TO: NQF Members and Public

FR: NQF Staff

RE: Ad-hoc Review of Measure #0255 Measurement of Serum Phosphorus Concentration

DA: October 21, 2013

The purpose of this memo is to notify NQF members about the ad hoc review of measure 0255, *Measurement of Serum Phosphorus Concentration*, and solicit NQF member and public comment on the Expert Panel's recommendation.

All comments must be submitted no later than 6:00 PM ET, November 1, 2013.
Thank you for your interest in the NQF's work. We look forward to your review and comments.

Measure 0255 Measurement of Serum Phosphorus Concentration

Following is a brief description of the measure. The detailed specifications and evaluation summary from 2011 for measure 0255 are provided at the end of this document.

Description: Percentage of all adult (>= 18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum phosphorus measured at least once within month.
Numerator Statement: Number of adult (>= 18 years of age) dialysis patients included in denominator with serum phosphorus measured at least once within month
Denominator Statement: All adult peritoneal dialysis and hemodialysis patients included in the sample for analysis.
Exclusions: Transient dialysis patients (in unit < 30 days), pediatric patients and kidney transplant recipients with a functioning graft
Level of Analysis: Facility
Type of Measure: Process
Data Source: Electronic Clinical Data
Measure Steward: Centers for Medicare & Medicaid Services

Reason for this Request
Kidney Care Partners (KCP) has requested an ad hoc review, asserting that implementation of the measure will result in unintended consequences.

The measure as endorsed calls for monthly measurement of serum phosphorus and the request is to amend the measure specifications to allow for either serum or plasma phosphorus. KCP contends that testing plasma phosphorus concentration is an acceptable alternative to serum phosphorus therefore, performance scores of facilities using plasma testing could inappropriately indicate lower quality.

Although KCP cited unintended consequences as the reason for the request, their position is based on the assertion that plasma testing of phosphorus is an acceptable alternative to serum phosphorus. Therefore, the ad hoc review will necessarily focus on the evidence in regards to plasma testing of phosphorus and NQF's measure evaluation criteria and guidance for evaluating the evidence for a performance measure will apply.

Ad hoc Review Process

According to NQF policy for ad hoc reviews, an Expert Panel was convened to review the request and make a recommendation to the Consensus Standards Approval Committee (CSAC).

Jeffrey Berns, MD, University of Pennsylvania School of Medicine
Peter Crooks, MD, Southern California Permanente Medical Group
Debra Hain, PhD, APRN, ANP-BC, GNP-BC, Florida Atlantic University, Cleveland Clinic Florida
Michael Fischer, MD, MSPH, Department of Veterans Affairs, University of Illinois
Gregory Miller, PhD, Virginia Commonwealth University-Department of Pathology, VCU Health System
Joseph V. Nally Jr., MD, Cleveland Clinic Foundation
Andrew Narva, MD, National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health

The Panel met via conference call on Monday, October 1, 2013; both the requestor (KCP) and the measure developer (CMS and Arbor Research) participated on the call.

The Expert Panel's recommendation and comments received will be reviewed by the CSAC for a final decision on whether the measure should be amended. Their decision is then shared with the NQF Board of Directors for final ratification.

Summary of Expert Panel's Review and Conference Call of 10/1/13

The materials reviewed by the Expert Panel included KCP's request and submitted materials, NQF criteria and guidance regarding evaluating evidence, and CMS' recent Technical Expert Panel's recommendation. All the materials and the call recording can be accessed here under the *"Candidate Consensus Standards Review"* item.

Lisa McGonigal from KCP presented their rationale for requesting measure 0255 include plasma testing for phosphorus:

- Serum and plasma results are comparable
- An additional benefit with plasma testing is easier processing
- If serum and plasma testing are comparable, then the performance measure restricted only to serum testing would not be a valid reflection of quality of care

Dr. Joe Messana from Arbor Research, CMS' measure developer contractor, presented the CMS TEP's rationale for recommending that the measure not be changed to incorporate plasma testing:

- National and international guidelines specify serum testing
- A review of the peer reviewed literature found no evidence for comparability of serum and plasma testing specific to ESRD patients.

NQF Expert Panel discussion included the following key issues.

- Note: In follow-up communication, the Expert Panel clarified that the correct terminology to use is

"heparin plasma." There are several different types of plasma possible and only "heparin plasma" is suitable for use to measure phosphorous (for example, EDTA plasma is not suitable). All the discussion assumed heparin plasma.

- Clarified that the data submitted by KCP on study of bias in laboratory testing was conducted with ESRD patients but was focused only on serum testing and the variability across labs (Figures 9 and 10 on pdf page 34).
- Clarified that information in the appendix of the KCP letter (pdf p. 13) was the only data on matched plasma and serum samples and was based on small samples of 101 and 129. During the call, KCP sent and additional table and after the call, sent a summary document (also added to the call materials).
- The Expert Panel discussed laboratory testing procedures and noted the following:
    - the equipment used to measure phosphorus is FDA-approved for both serum and heparin plasma testing (see pdf p. 57)
    - generally, when ordered and reported, there is no designation if the sample was serum or heparin plasma
    - there is only one reference value for phosphorus, not different reference values for serum vs. heparin plasma results
    - current practice for many chemistry tests, including phosphorous, uses heparin plasma to avoid delays to allow serum to clot before measurement
    - there is only one lab code (LOINC) for phosphorus, not separate codes for serum and heparin plasma phosphorus
- Although the current guidelines (*KDOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease* and *KDIGO Guideline for Chronic Kidney Disease - Mineral and Bone Disorder*) specify serum phosphorus and the cited studies used serum phosphorus, the evidence does not specifically address the question of equivalency of serum and heparin plasma testing.
- The evidence to address the specific question of equivalency of serum and heparin plasma phosphorus testing in ESRD patients is not strong (small unpublished data); however, there is no evidence to indicate phosphorus testing in ESRD patients is different than for the general population.
- The biologic variability in phosphorus levels is larger than variability between serum and heparin plasma values.

