenance hemodialysis. *Journal of the American Society of Nephrology*: JASN 2004 15:2208-18.
- 2) Young EW, Albert JM, Satayathum S, et al. Predictors and consequences of altered mineral metabolism: the Dialysis Outcomes and Practice Patterns Study. *Kidney international* 2005 67:1179-87.
- 3) Kalantar-Zadeh K, Kuwae N, Regidor DL, et al. Survival predictability of time-varying indicators of bone disease in maintenance hemodialysis patients. *Kidney international* 2006 70:771-80.
- 4) Kimata N, Albert JM, Akiba T, et al. Association of mineral metabolism factors with all-cause and cardiovascular mortality in hemodialysis patients: the Japan dialysis outcomes and practice patterns study. *Hemodialysis international. International Symposium on Home Hemodialysis* 2007 11:340-8.
- 5) Tentori F, Blayney MJ, Albert JM, et al. Mortality risk for dialysis patients with different levels of serum calcium, phosphorus, and PTH: the Dialysis Outcomes and Practice Patterns Study (DOPPS). *American journal of kidney diseases: the official journal of the National Kidney Foundation* 2008 52:519-30.

1b.4 Summary of Data on disparities by population group:

N/A

1b.5 Citations for data on Disparities:

N/A

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*): Numerous studies have demonstrated the association of prolonged calcium and phosphorus dysregulation on patient morbidity and mortality (KDIGO 2009; KDOQI 2003). Observational cohort studies show a consistent adverse association of hypercalcemia with cardiovascular events and all-cause mortality [3-7]. Clinical data demonstrate the association of increased serum calcium with vascular [8,9] and valvular calcifications [10]. The basic science also supports a pathological role of high calcium in promoting soft tissue and vascular calcification [11-13]. Although there are no interventional studies demonstrating the benefit of correcting hypercalcemia, the current available evidence indicates that serum calcium concentrations >10.2 mg/dL place the patient at increased risk of poor outcomes.

1c.2-3. Type of Evidence: Cohort study, Observational study, Evidence-based guideline, Expert opinion, Systematic synthesis of research, Meta-analysis

1c.4 Summary of Evidence (*as described in the criteria; for outcomes, summarize any evidence that healthcare services/care processes influence the outcome*):

In March 2010, the C-TEP recommended that a CPM for the upper limit of total serum calcium be calculated as the proportion of patients with 3-month rolling average of total serum calcium greater than 10.2 mg/dL. This recommendation is consistent with the value indicated by the 2006 TEP, the KDOQI guidelines [1] published in 2003, and with the recently published KDIGO guidelines [2], since 10.2 mg/dl is the considered the upper limit of the normal range in the majority of clinical laboratories.

Review of the currently available literature indicates that observational cohort studies show a consistent adverse association of hypercalcemia with cardiovascular events and all-cause mortality [3-7]. There is also clinical data demonstrating the association of increased serum calcium with vascular [8,9] and valvular calcifications[10]. The basic science also supports a pathological role of high calcium in promoting soft tissue and vascular calcification [11-13]. Although there are no interventional studies demonstrating the

1c
 C
 P
 M
 N

benefit of correcting hypercalcemia, there was unanimous agreement among Clinical TEP members that calcium concentrations >10.2 mg/dL place the patient at increased risk of poor outcomes.

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

The Clinical TEP rated the strength of this measure as high.

1c.6 Method for rating evidence: The Clinical TEP followed similar methods of evidence assessment as those used in the development of clinical practice guidelines.

1c.7 Summary of Controversy/Contradictory Evidence: Review of the currently available literature indicates that observational cohort studies show a consistent adverse association of hypercalcemia with cardiovascular events and all-cause mortality [3-7]. There is also clinical data demonstrating the association of increased serum calcium with vascular [8,9] and valvular calcifications[10]. The basic science also supports a pathological role of high calcium in promoting soft tissue and vascular calcification [11-13].

1c.8 Citations for Evidence (*other than guidelines*): 1) National Kidney Foundation: K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. American Journal of Kidney Disease 2003 42:S1-S202 (suppl 3).

2) Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group: KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). Kidney International 2009 76 (Suppl 113): S1-S130.

