CBE ID

4650

Title

Facility Level Percentage of Chronic Hyperphosphatemia in Dialysis Patients

Project

Management of Acute Events, Chronic Disease, Surgery, and Behavioral Health

Endorsement Status

Endorsed

Is Under Review

No

Next Maintenance Cycle

Fall 2029

Previous Endorsement Cycle

Fall 2024

Initial Endorsement

Fri, 03/14/2025 - 12:14

Steward

Centers for Medicare & Medicaid Services

1.0 New or Maintenance

New

1.1 Measure Structure

Single Measure

1.3 Electronic Clinical Quality Measure (eCQM)

No

1.6 Measure Description

Percentage of adult dialysis patients with a 6-month rolling average phosphorus value greater than or equal to 6.5 mg/dL.

1.7 Composite Measure

No

1.7 Measure Type

Intermediate Outcome

1.8 Level of Analysis

Facility

1.9 Care Setting

Other

1.9b Other Care Setting

Dialysis Facility

1.10 Measure Rationale

The hyperphosphatemia measure was developed based on the recommendations of a clinical TEP's consideration of the multiple large, risk-adjusted observational studies demonstrating a consistent relationship between presence of hyperphosphatemia and adverse patient outcomes including cardiovascular complications, bone fracture, and increase mortality. In addition, prospective studies have reported lower mortality in patients treated with improved phosphorus control or who used phosphate-binding medications. Currently dialysis facilities report whether a phosphorus level was obtained on a monthly basis, but are not evaluated on how well phosphorus levels are controlled. This measure will help facilities identify patients with chronic elevation in phosphorus that may need additional intervention such as nutritional counseling, phosphorus binding medications or adjustment of dialysis prescription. Improvements in the proportion of patients with a chronically elevated phosphorus should help to decrease cardiovascular complications, hospitalizations, and overall mortality.

1.13 Data Dictionary

Not attached. I attest that all information will be provided where codes and/or value sets are needed (1.14a - 1.15c).

1.13a Attach Data Dictionary

Data dictionary Hyperphosphatemia.xlsx

1.14 Numerator

Number of patient reporting months in the denominator with a 6-month rolling average phosphorus greater than or equal to 6.5 mg/dL.

1.14a Numerator Details

A patient reporting month is defined as the last month of the six month observation period; for example, for the June 2023 reporting month, the hyperphosphatemia value is the average of the reporting month + the past five months (January – May 2023). August through December of the prior calendar year will be used to calculate the 6-month rolling average for January – May of the current reporting year. The 6-month rolling average phosphorus is calculated by taking the first phosphorus value from the current month and up to 5 prior consecutive calendar months for a given patient. These values are averaged to create a rolling average for the current reporting month. A facility's patient reporting months are included in the numerator when their 6-month rolling average phosphorus is greater than or equal to 6.5 mg/dL. If there are multiple phosphorus

measurements during the month, only the first value in the calendar month will be used for the calculation.

Missing is defined as no phosphorus value in >2 of the six months used in the reporting period. Up to 2 missing phosphorus values are allowed in a 6-month period. If more than 2 missing values are present in the 6-month period, then the patient-month is included in the numerator as having hyperphosphatemia.

1.15 Denominator

Number of patient reporting months among adult (greater than or equal to 18 years old) in-center hemodialysis, home hemodialysis, or peritoneal dialysis patients under the care of the dialysis facility for the entire reporting month who have had ESRD for greater than 90 days.

1.15a Denominator Details

A patient reporting month is included if the patient is >18 years of age, has had ESRD for 90 or more days, and has been receiving treatment at the same facility for the entire calendar month.

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 reporting 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 reporting period. New ESRD patients must be at the same dialysis facility for seven consecutive months before being included in the measure (first three months excluded due to the 90 day ESRD rule above, plus an additional four months to meet minimum number of reporting months to be included in the denominator since two missing months are allowed). Established ESRD patients who transfer to a new facility must have four consecutive months at the new facility to be included in the denominator (since two missing months are allowed). Patients on dialysis are determined as follows: Primary Type of Dialysis is Hemodialysis, Home Hemodialysis, CAPD or CCPD in the most recent month of the reporting period. Patients under the care of the facility for at least 30 days are 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 reporting period, then the patient's time under the care of the facility is calculated from the admit date to the last day of the most recent month of the reporting period; if the discharge date is prior to the last day of the most recent month of the reporting period, the patient is excluded from the calculation.