Expert Panel Recommendation
The Panel recommended that measure 0255 be amended to include either serum or heparin plasma phosphorus testing – i.e., remove "serum" or add "heparin plasma" to the specifications. The Expert Panel noted that the key issue addressed in measure 0255 is whether phosphorus levels are monitored in ESRD patients and either serum or heparin plasma testing would be appropriate.

An intermediate outcome measure of maintaining phosphorus levels within a specified range was not recommended for endorsement in the prior project, due to insufficient evidence that lowering elevated levels was associated with improvement in survival or other outcomes. The recommended change to measure #0255 to accept either serum or plasma phosphorus testing would not necessarily be a barrier to such an intermediate outcome measure in the future if the evidence was sufficient including hopefully a greater evidence base specifically for ESRD regarding the variability between serum vs. heparin plasma phosphorus vlaues.

NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 0255 NQF Project: Renal Endorsement Maintenance 2011

(for Endorsement Maintenance Review)
Original Endorsement Date: Nov 15, 2007 Most Recent Endorsement Date: Nov 15, 2007

BRIEF MEASURE INFORMATION

De.1 Measure Title: Measurement of Serum Phosphorus Concentration

Co.1.1 Measure Steward: Centers for Medicare & Medicaid Services

De.2 Brief Description of Measure: Percentage of all adult (>= 18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum phosphorus measured at least once within month.

2a1.1 Numerator Statement: Number of adult (>= 18 years of age) dialysis patients included in denominator with serum phosphorus measured at least once within month

2a1.4 Denominator Statement: All adult peritoneal dialysis and hemodialysis patients included in the sample for analysis.

2a1.8 Denominator Exclusions: Transient dialysis patients (in unit < 30 days), pediatric patients and kidney transplant recipients with a functioning graft

1.1 Measure Type: Process
2a1. 25-26 Data Source: Electronic Clinical Data
2a1.33 Level of Analysis: Facility

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (*title and NQF number if endorsed*):
N/A

STAFF NOTES (*issues or questions regarding any criteria*)

Comments on Conditions for Consideration:

Is the measure untested? Yes☐ No☐ If untested, explain how it meets criteria for consideration for time-limited endorsement:

1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (*check De.5*):
5. Similar/related endorsed or submitted measures (*check 5.1*):
Other Criteria:

Staff Reviewer Name(s):

1. IMPACT, OPPORTUITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence.
Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. High Impact: H☐ M☐ L☐ I ☐
(*The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)

De.4 Subject/Topic Areas *(Check all the areas that apply)*: Renal, Renal : End Stage Renal Disease (ESRD)
De.5 Cross Cutting Areas (*Check all the areas that apply)*: Population Health

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, Frequently performed procedure, High resource use, Patient/societal consequences of poor quality

1a.2 If "Other," please describe:

1a.3 Summary of Evidence of High Impact *(Provide epidemiologic or resource use data)*:
In healthy individuals, the kidney occupies an integral, multi-faceted role in the maintenance of calcium-phosphorus homeostasis. It follows that abnormalities of calcium-phosphorus regulation are exceedingly common in patients with advanced chronic kidney disease, which, indeed, most data indicate that only 25-35% of dialysis patients are able to maintain calcium in the suggested target range of 8.4-9.5 mg/dL (KDOQI 2003). Numerous studies have demonstrated the impact of prolonged calcium-phosphorus dysregulation on patient morbidity and mortality (KDOQI 2003), which can lead to progressive bone weakness, bone pain and increased susceptibility to fractures, and severe arteriosclerosis that can precipitate strokes, heart attacks, and other adverse cardiac events. Unfortunately, overt symptoms can often remain unmanifested in many but the most extreme disordered states of calcium-phosphorus regulation, which is why routine blood tests are necessary to detect and monitor abnormal states of calcium and phosphorus balance in this especially vulnerable population.

1a.4 Citations for Evidence of High Impact cited in 1a.3: National Kidney Foundation. 2003. "K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease," American Journal of Kidney Disease, 42(Suppl 3): S17. Found at: http://www.kidney.org/professionals/kdoqi/guidelines_bone/index.htm

1b. Opportunity for Improvement: H☐ M☐ L☐ I ☐
(*There is a demonstrated performance gap - variability or overall less than optimal performance*)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:
Consistent monitoring of phosphorus levels helps ensure regulation of patient morbidity and mortality, including stabilization of bone density, decreased bone pain, fracture prevention and decreased rates of arteriosclerosis and related conditions (e.g., stroke, heart attack). Routine blood tests will also aid in detection of and monitoring for abnormal states phosphorus balance in this especially vulnerable population.

1b.2 Summary of Data Demonstrating Performance Gap *(Variation or overall less than optimal performance across providers)*:
[*For Maintenance – Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*]
The following statistics were generated from January 2010 CROWNWeb clinical data: mean(SD)=0.77(0.19); min=0.00; max=1.00; 25th percentile=0.71; 50th percentile=0.80; 75th percentile=0.88.