3) Block GA, Klassen PS, Lazarus JM, et al. Mineral metabolism, mortality, and morbidity in maintenance hemodialysis. Journal of the American Society of Nephrology : JASN 2004 15:2208-18.

4) Young EW, Albert JM, Satayathum S, et al. Predictors and consequences of altered mineral metabolism: the Dialysis Outcomes and Practice Patterns Study. Kidney international 2005 67:1179-87.

5) Kalantar-Zadeh K, Kuwae N, Regidor DL, et al. Survival predictability of time-varying indicators of bone disease in maintenance hemodialysis patients. Kidney international 2006 70:771-80.

6) Kimata N, Albert JM, Akiba T, et al. Association of mineral metabolism factors with all-cause and cardiovascular mortality in hemodialysis patients: the Japan dialysis outcomes and practice patterns study. Hemodialysis international. International Symposium on Home Hemodialysis 2007 11:340-8.

7) Tentori F, Blayney MJ, Albert JM, et al. Mortality risk for dialysis patients with different levels of serum calcium, phosphorus, and PTH: the Dialysis Outcomes and Practice Patterns Study (DOPPS). American journal of kidney diseases : the official journal of the National Kidney Foundation 2008 52:519-30.

8) Chertow G.M., Raggi P., Chasan-Taber S., Bommer J., Holzer H., Burke S.K. Determinants of progressive vascular calcification in haemodialysis patients. Nephrology Dialysis Transplantation 2004 19 (6), pp. 1489-1496.

9) Dhingra R, Sullivan LM, Fox CS, Wang TJ, D'Agostino RB Sr, Gaziano JM, Vasani RS: Relations of serum phosphorus and calcium levels to the incidence of cardiovascular disease in the community. Arch Intern Med 2007 167: 879-885.

10) Wang AY, Lam CW, Wang M, Chan IH, Lui SF, Sanderson JE. Is valvular calcification a part of the missing link between residual kidney function and cardiac hypertrophy in peritoneal dialysis patients? Clinical journal of the American Society of Nephrology 2009 4:1629-36.

11) Ketteler M, Schlieper G, Floege J. Calcification and cardiovascular health: new insights into an old phenomenon. Hypertension 2006 47:1027-1034.

12) Giachelli CM. Vascular calcification mechanisms. Journal of the American Society of Nephrology : JASN 2004 15:2959-2964.

13) Yang H, Curinga G, Giachelli CM. Elevated extracellular calcium levels induce smooth muscle cell matrix mineralization in vitro. *Kidney Int.* 2004;66(6):2293-2299.

1c.9 Quote the Specific guideline recommendation (including guideline number and/or page number):

1) KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD):

4.1.2. In patients with CKD stages 3-5D, we suggest maintaining serum calcium in the normal range (2D).

2) KDOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease:

Guideline 6.2. In CKD Patients With Kidney Failure (Stage 5): Serum levels of corrected total calcium should be maintained within the normal range for the laboratory used, preferably toward the lower end (8.4 to 9.5 mg/dL [2.10 to 2.37 mmol/L]). (OPINION)

1c.10 Clinical Practice Guideline Citation: 1) Kidney Disease: Improving Global Outcomes (KDIGO) CKD-MBD Work Group: KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). *Kidney International* 2009 76 (Suppl 113): S1-S130.

2) National Kidney Foundation: K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. *American Journal of Kidney Disease* 2003 42:S1-S202 (suppl 3).

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):

1) Grade for strength of recommendation. Level 1/Strong/ 'We recommend ... should' and Level 2/Weak/'We suggest ... might'. Grade for quality of evidence. A = High; B= Moderate; C = Low; D = Very low.

2) When no definite evidence existed or the evidence was considered inconclusive, and either the guideline or steps in its rationale were based on judgment they were labeled "Opinion."

1c.13 Method for rating strength of recommendation (If different from [USPSTF system](#), also describe rating and how it relates to USPSTF):

The method used is similar to those used in developing clinical practice guidelines, in which experts decide which recommendations are supported by evidence and which by consensus of the Work Group opinion. Evidence-based guideline recommendations were graded as strong or moderate or weak. This approach is consistent with the USPSTF grading method.

