**National Quality Forum—Evidence (subcriterion 1a)**

**Measure Number** (*if previously endorsed*)**:** 0255

**Measure Title**: Measurement of Serum Phosphorus Concentration

**IF the measure is a component in a composite performance measure, provide the title of the Composite Measure here:** Click here to enter composite measure #/ title

**Date of Submission**: Click here to enter a date

|  |
| --- |
| **Instructions**  *For composite performance measures:*  *A separate evidence form is required for each component measure unless several components were studied together.*  *If a component measure is submitted as an individual performance measure, attach the evidence form to the individual measure submission.*   * Respond to all questions as instructed with answers immediately following the question. All information needed to demonstrate meeting the evidence subcriterion (1a) must be in this form. An appendix of *supplemental* materials may be submitted, but there is no guarantee it will be reviewed. * If you are unable to check a box, please highlight or shade the box for your response. * Maximum of 10 pages (*incudes questions/instructions*; minimum font size 11 pt; do not change margins). ***Contact NQF staff if more pages are needed.*** * Contact NQF staff regarding questions. Check for resources at [Submitting Standards webpage](http://www.qualityforum.org/Measuring_Performance/Submitting_Standards.aspx). |

|  |
| --- |
| **Note: The information provided in this form is intended to aid the Steering Committee and other stakeholders in understanding to what degree the evidence for this measure meets NQF’s evaluation criteria.**   1a. Evidence to Support the Measure Focus The measure focus is evidence-based, demonstrated as follows:   * Health outcome: [**3**](#Note3) a rationale supports the relationship of the health outcome to processes or structures of care. Applies to patient-reported outcomes (PRO), including health-related quality of life/functional status, symptom/symptom burden, experience with care, health-related behavior. * Intermediate clinical outcome: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4)that the measured intermediate clinical outcome leads to a desired health outcome. * Process: [**5**](#Note5) a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured process leads to a desired health outcome. * Structure: a systematic assessment and grading of the quantity, quality, and consistency of the body of evidence [**4**](#Note4) that the measured structure leads to a desired health outcome. * Efficiency: [**6**](#Note6) evidence not required for the resource use component.   **Notes**  **3.** Generally, rare event outcomes do not provide adequate information for improvement or discrimination; however, serious reportable events that are compared to zero are appropriate outcomes for public reporting and quality improvement.  **4.** The preferred systems for grading the evidence are the U.S. Preventive Services Task Force (USPSTF) [grading definitions](http://www.uspreventiveservicestaskforce.org/uspstf/grades.htm) and [methods](http://www.uspreventiveservicestaskforce.org/methods.htm), or Grading of Recommendations, Assessment, Development and Evaluation [(GRADE) guidelines](http://www.gradeworkinggroup.org/publications/index.htm).  **5.** Clinical care processes typically include multiple steps: assess → identify problem/potential problem → choose/plan intervention (with patient input) → provide intervention → evaluate impact on health status. If the measure focus is one step in such a multistep process, the step with the strongest evidence for the link to the desired outcome should be selected as the focus of measurement. Note: A measure focused only on collecting PROM data is not a PRO-PM.  **6.** Measures of efficiency combine the concepts of resource use and quality (see NQF’s [Measurement Framework: Evaluating Efficiency Across Episodes of Care](http://www.qualityforum.org/Publications/2010/01/Measurement_Framework__Evaluating_Efficiency_Across_Patient-Focused_Episodes_of_Care.aspx); [AQA Principles of Efficiency Measures](http://www.aqaalliance.org/files/PrinciplesofEfficiencyMeasurementApril2006.doc)). |

**1a.1.This is a measure of**: (*should be consistent with type of measure entered in De.1*)

Outcome

Health outcome: Click here to name the health outcome

Patient-reported outcome (PRO): Click here to name the PRO

*PROs include HRQoL/functional status, symptom/symptom burden, experience with care, health-related behaviors*

Intermediate clinical outcome (*e.g., lab value*): Click here to name the intermediate outcome

Process: Measurement of phosphorus

Structure: Click here to name the structure

Other: Click here to name what is being measured

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**HEALTH OUTCOME/PRO PERFORMANCE MEASURE**  *If not a health outcome or PRO, skip to* [*1a.3*](#Section1a3)

**1a.2.** **Briefly state or diagram the path between the health outcome (or PRO) and the healthcare structures, processes, interventions, or services that influence it.**

N/A

**1a.2.1.** **State the rationale supporting the relationship between the health outcome (or PRO) to at least one healthcare structure, process, intervention, or service (*i.e., influence on outcome/PRO*).**

N/A

*Note: For health outcome/PRO performance measures, no further information is required; however, you may provide evidence for any of the structures, processes, interventions, or service identified above.*

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**intermediate outcome, PROCESS, or STRUCTURE PERFORMANCE measure**

**1a.3.****Briefly state or diagram the path between structure, process, intermediate outcome, and health outcomes**. Include all the steps between the measure focus and the health outcome.