1b.3 Citations for Data on Performance Gap: [*For Maintenance – Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
The data reported in 1b.4 were generated from January 2010 CROWNWeb clinical data (3,475 facilities and 293,223 patients).

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance –Descriptive statistics for performance results for this measure by population group*]
To our knowledge, disparity in care (with respect to measurement of serum phosphorus) is an issue that has neither been systematically explored nor developed. It is unlikely to play a major role since phosphorus measurements are typically included in the routine blood screening covered by Medicare.

1b.5 Citations for Data on Disparities Cited in 1b.4: [*For Maintenance – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
N/A

1c. Evidence (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the measure focus a health outcome? Yes☐ No☐ If not a health outcome, rate the body of evidence.

Quantity: H☐ M☐ L☐ I☐ Quality: H☐ M☐ L☐ I☐ Consistency: H☐ M☐ L☐ I☐

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise No☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise No☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the measure pass subcriterion1c? Yes☐ IF rationale supports relationship

1c.1 Structure-Process-Outcome Relationship *(Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome)*:
The measure focus is the facility´s process of measuring serum phosphorus each month for ESRD dialysis patients. This process leads to improvement in mortality as follows: Measure serum phosphorus--> Assess value-->Identify problem-->Identify treatment options-->Administer the appropriate treatment-->Patient experiences improvement in mortality.

1c.2-3 Type of Evidence *(Check all that apply)*:
Clinical Practice Guideline, Selected individual studies (rather than entire body of evidence)

1c.4 Directness of Evidence to the Specified Measure *(State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population)*:
The body of evidence shows a relationship between prolonged calcium-phosphorus dysregulation and ESRD patient morbidity/mortality, which can lead to progressive bone weakness, bone pain and increased susceptibility to fractures, and severe arteriosclerosis that can precipitate strokes, heart attacks, and other adverse cardiac events.

1c.5 Quantity of Studies in the Body of Evidence *(Total number of studies, not articles)*: 6

1c.6 Quality of Body of Evidence (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events*): The submitting organization recognizes the opinion-based level of evidence supporting the KDIGO Clinical Practice Guidelines for measurement of serum concentration of phosphorus. As such, the overall quality of the body of evidence or the quality of individual studies is not rated in the KDIGO guidelines. Notwithstanding, research in many studies have observed that abnormalities of serum phosphorus concentration are common in the CKD population and that failure to monitor and correct such abnormalities are strongly associated with morbidity and mortality. Observational studies have shown a consistent adverse association of low serum phosphorus with all-cause mortality. Furthermore, the basic science supports a pathological role of low serum phosphorus and intracellular phosphorus depletion in disturbed cellular function.

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect):* Serum phosphorus is consistently demonstrated to be an important biomarker, strongly associated with adverse cardiovascular outcomes. In addition, the data from in-vitro and in-vivo animal studies establish the biologic plausibility of the adverse effects of inappropriate levels of serum phosphorus on cardiovascular outcomes. Observational data consistently report an increased level of cardiovascular events and mortality when serum phosphorus rises above the normal range in patients with Stage 5 CKD.

1c.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:

Monitoring phosphorus levels in the ESRD population reduces the likelihood that this susceptible population develops hyper- or hypophosphatemia, conditions that the body of evidence shows are strongly linked to adverse cardiovascular outcomes. A meta-analysis of the available literature (47 cohort studies) showed an 18% increase in mortality for every 1-mg/dL increase in serum phosphorus (RR=1.18, 95% CI=1.12-1.25) [30].

1c.9 Grading of Strength/Quality of the Body of Evidence. Has the body of evidence been graded? No

1c.10 If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: N/A

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: The body of evidence was not graded.

1c.13 Grade Assigned to the Body of Evidence: N/A

1c.14 Summary of Controversy/Contradictory Evidence: There are numerous observational studies that consistently demonstrate a (positive) correlation between mortality and phosphorus levels. However, to date, there are no randomized control trials that provide strong evidentiary support that would inform healthcare providers as to the best means of achieving appropriate phosphorus levels.

1c.15 Citations for Evidence other than Guidelines*(Guidelines addressed below)*:

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.Giachelli CM. Vascular calcification mechanisms. Journal of the American Society of Nephrology : JASN 2004 15:2959–2964.
12) 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.
13) Gauci C, Moranne O, Fouqueray B et al: Pitfalls of measuring total blood calcium in patients with CKD. Journal of the American Society of Nephrology 2008;1592-1598.
14) Foley RN, Parfrey PS, Harnett JD, et al. Hypocalcemia, morbidity, and mortality in end-stage renal disease. American journal of