A treatment history file is the data source for the denominator calculation used for the analyses supporting this submission. This file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period

associated with a specific modality and dialysis facility. EQRS is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source of information in certain situations. Information regarding first ESRD service date, death, and transplant is obtained from EQRS (including the CMS Medical Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the Organ Procurement and Transplant Network (OPTN).

1.15b Denominator Exclusions

In addition to exclusions that are implicit in the measure definition (age <18 years old, <90 days of ESRD, or not receiving treatment at the facility for the full calendar month) there are two additional exclusions:

- 6-month rolling average albumin of less than 3.5 mg/dL
- BMI under 18.5

1.15c Denominator Exclusions Details

For a given patient reporting month, the exclusion criteria must not be met within the entire 6-month window used to calculate rolling averages for phosphorus and albumin. Therefore, age and duration of ESRD at start of each rolling average “window” is needed to calculate denominator exclusions, as well as valid albumin and phosphorus values. A patient needs at least 4 out of a possible 6 valid values in the rolling average window to have a valid 6-month rolling average phosphorus or albumin value.

1.15d Age Group

Adults (18-64 years), Older Adults (65 years and older)

1.16 Type of Score

Rate/proportion

1.17 Measure Score Interpretation

Better performance = Lower score

1.18 Calculation of Measure Score

Patient reporting months with a 6-month rolling average phosphorus of 6.5 mg/dL or greater are included in the numerator. The number of patient reporting months with a phosphorus average of 6.5 mg/dL or greater is divided by the total number of patient reporting months, by facility. This value is multiplied by 100 to get the percentage of patient reporting months with hyperphosphatemia for each facility (only facilities with greater than 10 patients for the reporting period).

1.18a Attach measure score calculation diagram

Flowchart_Hyperphosphatemia.pdf

1.19 Measure Stratification Details

The measure is not stratified.

1.20 Types of Data Sources

Claims Data, Other

1.20a Other Data Source

ESRD Quality Reporting System (EQRS): national registry of dialysis patients with mandatory participation from all Medicare-certified dialysis facilities

1.25 Data Source Details

Phosphorus values are sourced from EQRS, a mandatory reporting mechanism for all CMS-certified dialysis facilities.

Data for patient placement are derived from an extensive national ESRD patient database, which is primarily based on the Renal Management Information System (REMIS), EQRS facility-reported clinical and administrative data (including CMS-2728 Medical Evidence Form, CMS-2746 Death Notification Form, and CMS-2744 Annual Facility Survey Form and patient tracking data), the Medicare Enrollment Database (EDB), and Medicare dialysis claims data (primarily outpatient). In addition, the database includes transplant data from the Scientific Registry of Transplant Recipients (SRTR), and data from the Nursing Home Minimum Dataset, the Quality Improvement Evaluation System (QIES) Business Intelligence Center (QBIC) (which includes Provider and Survey and Certification data from Automated Survey Processing Environment (ASPEN)), and the Dialysis Facility Care Compare.

1.26 Minimum Sample Size

Public reporting of this measure on Care Compare or in the ESRD QIP would be restricted to facilities with at least 11 eligible patients for the measure to comply with restrictions on reporting of potentially patient identifiable information related to small cell size. We have applied this restriction to all the reliability and validity testing reported here.

2.1 Attach Logic Model

Hyperphosphatemia_Logic_Model.pdf

2.2 Evidence of Measure Importance

Kidney disease is almost always associated with complex alterations of mineral metabolism. The

magnitude and severity of these alterations typically become more severe with worsening kidney failure and progression to End Stage Kidney Disease (ESKD). Primary mineral alterations include loss of active vitamin D (calcitriol) synthesis by the kidneys and reduced renal clearance of serum phosphorus, leading to hypercalcemia, hyperphosphatemia and secondary hyperparathyroidism. Disruptions have been identified for other interrelated markers such as FGF-23 and circulating Klotho receptor. These primary alterations create a pathologic milieu that, over a period of years, predisposes patients to metabolic bone disease and other complications. (Hamato Kidney Int 106:191-195, 2024; Murray AJKD 83(2):241-256, 2024)