The measure focus is the facility´s process of measuring serum or plasma phosphorus each month for ESRD dialysis patients. This process leads to improvement in mortality as follows: Measure serum or plasma phosphorus--> Assess value-->Identify problem-->Identify treatment options-->Administer the appropriate treatment-->Patient experiences improvement in mortality.

**1a.3.1.** **What is the source of the systematic review of the body of evidence that supports the performance measure?**

Clinical Practice Guideline recommendation – ***complete sections*** [***1a.4***](#Section1a4)***, and*** [***1a.7***](#Section1a7)

US Preventive Services Task Force Recommendation – ***complete sections*** [***1a.5***](#Section1a5) ***and*** [***1a.7***](#Section1a7)

Other systematic review and grading of the body of evidence (*e.g., Cochrane Collaboration, AHRQ Evidence Practice Center*) – ***complete sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)

Other – ***complete section*** [***1a.8***](#Section1a8)

*Please complete the sections indicated above for the source of evidence. You may skip the sections that do not apply.*

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.4. CLINICAL PRACTICE GUIDELINE RECOMMENDATION**

**1a.4.1.** **Guideline citation** (*including date*) and **URL for guideline** (*if available online*):

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 (CKDMBD). In Chapter 3.1: Diagnosis of CKD-MBD: biochemical abnormalities. Kidney International: 2009;76 (Suppl 113);S22-S49. http://kdigo.org/home/mineral-bone-disorder/

**1a.4.2.** **Identify guideline recommendation number and/or page number** and **quote verbatim, the specific guideline recommendation**.

"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."

**1a.4.3.** **Grade assigned to the quoted recommendation with definition of the grade:**

The recommendation has not been graded.

**1a.4.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: If separate grades for the strength of the evidence, report them in section 1a.7.*)

N/A

**1a.4.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.4.1*)**:**

N/A

**1a.4.6. If guideline is evidence-based (rather than expert opinion), are the details of the quantity, quality, and consistency of the body of evidence available (e.g., evidence tables)?**

Yes **→ *complete section*** [***1a.7***](#Section1a7)

No **→ *report on another systematic review of the evidence in sections*** [***1a.6***](#Section1a6) ***and*** [***1a.7***](#Section1a7)***; if another review does not exist, provide what is known from the guideline review of evidence in*** [***1a.7***](#Section1a7)

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.5.** **UNITED STATES PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

**1a.5.1.** **Recommendation citation** (*including date*) and **URL for recommendation** (*if available online*):

N/A

**1a.5.2.** **Identify recommendation number and/or page number** and **quote verbatim, the specific recommendation**.

N/A

**1a.5.3.** **Grade assigned to the quoted recommendation with definition of the grade**:

N/A

**1a.5.4. Provide all other grades and associated definitions for recommendations in the grading system.** (*Note: the* *grading system for the evidence should be reported in section 1a.7.*)

N/A

**1a.5.5. Citation and URL for methodology for grading recommendations** (*if different from 1a.5.1*)**:**

N/A

***Complete section*** [***1a.7***](#Section1a7)

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.6. OTHER SYSTEMATIC REVIEW OF THE BODY OF EVIDENCE**

**1a.6.1.** **Citation** (*including date*) and **URL** (*if available online*):

N/A

**1a.6.2.** **Citation and** **URL for methodology for evidence review and grading** (*if different from 1a.6.1*)**:**

N/A

***Complete section*** [***1a.7***](#Section1a7)

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.7. FINDINGS FROM SYSTEMATIC REVIEW OF BODY OF THE EVIDENCE supporting the measure**

*If more than one systematic review of the evidence is identified above, you may choose to summarize the one (or more) for which the best information is available to provide a summary of the quantity, quality, and consistency of the body of evidence. Be sure to identify which review is the basis of the responses in this section and if more than one, provide a separate response for each review.*

**1a.7.1.** **What was the specific structure, treatment, intervention, service, or intermediate outcome addressed in the evidence review?**

N/A

**1a.7.2.** **Grade assigned for the quality of the quoted evidence with definition of the grade**:

N/A

**1a.7.3. Provide all other grades and associated definitions for strength of the evidence in the grading system.**

N/A

**1a.7.4.** **What is the time period covered by the body of evidence? (*provide the date range, e.g., 1990-2010*). Date range**: Click here to enter date range

N/A

**QUANTITY AND QUALITY OF BODY OF EVIDENCE**

**1a.7.5.****How many and what type of study designs are included in the body of evidence**? (*e.g., 3 randomized controlled trials and 1 observational study*)