nephrology 1996 16:386-93.
15) Koch M, Lund R, Oldemeyer B, Meares AJ, Dunlay R. Refeeding hypophosphatemia in a chronically hyperphosphatemic hemodialysis patient. Nephron 2000;86(4):552.
16) Travis SF, Sugerman HJ, Ruberg RL, Dudrick SJ, Delivoria-Papadopoulos M, Miller LD, Oski FA. Alterations of red-cell glycolytic intermediates and oxygen transport as a consequence of hypophosphatemia in patients receiving intravenous hyperalimentation. N Engl J Med. 1971 Sep 30;285(14):763-8.
17) Knochel JP. The pathophysiology and clinical characteristics of severe hypophosphatemia. Arch Intern Med. 1977 Feb;137(2):203-20.
18) Marinella MA. The refeeding syndrome and hypophosphatemia. Nutr Rev. 2003 Sep;61(9):320-3.
19) Lindsay RM; Daily/Nocturnal Dialysis Study Group. The London, Ontario, Daily/Nocturnal Hemodialysis Study. Semin Dial. 2004 Mar-Apr;17(2):85-91.
20) Walsh M, Manns BJ, Klarenbach S, Tonelli M, Hemmelgarn B, Culleton B. The effects of nocturnal compared with conventional hemodialysis on mineral metabolism: A randomized-controlled trial. Hemodial Int. 2009 Dec 22.
21) Drechsler C, Krane V, Grootendorst DC, et al. The association between parathyroid hormone and mortality in dialysis patients is modified by wasting. Nephrology, dialysis, transplantation : official publication of the European Dialysis and Transplant Association - European Renal Association 2009 24:3151-7.
22) Gao P, D´Amour P: Evolution of the parathyroid hormone (PTH) assay--importance of circulating PTH immunoheterogeneity and of its regulation. Clinical Laboratory 51(1-2):21-9, 2005.
23) Souberbielle JC, Boutten A, Carlier MC et al. Inter-method variability in PTH measurement: implication for the care of CKD patients. Kidney International 70(2):345-50, 2006.
24) Souberbielle JC, Roth H, Fouque DP. Parathyroid hormone measurement in CKD. Kidney International 2010 Jan;77(2):93-100.
25) Glassock RJ, Pecoits-Filho R, Barberato SH. Left ventricular mass in chronic kidney disease and ESRD. Clin J Am Soc Nephrol. 2009 Dec;4 Suppl 1:S79-91.
26) Genovesi S, Pogliani D, Faini A, Valsecchi MG, Riva A, Stefani F, Acquistapace I, Stella A, Bonforte G, DeVecchi A, DeCristofaro V, Buccianti G, Vincenti A. Prevalence of atrial fibrillation and associated factors in a population of long-term hemodialysis patients. American Journal of Kidney Disease 2005 Nov;46(5):897-902.
27) Vazquez E, Sanchez-Perales C, Garcia-Garcia F, Castellano P, Garcia-Cortes MJ, Liebana A, Lozano C. Atrial fibrillation in incident dialysis patients. Kidney International 2009 Aug;76(3):324-30.
28) Goodman WG, Goldin J, Kuizon BD et al: Coronary-artery calcification in young adults with end-stage renal disease who are undergoing dialysis. New England Journal of Medicine 2000 342(20):1478-83.
29) Shroff RC, et al. Chronic mineral dysregulation promotes vascular smooth muscle cell adaptation and extracellular matrix calcification. Journal of the American Society of Nephrology : JASN 2010; 21:103-112.
30) Palmer SC, et al. Serum levels of phosphorus, parathyroid hormone, and calcium and risks of death and cardiovascular disease in individuals with chronic kidney disease: a systematic review and meta-analysis. Journal of the American Medical Association : JAMA 2011;305(11):1119-27.

1c.16 Quote verbatim, the specific guideline recommendation *(Including guideline # and/or page #)*:
"3.1.2 In patients with CKD stages 3-5D, it is reasonable to base the frequency of monitoring serum calcium, phosphorus, and PTH on the presence and magnitude of abnormalities, and the rate of progression of CKD. Reasonable monitoring intervals would be:

"...In CKD stages 5, including 5D: for serum calcium and phosphorus, every 1-3 months; and for PTH, every 3-6 months.

"In CKD patients receiving treatments for CKD-MBD, or in whom biochemical abnormalities are identified, it is reasonable to increase the frequency of measurements to monitor for trends and treatment efficacy and side-effects."

1c.17 Clinical Practice Guideline Citation: Kidney Disease: Improving Global Outcomes (KDOGI). KDIGO Clinical Practice Guideline for the Diagnosis, Evaluation, Prevention, and Treatment of Chronic Kidney Disease-Mineral and Bone Disorder (CKD-MBD). In Chapter 3.1: Diagnosis of CKD-MBD: biochemical abnormalities. Kidney International : 2009;76(Suppl 113);S22-S49.

1c.18 National Guideline Clearinghouse or other URL: http://www.kdigo.org/guidelines/mbd/guide3.html#chap31

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? No

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation

and any disclosures regarding bias:

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: The guideline recommendation was not graded.

1c.23 Grade Assigned to the Recommendation: N/A

1c.24 Rationale for Using this Guideline Over Others: No other guidelines are available.

Based on the NQF descriptions for rating the evidence, what was the developer's assessment of the quantity, quality, and consistency of the body of evidence?
1c.25 Quantity: High 1c.26 Quality: High1c.27 Consistency: High

Was the threshold criterion, *Importance to Measure and Report*, met?
(*1a & 1b must be rated moderate or high and 1c yes*) Yes☐ No☐
Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - 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)
Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.

S.1 Measure Web Page *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained*). Do you have a web page where current detailed specifications for this measure can be obtained? Yes

S.2 If yes, provide web page URL: http://www.arborresearch.org/ESRD_QMS.aspx

2a. RELIABILITY. Precise Specifications and Reliability Testing: H☐ M☐ L☐ I☐

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 Numerator Statement *(Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)*:
Number of adult (>= 18 years of age) dialysis patients included in denominator with serum phosphorus measured at least once within month

2a1.2 Numerator Time Window *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:
One month

2a1.3 Numerator Details *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses*:
The numerator comprises all eligible patients who, during the 1-month study period, have a non-missing value in for the variable "Serum Phosphorus"

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
All adult peritoneal dialysis and hemodialysis patients included in the sample for analysis.