End stage Kidney Disease (ESKD) mineral and bone disease (MBD) has been associated with several adverse clinical outcomes including increased mortality, cardiovascular complications, several bone disorders including osteitis fibrosa cystica (consequent to chronic high-turnover bone disease), osteomalacia (consequent to low turnover bone disease), osteopenia/porosis, among others contributing to the excessive outcome and symptom burden in this population. (Noordzij NDT 21(9):2676-7, 2006; Kestenbaum AJKD 60(1):3-4, 2012; Waheed NDT 28(12):2961-8, 2013; Doshe Kidney Int Reports 2022; Scialla AJKD 77(1):132-141, 2021; KDIGO 2017 Update Kidney Int Supplements 7(1), 2017)

Dialysis facilities and clinical providers have been at the center of efforts to treat ESKD MBD for over fifty years in order to mitigate the deleterious effects of MBD on the individuals they treat. Blood biochemical markers associated with ESKD MBD and its treatments are regularly obtained from almost all US dialysis patients (i.e. monthly blood calcium and phosphorus, alkaline phosphatase and other enzymes reflecting bone metabolic activity; quarterly to annual parathyroid hormone concentrations; etc.). (see Dialysis Facility Care Compare for details) Medicare ESKD Dialysis Facility regulations (Interpretive-Guidance-Version1.1-508.pdf, downloaded from https://www.cms.gov/medicare/health-safety-standards/guidance-for-laws-... 8/7/2024) specify diagnosis and treatment of ESKD MBD as the responsibility of the dialysis facility's Interdisciplinary Treatment team (CfC 494, V505, V508, V545, V546). The majority of ESKD dialysis patients are treated with phosphorus binders alone or in combination with other agents to treat MBD. (Hall CJASN 15:1603-13, 2020-) Federal statute require quality metrics that inform policy makers on the effectiveness of ESKD MBD treatment in the US chronic dialysis population. Finally, many national and international evidence-based consensus quality guidelines defining goals for high-quality treatment and prevention of ESKD MBD and its complications have been published and/or updated over the last two decades. (The most recent guideline is: KDIGO 2017 Update Kidney Int Supplements 7(1), 2017)

Historically, extensive observational literature established a strong association between hyperphosphatemia and adverse outcomes (all-cause and/or CV mortality; hospitalization, esp. CV-related) in chronic dialysis patients. A large number of observational studies, mostly at the patient-level, over two decades convincingly demonstrate the consistent association between hyperphosphatemia and clinically important increases in patient adverse outcomes. (Block AJKD 31(4):607-17, 1998; Block JASN 15(8):2208-18, 2004; Ganesh JASN 12(10):2131-2139, 2001;

Kalantar-Zadeh Kidney Int 70:771-780, 2006; Young Kidney Int 67(3):1179-87, 2005; Zitt CJASN 6(11):2650-56, 2011; Block CJASN 8:2132-40, 2013; Fukagawa AJKD 63(6):979-87, 2014; Rivara JASN 26(7):1671-81, 2015; Zhang JAMA Network Open 6(5):e2310909, 2023; Kim NDT 2024 online ahead of print.)

The purported mechanisms linking hyperphosphatemia and these outcomes include acceleration of calcific uremic vasculopathy and related cardiovascular, cerebrovascular, and peripheral vascular events either directly, or potentially in part, through stimulation of hyperparathyroidism. (Cannata-Andia Nephrol Dial Transplant. 2002;17 Suppl 11:16-9; Gross Circulation J 78:2339-2346, 2014) More recently, identification of additional circulating hormones associated with MBD in general and hyperphosphatemia specifically (e.g. FGF-23, circulating Klotho receptor, etc.) have increased interest in the potential link between hyperphosphatemia and cardiac hypertrophy and clinical consequences of cardiac hypertrophy on clinical outcomes in this patient population. (Moe Circulation 132(1):27-39, 2015) Experimental laboratory animal models support all of the potential causal mechanisms described above. (Gross Circulation J 78:2339-2346, 2014)