1c.14 Rationale for using this guideline over others:

The KDIGO guidelines present the most up-to-date summary of available knowledge in the field of mineral and bone disorder. As stated in their mission statement, KDIGO guidelines were developed "To improve the care and outcomes of kidney disease patients worldwide through promoting coordination, collaboration and integration of initiatives to develop and implement clinical practice guidelines."

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-
specs
C
P

2a. Precisely Specified

<p>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 the denominator with 3-month rolling average of total uncorrected serum calcium greater than 10.2 mg/dL</p> <p>2a.2 Numerator Time Window (<i>The time period in which cases are eligible for inclusion in the numerator</i>): Prior 3 months.</p> <p>2a.3 Numerator Details (<i>All information required to collect/calculate the numerator, including all codes, logic, and definitions</i>): If there are multiple serum calcium measurements during the month, the last value will be used for the calculation.</p>	M <input type="checkbox"/> N <input type="checkbox"/>
<p>2a.4 Denominator Statement (<i>Brief, text description of the denominator - target population being measured</i>): Number of adult (>= 18 years old) hemodialysis or peritoneal dialysis patients treated at the outpatient dialysis facility for at least 30 days who have been on dialysis for greater than 90 days with at least one calcium measurement during the prior 90 days.</p> <p>2a.5 Target population gender: Female, Male</p> <p>2a.6 Target population age range: Adults 18 years or older</p> <p>2a.7 Denominator Time Window (<i>The time period in which cases are eligible for inclusion in the denominator</i>): Prior 3 months.</p> <p>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>): See above Denominator Statement</p>	
<p>2a.9 Denominator Exclusions (<i>Brief text description of exclusions from the target population</i>): None</p> <p>2a.10 Denominator Exclusion Details (<i>All information required to collect exclusions to the denominator, including all codes, logic, and definitions</i>): N/A</p>	
<p>2a.11 Stratification Details/Variables (<i>All information required to stratify the measure including the stratification variables, all codes, logic, and definitions</i>): N/A</p>	
<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 = Lower score</p> <p>2a.21 Calculation Algorithm (<i>Describe the calculation of the measure as a flowchart or series of steps</i>): Patients are included in the denominator if they are >= 18 years old as of the first day of the most recent month of the study period, are on dialysis for more than 90 days as of the first day of the most recent month of the study period, are in the facility for at least 30 days as of the last day of the most recent month of the study period, and have at least one serum calcium measurement within the study period.</p> <p>The patient's age will be determined by subtracting the patient's date of birth from the first day of the most recent month of the study period. The patient's time on dialysis will be determined by subtracting the patient's date regular Chronic Dialysis Began from the first day of the most recent month of the study period. Patients on dialysis are determined as follows: Primary Type of Dialysis is Hemodialysis, CAPD or CCPD in the most recent month of the study period. Patients in a facility for at least 30 days are</p>	

determined as follows: if the discharge date from the specified facility is missing/null or is after the last day of the most recent month of the study period, then the patient's time in the facility is calculated from the admit date to the last day of the most recent month of the study period; if the discharge date is prior to the last day of the most recent month of the study period, the patient is excluded from the calculation. In addition, the patient must have at least one valid measurement of total serum calcium within the study period.

The numerator will be determined by counting the patients in the denominator who meet the following criteria: the average total serum calcium over the 3-month study period is greater than 10.2 mg/dL. If there is more than one serum calcium measurement within each month of the study period, the last value for the month shall be used for the calculation of the average.

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):* Two data collection forms were used in the 2006 ESRD CPM Project. One form was used to abstract the records of adult and pediatric incenter hemodialysis patients; the other form was used to abstract the records of adult and pediatric peritoneal dialysis patients. Facility staff conducted the abstractions in the early summer of 2006, while Network staff conducted re-abstractions in the fall of 2006. Note that the LDOs submitted their data electronically. Network staff either received medical records from the facilities or went to the facilities to reabstract the data. SAS data files were created by Arbor Research for analysis. The patient identification number was used to pair the facility data with the Network data. Please see data Collection on page 5 of the 2006 End Stage Renal Disease Clinical Performance Measures Reliability Report (<http://www.cms.gov/CPMProject/Downloads/ESRD2006ReliabilityReport.pdf>).