2a1.5 Target Population Category *(Check all the populations for which the measure is specified and tested if any)*: Adult/Elderly Care

2a1.6 Denominator Time Window *(The time period in which cases are eligible for inclusion)*:
One month

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
The denominator comprises all patients who, during the 1 month study period, have an "Admit Date" prior or equal to the first day of the month; whose "Discharge Date" is blank or greater than or equal to the last day of the month; whose "Primary Type of Treatment" = ´Hemodialysis,´ ´CAPD´ or ´CCPD´ on the last day of the study period; and whose "Primary Dialysis Setting" = ´Dialysis Facility/Center´ on the last day of the Study Period

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
Transient dialysis patients (in unit < 30 days), pediatric patients and kidney transplant recipients with a functioning graft

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
We exclude records with an "Admit Date" later than the first day of the study month or with a "Discharge Date" less than the last day of the study month. We also exclude patients whose age is less than 18 years. For all CROWNWeb-collected measures, we make a global exclusion for patients not on either HD or PD, which includes kidney transplant recipients with a functioning graft.

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses)*:
N/A

2a1.11 Risk Adjustment Type *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*: No risk adjustment or risk stratification 2a1.12 If "Other," please describe:

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.)*:
N/A

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:

2a1.17-18. Type of Score: Rate/proportion

2a1.19 Interpretation of Score *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*: Better quality = Higher score

2a1.20 Calculation Algorithm/Measure Logic*(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)*:
1. Using CROWNWeb-reported data (data stored as SAS files), identify the number of adult HD and PD patients under the care of a facility.
2. From this group, remove patients who were not in the facility for the entirety of the month (i.e., transient patients).
3. To form the denominator, remove from this group any kidney transplant recipients with a functioning graft.
4. To form the numerator, remove all denominator-eligible patients who do not have a serum phosphorus (variable name, "phosphorus") measurement for the study month.
5. Calculate the facility´s rate of serum phosphorus measurement by dividing the number calculated in Step 3 (the denominator) by

the number calculated in Step 4 (the numerator).

2a1.21-23 Calculation Algorithm/Measure Logic Diagram URL or attachment:
Attachment
Phos_Calculation_Flowchart.pdf

2a1.24 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

2a1.25 Data Source *(Check all the sources for which the measure is specified and tested*). If other, please describe:
Electronic Clinical Data

2a1.26 Data Source/Data Collection Instrument (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): CROWNWeb

2a1.27-29 Data Source/data Collection Instrument Reference Web Page URL or Attachment: URL
www.projectcrownweb.org

2a1.30-32 Data Dictionary/Code Table Web Page URL or Attachment:
URL
http://projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents

2a1.33 Level of Analysis (*Check the levels of analysis for which the measure is specified and tested)*: Facility

2a1.34-35 Care Setting *(Check all the settings for which the measure is specified and tested)*: Dialysis Facility

2a2. Reliability Testing. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability*.)

2a2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
We analyzed CROWNWeb data from July 2009 - October 2010. The number of facilities ranged from 3393 - 3581; the total number of patients per month ranged from 263,430 - 330,187.

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:
We assessed reliability by calculating facility-level Pearson correlation coefficients between the current performance month and the preceding month for reporting months August 2009 - October 2010.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Reliability of this measure has improved over time. Correlation coefficients ranged from 0.66 to 0.95. The lowest correlation was observed in the first reporting month (August 2009 compared with July 2009). In 2010, correlations from month-to-month were high (range: 0.74-0.95), indicating the data elements for this measure are reliable.

2b. VALIDITY. Validity, Testing, including all Threats to Validity: H☐ M☐ L☐ I ☐

2b1.1 Describe how the measure specifications *(measure focus, target population, and exclusions)* are consistent with the evidence cited in support of the measure focus (*criterion 1c)* and identify any differences from the evidence:
The target population in the validity analysis comprised all adult, non-transient ESRD patients reported in CROWNWeb in 2009. The population and results from the validity analyses performed were consistent with the evidence provided. The validity analyses showed that relative to facilities with the highest performance scores, the Standardized Mortality Ratio (SMR) increased as performance scores decreased.

2b2. Validity Testing. (*Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.)*

2b2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
We used July 2009 - October 2010 CROWNWeb data to calculate monthly performance scores, and 2009 Medicare-paid dialysis claims and the Medical Evidence Form (Form CMS-2728) to calculate the SMR. Documentation regarding the Medicare claims used to calculate the SMR is attached.

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
We assessed validity using Poisson regresion models to measure the association between facility level quintiles of performance scores and the 2009 SMR (methodology on SMR calculations is attached). Facility-level performance scores were divided into quintiles, and the relative risk (RR) of mortality was calculated for each quintile. The highest quintile represented the reference group. Thus, a RR>1.0 for the lower performance score quintiles would indicate a higher relative risk of mortality.