Most ESKD MBD treatment algorithms suggest mitigation of hyperphosphatemia as a foundational component of efforts to reduce the debilitating and potentially lethal complications of this condition. Strategies recommended to control hyperphosphatemia include patient education, counselling, and dietary planning by registered dietitians at each dialysis facility to facilitate dietary phosphorus reduction, reduction of GI tract absorption of phosphorus with dietary phosphorus binders and/or more recently developed GI phosphorus absorption inhibitors, and increasing dialytic clearance of phosphorus with intensified dialysis regimens. (Navaneetham Cochrane Database Systemic Review 16(2), 2011- meta-analysis; Noori CJASN 5(4):683-92, 2010; Floege J Nephrol 33:497-508, 2020; FHN Trial Investigators NEJM 363(24):2287-2300, 2010; Rocco Kidney Int 80(10):1080-91, 2011; Schorr J Renal Nutrition 21(3):271-6, 2011; Ok NDT 26(4):1287-96, 2011; Walsh Hemodialysis Int 14(2):174-81, 2010; Culleton JAMA 298(11):1291-99, 2007;)There are a relatively large number of phosphorus lowering drug trials that demonstrate the ability to reduce phosphorus concentrations. Some of those trials include endpoints that inform on the outcomes of interest. However, there are no placebo-controlled trials that allow determination of the magnitude of effect of these phosphorus-reducing interventions on ESKD patients. (Palmer AJKD 68(5):691-702, 2016- meta-analysis) These phosphorus-control interventions are clearly and unequivocally under the control of the ESKD dialysis interdisciplinary team.

The initial KDIGO Consensus Guidelines for treatment of MBD were published in 2009. In 2017, KDIGO consensus guidelines for treatment of CKD-related MBD updates were published. (KDIGO 2017 Update Kidney Int Supplements 7(1), 2017) The following list, including the 2017 guidelines for control of hyperphosphatemia, summarize the updated guidelines (Section 4.1) relevant to the measure topic presented here.

- 4. 1.1: In patients with CKD G3a to G5D, treatments of CKD–MBD should be based on serial assessments of phosphate, calcium, and PTH levels, considered together. (Not graded)
- 4. 1.2: In patients with CKD G3a to G5D, we suggest lowering elevated phosphate levels toward the normal range. (Grade 2C)
- 4. 1.5: In patients with CKD G3a to G5D, decisions about phosphate-lowering treatment should be based on progressively or persistently elevated serum phosphate. (Not graded)
- 4. 1.8: In patients with CKD G3a to G5D, we suggest limiting dietary phosphate intake in the treatment of hyperphosphatemia alone or in combination with other treatments. (Grade 2D). It is reasonable to consider phosphate source (e.g., animal, vegetable, additives) in making dietary recommendations. (Not graded)
- 4. 1.9: In patients with CKD G5D, we suggest increasing dialysis phosphate removal in the treatment of persistent hyperphosphatemia.(Grade 2C)

Prior to convening a clinical technical expert panel in 2024 charged with recommendation of new quality measures for dialysis facility MBD treatment, the UM-KECC team supplemented the prior KDIGO systematic literature searches by replicating the KDIGO search strategy from the 2017 update, using January. 2015 through early 2024 as the publication search date range. We also searched known sources for both U.S. and international CKD MBD consensus guidelines, published since the KDIGO 2017 update. We identified the 2017 KDIGO Bone and Mineral Guideline Update as the most recent comprehensive guideline set for this topic. Several national and regional international consensus organizations have subsequently commented on the 2017 KDIGO updated guidelines.

One KECC investigator scanned the initial search result set of approximately 16,800 citations to identify extraneous or off-topic results. We excluded any citations not directly related to primary MBD management, focusing primarily on the ESKD chronic dialysis patient population.

After exclusions, our search returned approximately 2600 unique citations of varying quality, including reviews, meta-analyses and original scientific publications. The UM-KECC team identified three primary topics (phosphorus control, clinical lab target values, and treatment of secondary hyperparathyroidism) of interest for our primary review. Three KECC investigators with clinical experience in management of chronic dialysis treatment reviewed the citation set for potentially informative studies related to the clinical topics of interest. Potentially informative citations, including abstract and comments from the primary KECC reviewer, organized by primary topic were provided to our clinical TEP members for review prior to the TEP meetings. In addition, the TEP co-chairs contributed additional related citations to facilitate TEP discussion.