2b.2 Analytic Method *(type of reliability & rationale, method for testing):*
The inter-rater reliability analysis was conducted using SAS for Windows version 9.1 to compute agreement rates, levels of concurrence, and kappa statistics. Some continuous data (such as those shown in Tables 4

2b
C
P
M
N

<p>and 6) were re-coded as categorical data for the purpose of generating the kappa statistic. As a result, some facility-abstracted data and Network re-abstracted data may fall into the same category and thus achieve agreement, even though the values are not exactly the same. For example, Table 6 demonstrates a high level of concurrence for the data category of hemoglobin = 9 gm/dL. As the category implies, specific hemoglobin values abstracted from the medical record are grouped together categorically with a cut-point of 9 mg/dL. Thus, a facility abstractor could have reported 11 gm/dL, while the Network reabstractor could have reported 10 gm/dL, yet they achieve agreement because both values are placed in the same categorical field. (The designated cut-points for re-coding the categorical data were provided by CMS.) Please see Statistical Methods on page 4 of the 2006 End Stage Renal Disease Clinical Performance Measures Reliability Report (http://www.cms.gov/CPMProject/Downloads/ESRD2006ReliabilityReport.pdf).</p> <p>2b.3 Testing Results (<i>reliability statistics, assessment of adequacy in the context of norms for the test conducted</i>): Please see page 25 of the 2006 End Stage Renal Disease Clinical Performance Measures Reliability Report (http://www.cms.gov/CPMProject/Downloads/ESRD2006ReliabilityReport.pdf).</p>	
<p>2c. Validity testing</p> <p>2c.1 Data/sample (<i>description of data/sample and size</i>): Data is not available to test the validity of the measure; however, a C-TEP evaluated the measure. Please see the TEP report at http://www.cms.gov/CPMProject/Downloads/ESRD2010TechnicalExpertPanelReport.pdf.</p> <p>2c.2 Analytic Method (<i>type of validity & rationale, method for testing</i>): Face validity is the only validity assessed. The validity was assessed by a vote by the C-TEP. Please see the TEP report at http://www.cms.gov/CPMProject/Downloads/ESRD2010TechnicalExpertPanelReport.pdf.</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. Please see the TEP report at http://www.cms.gov/CPMProject/Downloads/ESRD2010TechnicalExpertPanelReport.pdf.</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): N/A</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>): N/A</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</p>

<p>2f.1 Data/sample from Testing or Current Use (<i>description of data/sample and size</i>): CROWNWeb data from March until May, 2010 was used to perform analyses on determining the percentage of dialysis patients with serum calcium greater than 10.2</p> <p>2f.2 Methods to identify statistically significant and practically/meaningfully differences in performance (<i>type of analysis & rationale</i>): Facility level performance was evaluated by the calculation of facility percentages.</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>): CROWNWeb facility level analyses indicate that in 95% (n = 3,318) of the 3,493 facilities, 13% of patients met the criteria for this measure.</p>	<p>C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>2g. Comparability of Multiple Data Sources/Methods</p> <p>2g.1 Data/sample (<i>description of data/sample and size</i>): N/A</p> <p>2g.2 Analytic Method (<i>type of analysis & rationale</i>): N/A</p> <p>2g.3 Testing Results (<i>e.g., correlation statistics, comparison of rankings</i>): N/A</p>	<p>2g C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>2h. Disparities in Care</p> <p>2h.1 If measure is stratified, provide stratified results (<i>scores by stratified categories/cohorts</i>): 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 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> 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 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>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: In use</p> <p>3a.2 Use in a public reporting initiative (disclosure of performance results to the public at large) (<i>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</i>): N/A</p> <p>3a.3 If used in other programs/initiatives (<i>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</i>): Please see the 2008 Annual Report for the ESRD Clinical Performance Measures Project (http://www.esrdnetwork.org/assets/pdf/data/2008cpmanualreport.pdf)</p> <p>Testing of Interpretability (<i>Testing that demonstrates the results are understood by the potential users</i>)</p>	<p>3a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