2b2.3 Testing Results *(Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)*:
Quintiles of the performance scores were defined as follows:
Q1:0-<74%
Q2:74%-<81%
Q3:81%-<86%
Q4:86%-<90%
Q5:90%-100%
Results from the Poisson model indicated lower performance scores were significantly associated with SMR (p<0.001). Relative risks of mortality was highest in the lowest performance measure quintile (RR=1.17;95% CI: 1.13-1.21). The RR for Q2 was 1.13 (95% CI:1.09-1.17), for Q3 was 1.12 (95% CI:1.08-1.16) and for Q4 was 1.09 (95% CI:1.06-1.13).
These findings confirm the association between frequent (monthly) evaluation of hemodialysis adequacy and improved mortality.

POTENTIAL THREATS TO VALIDITY. (*All potential threats to validity were appropriately tested with adequate results.*)

2b3. Measure Exclusions. (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

2b3.1 Data/Sample for analysis of exclusions *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
CROWNWeb data from July 2009 through October 2010 included up to 3581 facilities per month, with an average of 86 patients per facility. The total number of patients per month ranged from 263,430 to 330,187. We excluded patients who were not in the facility for the entirety of the reporting month.

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference)*:
N/A

2b3.3 Results *(Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):*
N/A

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

2b4.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
No risk adjustment is performed for this measure.

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables)*:
N/A

2b4.3 Testing Results *(Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot,*

and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata):
N/A

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: We observed no disparities by population group (see results in Section 1b.4). Furthermore, there is no evidence suggesting this measure should be risk adjusted.

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

2b5.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
We performed analyses using CROWNWeb data from January 2010. There were 3475 facilities and a total of 293,223 patients in this reporting month. Mean number of patients per facility was 84 (SD=52).

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)*:
We calculated facility-level rates of monthly serum phosphorus measurements as the number of patients within the facility with serum phosphorus reported divided by the total number of eligible patients in the facility. We also calculated the mean, SD and quartiles.

2b5.3 Results *(Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
Analysis of CROWNWeb data from January 2010 indicated the mean percentage of patients with a monthly serum phosphorus measurement was 77% (SD=19%). Distribution: Min=0%, Max=100%, 1st quartile=71%, median=80%, 3rd quartile=88%.
These results indicate that on average, facilties are not measuring serum phosphorus in 20% of patients. Furthermore, during this month some facilities measured none of their patients, and up to 25% of facilities measured serum phosphorus in only 71% of patients.

2b6. Comparability of Multiple Data Sources/Methods. (*If specified for more than one data source, the various approaches result in comparable scores.*)

2b6.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
We used only one data source (CROWNWeb).

2b6.2 Analytic Method *(Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)*:
N/A

2b6.3 Testing Results *(Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted)*:
N/A

2c. Disparities in Care: H☐ M☐ L☐ I ☐ NA☐ (*If applicable, the measure specifications allow identification of disparities.*)

2c.1 If measure is stratified for disparities, provide stratified results *(Scores by stratified categories/cohorts)*: N/A

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:
N/A

2.1-2.3 Supplemental Testing Methodology Information:

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?
(*Reliability and Validity must be rated moderate or high*) Yes☐ No☐
Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (evaluation criteria)

C.1 Intended Purpose/ Use *(Check all the purposes and/or uses for which the measure is intended)*: Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3.1 Current Use *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*: Public Health/ Disease Surveillance, Regulatory and Accreditation Programs, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization)

3a. Usefulness for Public Reporting: H☐ M☐ L☐ I ☐
(*The measure is meaningful, understandable and useful for public reporting.*)

3a.1. Use in Public Reporting - disclosure of performance results to the public at large *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s)).* If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [*For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*]
CROWNWeb national rollout is planned for early 2012. Quality measure results will then be evaluated for public reporting, potentially on Medicare's Dialysis Facility Compare website.

3a.2.Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results:
Meaningful: Serum phosphorus monitoring in the ESRD population will help ensure reduced mortality and morbidity for these already susceptible patients, many of whom have several comorbidities.
Understandable: Both patients and healthcare providers understand the process of monitoring, as well as the fact that this mineral being out of a "normal" range can cause adverse outcomes. Furthermore, this measure has been reported in previous ESRD CPM Annual Reports (publicly available).

3.2 Use for other Accountability Functions (payment, certification, accreditation). If used in a public accountability program, provide name of program(s), locations, Web page URL(s): N/A

3b. Usefulness for Quality Improvement: H☐ M☐ L☐ I ☐
(*The measure is meaningful, understandable and useful for quality improvement.*)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):
[*For Maintenance – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].
N/A

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. If usefulness was demonstrated *(e.g., QI initiative),* describe the data, method and results:
Although this measure is not currently used in a quality improvement program, it has previously been included in ESRD CPM Annual Reports. The ESRD CPM Project was a national effort designed by CMS to assist dialysis providers to improve patiet care and outcomes.

Overall, to what extent was the criterion, *Usability*, met? H☐ M☐ L☐ I ☐

Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. (evaluation criteria)

4a. Data Generated as a Byproduct of Care Processes: H☐ M☐ L☐ I ☐

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition, Coded by someone other than person obtaining original information (e.g., DRG, ICD-9 codes on claims), Abstracted from a record by someone other than person obtaining original information (e.g., chart abstraction for quality measure or registry)

4b. Electronic Sources: H☐ M☐ L☐ I ☐

4b.1 Are the data elements needed for the measure as specified available electronically *(Elements that are needed to compute measure scores are in defined, computer-readable fields)*: ALL data elements in electronic health records (EHRs)

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources:

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H☐ M☐ L☐ I ☐

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:
There are no significant potential barriers to retrieving the needed data, and there are no data availability issues.