As a result of our supplemental searches, we identified several recent observational studies confirming the association between hyperphosphatemia and patient outcomes previously reported (generally mortality and/or hospitalization). Two of these studies were of particular interest to TEP members and were central to their strong recommendation to develop a quality measure based on chronic hyperphosphatemia with a definition threshold of 6.5 mg/dL for

hyperphosphatemia. (Lopes NDT 35:1794-1801, 2020- TAC phos in HD; Lopes NDT 38: 193-202, 2023- TAC phos in PD.) Lopes, in separate publications for in-center hemodialysis and peritoneal dialysis DOPPS populations, described the associations between time-averaged concentration (TAC) of phosphorus over 6 months with patient outcomes. In addition, we identified two prospective observational cohort studies (ArMORR and COSMOS) studies demonstrating associations between use of phosphorous binders and survival, using rigorous risk-adjustment. In the ArMORR study, intent-to-treat analysis with extensive risk adjustment and stratification based on facility-level Standardized Mortality Ratio (SMR) revealed 29% lower mortality in incident patients treated with phosphorus binders. Similar magnitude of mortality reduction was seen in a propensity score matched model. (Isakova JASN 20(2):388-96, 2009) In the COSMOS study using patient-level Propensity Score modeling, phosphorus binder use was associated with approximately 50% and 36% reduction in all-cause and cardiovascular mortality, respectively. (Cannata-Andia Kidney Int 84:998-1008, 2013) The COSMOS study also utilized facility percentage of patients treated with a phosphorus binding agent in an instrumental variable analysis and demonstrated 8% and 7% risk reduction for all-cause and cardiovascular mortality, respectively, for each 10% increase in percent of patients treated with phosphorus binders at the dialysis facility. A 2012 DOPPS study used indicator variable analysis to associate facility level phosphorus control to predict patient outcomes. Subsequently, Block, et al also demonstrated risk reduction in patient mortality for patients treated in dialysis facilities with better MBD treatment outcomes. (Lopes AJKD 60(1):90-101, 2012- includes indicator variable facility-level analyses; Block BMC Nephrol 2016)

Finally, we identified a publication describing secondary analyses of the prospective, case-controlled, Japanese MBD-5D Study. (Fukugawa AJKD 63(6):979-987, 2014) Kato, et al. describe their secondary analyses of the MBD-5D study investigating the association between changing patterns of achieved phosphorus over time with mortality in Japanese chronic dialysis patients. (Kato BMC Nephrol 21: 432, 2020) In this study, individual patient results for phosphorus (and other MBD-related labs) were averaged over 3-month periods and categorized as Low (<4mg/dl), Middle (4-7 mg/dl) and High >7 mg/dl). Risk adjusted mortality in the current 3-month observation period was associated with patient-level achieved phosphorus category in the prior two 3-month periods (e.g. L-L, L-M, L-H, H-H, H-M, H-L) in order to evaluate the short-term effect of phosphorus category change on mortality risk. Compared to patients whose phosphorus category did not change, change from Low to Moderate or from High to Moderate was associated with significantly lower mortality compared to those remaining in the Low and High categories, respectively. Patients moving from Moderate to either Low or High categories were found to have increased mortality relative to the Moderate control group. Although observational in nature, these results from a carefully executed prospective, case-controlled study strongly suggest that treatment of hyperphosphatemia in this population may effect a reduction in mortality, and that avoidance of hypophosphatemia is prudent.

Summary

There is no high-quality direct evidence from prospective interventional clinical trials showing that phosphorus reduction results in better patient outcomes, nor is there evidence supporting one phosphorus lowering technique over others (including phosphorus binder use, GI phosphorus absorption blocker, or dietary/nutritional intervention) as preferred approach in lowering the risk

of mortality in this population. There is, however, a large and consistent body of representative observational literature that strongly and consistently supports the clinical association between phosphorus control and reduction of ESKD MBD-related complications. This observational literature clearly demonstrates the association of phosphorus control with better survival in both cross-sectional and prospective cohort studies. In addition, while choice of phosphorus binder class remains under debate, there is evidence that use of any phosphorus binders in this population is associated with significant reduction in all-cause and cardiovascular mortality in studies of patients treated in both the U.S and Europe. Finally, the primary responsibility for treatment of MBD in this population is clearly focused on dialysis facilities and clinicians. It is also important to restate that proven, effective, phosphorus reduction techniques are available and in widespread use worldwide by dialysis providers in the treatment of ESKD chronic dialysis patients.