N/A

**1a.7.6.** **What is the overall quality of evidence across studies in the body of evidence**? (*discuss the certainty or confidence in the estimates of effect particularly in relation to study factors such as design flaws, imprecision due to small numbers, indirectness of studies to the measure focus or target population*)

N/A

**ESTIMATES OF BENEFIT AND CONSISTENCY ACROSS STUDIES IN BODY OF EVIDENCE**

**1a.7.7.** **What are the estimates of benefit—magnitude and direction of effect on outcome(s) across studies in the body of evidence**? (*e.g., ranges of percentages or odds ratios for improvement/ decline across studies, results of meta-analysis, and statistical significance*)

N/A

**1a.7.8.** **What harms were studied and how do they affect the net benefit (benefits over harms)?**

N/A

**UPDATE TO THE SYSTEMATIC REVIEW(S) OF THE BODY OF EVIDENCE**

**1a.7.9.** **If new studies have been conducted since the systematic review of the body of evidence, provide for each new study: 1) citation, 2) description, 3) results, 4) impact on conclusions of systematic review**.

N/A

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**1a.8 OTHER SOURCE OF EVIDENCE**

*If source of evidence is NOT from a clinical practice guideline, USPSTF, or systematic review, please describe the evidence on which you are basing the performance measure.*

**1a.8.1** **What process was used to identify the evidence?**

The following list is comprised of published evidence reviewed by members of the three separate clinical technical expert panels that were involved in the development and maintenance of this measure (2006 TEP; 2010 TEP; 2013 TEP). 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 efficacy of phosphorus lowering strategies on improvement in clinical outcomes.

An additional two pieces of evidence were added to this list in spring of 2014, as a result of a literature review. One recent publication reports on the association between intermediate bone and mineral outcomes and survival in a large French dialysis cohort. [38]. In addition, a post hoc secondary analysis of the AURORA Trial, a prospective multicenter interventional trial of statin use in chronic dialysis patients, evaluated the association between cardiovascular outcomes and non-traditional clinical parameters, including serum phosphorus [39]. Our updated literature review did not uncover any new evidence from prospective, interventional trials informing specific measure development or re-specification of current measures. Finally, Rivara et al, found elevated concentrations of serum phosphorous were associated with increased risk of mortality [40]. Our updated literature review did not uncover any new evidence from prospective, interventional trials informing specific measure development or re-specification of current measures.

**1a.8.2.** **Provide the citation and summary for each piece of evidence.**

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 redcell 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 PTHimmunoheterogeneity 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. Abramowitz M, Muntner P, Coco M, et al. "Serum alkaline phosphatase and phosphate and risk of mortality and hospitalization." Clinical journal of the American Society of Nephrology : CJASN (2010) 5:1064-71. PMID: 20378645
31. Benner D, Nissenson AR, Van Wyck D. "Focused clinical campaign improves mineral and bone disorder outcomes." Journal of renal care (2012) 38:2-8. PMID: 22369592
32. Davenport A, Gardner C, Delaney M, et al. "Do differences in dialysis prescription impact on KDOQI bone mineral targets? The Pan Thames Renal Audit." Blood purification (2010) 30:111-7. PMID: 20714141
33. Floege J, Kim J, Ireland E, et al. "Serum iPTH, calcium and phosphate, and the risk of mortality in a European haemodialysis population." Nephrology, dialysis, transplantation : official publication of the European Dialysis and Transplant Association - European Renal Association (2011) 26:1948-55. PMID: 20466670
34. Gutiérrez OM, Anderson C, Isakova T, et al. "Low socioeconomic status associates with higher serum phosphate irrespective of race." Journal of the American Society of Nephrology : JASN (2010) 21:1953-60. PMID: 20847142
35. Navaneethan SD, Palmer SC, Vecchio M, et al. "Phosphate binders for preventing and treating bone disease in chronic kidney disease patients." Cochrane database of systematic reviews (Online) (2011):CD006023. PMID: 21328279
36. Shanahan CM, Crouthamel MH, Kapustin A, et al. "Arterial calcification in chronic kidney disease: key roles for calcium and phosphate." Circulation research (2011) 109:697-711. PMID: 21885837
37. 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.
38. Fouque D, Roth H, Pelletier S et al. Control of mineral metabolism and bone disease in haemodialysis patients: which optimal targets? Nephrol Dial Transplant 28: 360–367, 2013
39. Schneider A, Jardine A, Schneider M et al. Determinants of Cardiovascular Risk in Haemodialysis Patients: Post hoc Analyses of the AURORA StudyAm J Nephrol 37:144–151, 2013
40. Rivara M, Ravel V, Kalantar-Zadeh K et al. Uncorrected and Albumin-Corrected Calcium, Phosphorus, and Mortality in Patients Undergoing Maintenance Dialysis. J Am Soc Nephrol 26: 2015