4d. Data Collection Strategy/Implementation: H☐ M☐ L☐ I ☐

A.2 Please check if either of the following apply (*regarding proprietary measures*):
4d.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 and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues *(e.g., fees for use of proprietary measures)*:
Because this measure has been collected for several years as part of the CPM project, facilities are familiar with the data required for this measure, and data are readily available. It is unlikely that data elements will be susceptible to inaccuracies or errors.

Overall, to what extent was the criterion, *Feasibility*, met? H☐ M☐ L☐ I ☐
Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes☐ No☐
Rationale:

If the Committee votes No, STOP.
If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population*), list the NQF # and title of all related and/or competing measures:
0261 : Measurement of Serum Calcium Concentration

5a. Harmonization
5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s): Are the measure specifications completely harmonized? 5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:
5b. Competing Measure(s)
5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s): Describe why this measure is superior to competing measures *(e.g., a more valid or efficient way to measure quality);* OR provide a rationale for the additive value of endorsing an additional measure. *(Provide analyses when possible)*:

CONTACT INFORMATION
Co.1 Measure Steward (Intellectual Property Owner): Centers for Medicare & Medicaid Services, 7500 Security Boulevard , Mail Stop S3-01-02, Baltimore, Maryland, 21244-1850 Co.2 Point of Contact: Edward Q., Garcia III, MHS, Health Policy Analyst, MMSNQF@hsag.com, 410-786-6738-
Co.3 Measure Developer if different from Measure Steward: Arbor Research Collaborative for Health/University of Michigan Kidney Epidemiology & Cost Center, 340 East Huron Street, Ste 300, Ann Arbor, Michigan, 48104 Co.4 Point of Contact: Claudia, Dahlerus, claudia.dahlerus@arborresearch.org, 734-665-4108-
Co.5 Submitter: Claudia, Dahlerus, claudia.dahlerus@arborresearch.org, 734-665-4108-, Arbor Research Collaborative for Health/University of Michigan Kidney Epidemiology & Cost Center
Co.6 Additional organizations that sponsored/participated in measure development:
Co.7 Public Contact: ESRD Quality Measures, Help Desk, ESRD_Quality_Measures@ArborResearch.org, 877-665-1680-, Arbor Research Collaborative for Health

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. TEP convened for original measure submission in 2006: Matt Howard (ESRD Network 15) Raynel Kinney (ESRD Network 9) Chris Lovell (DCI) Norma Ofsthun (Fresenius)
Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward: N/A
Measure Developer/Steward Updates and Ongoing Maintenance Ad.3 Year the measure was first released: 2008 Ad.4 Month and Year of most recent revision: Ad.5 What is your frequency for review/update of this measure? Every 3 years Ad.6 When is the next scheduled review/update for this measure? 06, 2013
Ad.7 Copyright statement:

Ad.8 Disclaimers:
Ad.9 Additional Information/Comments: This form was revised on November 17, 2011. The items revised were 1c.6, 1c.7, and 3.1.
Date of Submission (*MM/DD/YY*): 06/23/2011

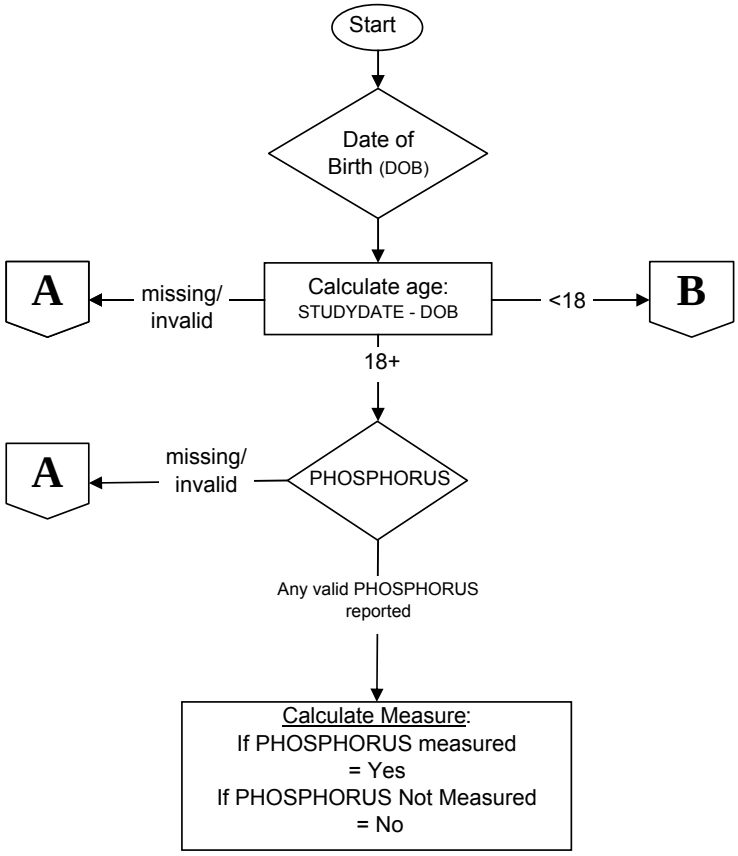
Mineral Metabolism

CPM I: Measurement of Serum Phosphorus

Numerator: Number of adult dialysis patients included in denominator with serum phosphorus measured at least once within the study measurement period. Study measurement periods are 1 month for in-unit HD for a total 3-month study period and 2 months for PD and home HD for a total 6-month study period.