<p><i>for public reporting and quality improvement)</i> 3a.4 Data/sample (description of data/sample and size): Please see the 2008 Annual Report for the ESRD Clinical Performance Measures Project (http://www.esrdnetwork.org/assets/pdf/data/2008cpmanualreport.pdf)</p> <p>3a.5 Methods (e.g., focus group, survey, QI project): Please see the 2008 Annual Report for the ESRD Clinical Performance Measures Project (http://www.esrdnetwork.org/assets/pdf/data/2008cpmanualreport.pdf)</p> <p>3a.6 Results (qualitative and/or quantitative results and conclusions): Please see the 2008 Annual Report for the ESRD Clinical Performance Measures Project (http://www.esrdnetwork.org/assets/pdf/data/2008cpmanualreport.pdf)</p>	
<p>3b/3c. Relation to other NQF-endorsed measures</p> <p>3b.1 NQF # and Title of similar or related measures:</p>	
<p>(for NQF staff use) Notes on similar/related <u>endorsed</u> or submitted measures:</p>	
<p>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 harmonized? If not, why?</p>	<p>3b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>3c. Distinctive or Additive Value 3c.1 Describe the distinctive, improved, or additive value this measure provides to existing NQF-endorsed measures:</p> <p>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</p>	<p>3c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Usability</i>?</p>	<p>3</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Usability</i>, met? Rationale:</p>	<p>3 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
4. FEASIBILITY	
<p>Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)</p>	<p>Eval Rating</p>
<p>4a. Data Generated as a Byproduct of Care Processes</p> <p>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)</p>	<p>4a C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4b. Electronic Sources</p> <p>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</p> <p>4b.2 If not, specify the near-term path to achieve electronic capture by most providers.</p>	<p>4b C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>

<p>4c. Exclusions</p> <p>4c.1 Do the specified exclusions require additional data sources beyond what is required for the numerator and denominator specifications? No</p> <p>4c.2 If yes, provide justification.</p>	<p>4c C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/> NA <input type="checkbox"/></p>
<p>4d. Susceptibility to Inaccuracies, Errors, or Unintended Consequences</p> <p>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. N/A</p>	<p>4d C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>4e. Data Collection Strategy/Implementation</p> <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: All data required to calculate the measure are currently collected in CROWNWeb.</p> <p>4e.2 Costs to implement the measure (<i>costs of data collection, fees associated with proprietary measures</i>): N/A</p> <p>4e.3 Evidence for costs: N/A</p> <p>4e.4 Business case documentation: Evidence from the published literature indicates that hypercalcemia is associated with increased risk of cardiovascular events and hospitalizations (references 3, 4, 8 and 9 from list above). Since cardiovascular events and hospital admissions are associated with increased costs, efforts to reduce hospitalization, including reducing the prevalence and incidence of hypercalcemia, may potentially result in cost-savings.</p>	<p>4e C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
<p>TAP/Workgroup: What are the strengths and weaknesses in relation to the subcriteria for <i>Feasibility</i>?</p>	<p>4</p>
<p>Steering Committee: Overall, to what extent was the criterion, <i>Feasibility</i>, met? Rationale:</p>	<p>4 C <input type="checkbox"/> P <input type="checkbox"/> M <input type="checkbox"/> N <input type="checkbox"/></p>
RECOMMENDATION	
<p>(for NQF staff use) Check if measure is untested and only eligible for time-limited endorsement.</p>	<p>Time-limited <input type="checkbox"/></p>
<p>Steering Committee: Do you recommend for endorsement? Comments:</p>	<p>Y <input type="checkbox"/> N <input type="checkbox"/> A <input type="checkbox"/></p>
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>	

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, 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. Stuart Sprague, Panel Chair (NorthShore University HealthSystem, University of Chicago Pritzker School of Medicine, Chicago, IL) Dr. Dennis Andress (Abbott Global Pharmaceutical Research & Development, Abbott Park, IL) Dr. Geoffrey Block (Denver Nephrology Associates, Denver, CO) Ms. Jan Deane (Renal Network of the Upper Midwest, Inc. (Network 11), St. Paul, MN) Ms. Linda McCann (Quality Satellite Healthcare, Mountain View, CA) Dr. David Spiegel (University of Colorado Health Sciences Division, Denver, CO) Dr. Francesca Tentori, Moderator (Arbor Research Collaborative for Health) Ms. Shannon Hunter (University of Michigan Kidney Epidemiology and Cost Center)
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 (<i>MM/DD/YY</i>): 12/16/2010