Denominator: All adult (≥ 18 years old) peritoneal dialysis and hemodialysis patients included in the sample for analysis.

Exclusions: Transient dialysis patients (in this center < 30 days), acute HD, pediatric patients and kidney transplant patients.



A Excluded due to missing/invalid data

B Exclude for failing to meet inclusion criteria

Mineral Metabolism

0255 Measurement of Serum Phosphorus Concentration Specifications Submission
Description: Percentage of all adult (>= 18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum phosphorus measured at least once within month. Numerator Statement: Number of adult (>= 18 years of age) dialysis patients included in denominator with serum phosphorus measured at least once within month Denominator Statement: All adult peritoneal dialysis and hemodialysis patients included in the sample for analysis. Exclusions: Transient dialysis patients (in unit < 30 days), pediatric patients and kidney transplant recipients with a functioning graft Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A Level of Analysis: Facility Type of Measure: Process Data Source: Electronic Clinical Data Measure Steward: Centers for Medicare & Medicaid Services
1.Importance to Measure and Report (based on decision logic): Workgroup: Yes Steering Committee: Y-20; N-2 1a. Impact: Workgroup: H-7; M-1; L-1; I-0 1b. Performance Gap: Workgroup: H-0; M-4; L-4; I-1 Rationale: 1a. Impact - Serum phosphorus level has substantial associated clinical consequences. 1b. Performance Gap- The preliminary ratings were spread across all the rating categories. One member questioned whether the performance gap data indicating an average performance of 77% was accurate because most if not all inpatient dialysis facilities are already capturing phosphorus levels of those patients who are treated in the facility. After further discussion, the workgroup agreed that there is a performance gap for this measure. 1c. Evidence (based on decision logic): Workgroup: Yes Quantity: Workgroup: H-3; M-6; L-0; I-0 Quality: Workgroup: H-0; M-6; L-3-; I-0 Consistency: Workgroup: H-3; M-4; L-2; I-0 Rationale: The evidence is indirect, i.e., it is about the association between phosphorus and mortality rather than the frequency of assessment and there was no information submitted about any studies that show a decrease in phosphorus levels will lead to better mortality outcomes. A Committee member noted the inferiority of a measure simply of the frequency of assessment, given the recent NQF guidance on the evaluation criteria. However, the evidence does not support a measure of a specific phosphorus value (also noted by KDIGO). One member noted that the evidence of the association between phosphorus levels and mortality (18% increase in mortality for every 1 mg/dL increase in serum phosphorus) is much stronger than for the association with calcium or PTH. Additionally, the information presented in validity testing demonstrated an association between facility performance on this measure and the facility standardized mortality ratio. While there is excellent evidence correlating phosphorus levels with mortality, there is no evidence that intervention to lower phosphorus levels affects clinical outcomes. Furthermore, there is no evidence that monthly monitoring of phosphorus leads to improved outcomes. Nonetheless, given the absence of such evidence, the preponderance of evidence suggests that very high phosphorus levels should be followed and treated. Several committee members commented that even if one concedes that it should be monitored, there probably is no need to do so on a monthly basis. Another committee member noted that there is no data one way or the other for frequency. Monthly measurement is primarily a function of usual practice because it is paid for on a monthly basis with other lab tests. 2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: Yes Steering Committee: Y-19; N-3 2a. Reliability: Workgroup: H-5; M-3; L-1; I-0 2b. Validity: Workgroup: H-3; M-5; L-1; I-0 Rationale: 2a. Reliability The preliminary reliability ratings were mixed, but CMS did submit additional reliability testing that indicated the interunit reliability was 0.94. 2b. Validity – Validity testing demonstrated association between facility performance on this measure and the facility standardized mortality ratio. The lowest quintile of performance on this assessment measure had a 17% greater risk of mortality than the highest performing quintile; and the risk of mortality decreased as the quintile of performance increased. 3. Usability: Workgroup: H-6; M-1; L-2; I-0 Steering Committee: H-8; M-11; L-3; I-0 Rationale: Because of the limitations already noted under evidence, some Committee members did not think this measure would be that useful for evaluating quality.

0255 Measurement of Serum Phosphorus Concentration Specifications Submission
4. Feasibility: Workgroup: H-7; M-2; L-0; I-0 Steering Committee: H-16; M-5; L-1; I-0 Rationale: Phosphorus is measurable and should be relatively easy to get. Assessment of Criteria Met/Suitable for Endorsement: Workgroup: Y-6; N-2 Rationale: One member noted that while it is an important issue, it is going to be measured as a part of a patient's general care plan and should not necessarily be a performance measure. Some Committee members were concerned about misinterpretation of the importance if no measure related to serum phosphorus was recommended. For phosphorus, the correlative data to survival is so remarkably strong that it is important enough to be a performance measure.
Steering Committee Recommendation for Endorsement: Y-19; N-3 Rationale: Phosphorus has the greatest implications for mortality. However, the current state of science does not suggest a measure of intermediate outcome or intervention, so a measure of assessment frequency is the best that could be implemented.
Public and Member Comment Comments included: • endorse only for 2-3 years until replaced with intermediate outcome; • put in reserve status All NQF endorsed measures must undergo evaluation for continued endorsement every 3 years. Whether an intermediate outcome or intervention measure can be developed is dependent on the state of the science to support identifying specific levels that determine optimal care or effective interventions. The measure does not qualify for reserve status because it is not proximal to desired outcomes.