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2.3 Anticipated Impact

Reducing the number of patient months with chronic hyperphosphatemia is expected to have the following impact: (1) reduction in hospitalization and (2) reduction in all-cause and cardiovascular mortality at the dialysis facility level. The cost-savings from reduced hospitalization rates are offset by increased costs associated with phosphate binder and phosphate absorption inhibiting medications, which are currently not included in the ESRD bundled payment. There are two main unanticipated consequences for the measure. First, the 2024 TEP raised the concern that patients could become malnourished in the process of trying to control chronic hyperphosphatemia. To mitigate against this risk, we exclude patients who are at increased risk for malnutrition as indicated by a low serum albumin or underweight body status as defined by BMI. The other potential unintended consequence relates to the pill burden associated with phosphate binders, their palatability, and the subsequent impact on quality of life.

2.4 Performance Gap

Data are from EQRS Clinical files for years 2021-2022. All reporting months are for calendar year 2022. Data from August 2021 – December 2021 were only used to calculate 6-month rolling averages for the first five months of 2022 which needed data from months prior to January 2022. The total number of dialysis facilities included in the performance scores was 7,497. The total number of patients included in the performance scores was 447,576.

Table 1. Performance Scores by Decile

Performance Gap

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Mean Performance Score	23.1%	0%	7.8%	13.4%	16.0%	18.4%	20.6%	22.9%	25.4%	28.3%	32.1%	45.8%	100%
N of Entities	7497	15	749	750	749	751	749	750	750	746	754	749	28
N of Persons / Encounters / Episodes	3,758,302	2,265	299,891	379,102	403,430	412,333	408,232	409,928	396,900	400,499	366,704	281,283	7,833

2.5 Health Care Quality Landscape

There is currently no measure of chronic hyperphosphatemia for dialysis patients. There is only a reporting requirement currently that a phosphorus level is being checked on a monthly basis. This is insufficient to assess chronic control of elevated phosphorus. At best, dialysis facilities review on a monthly basis the number of patients who have an elevated phosphorus, but this does not differentiate those patients who have *chronically* elevated phosphorus levels and are at highest risk for adverse cardiovascular morbidity and mortality.

2.6 Meaningfulness to Target Population

Although some patients have symptoms related to chronic hyperphosphatemia such as itching or other dermatologic manifestations, many patients are asymptomatic. However, less time spent in the hospital and living longer, particularly if it allows a dialysis patient to reach kidney transplantation, are meaningful outcomes.

3.1 Contributions Towards Closing Care Gaps

We elect not to provide a response to this optional question.

4.1 Feasibility Assessment

Phosphorus levels are routinely checked during routine care delivery in a dialysis facility, and the data is a required submission element for the End Stage Renal Disease Quality Reporting System (EQRS) for Medicare certified dialysis facilities (the measured entity of this measure). All required data elements for the measure are routinely generated during care delivery for dialysis patients. Therefore, there is no additional cost or burden for data collection and no impact on clinical workflow. Given the existing processes in place for data collection, we have no concerns about feasibility if the measure is implemented.

4.3 Feasibility Informed Final Measure

Due to the high feasibility of the measure, no adjustments were needed during measure development to address feasibility.

4.4 Proprietary Information

Not a proprietary measure and no proprietary components

5.1.1 Data Used for Testing

Data used for testing is from EQRS clinical files for years 2021 and 2022. All reporting months with a 6-month phosphorus average are from 2022, and only phosphorus values in months from 2021 needed to calculate these averages are used from that year.

5.1.2 Differences in Data

none

5.1.3 Characteristics of Measured Entities

7,497 facilities with 10 or more eligible adult patients during January 2022 – December 2022 were included in the analysis.

Public reporting of this measure on DFC or in the ESRD QIP would be restricted to facilities with at least 10 eligible patients for the measure to comply with restrictions on reporting of potentially patient identifiable information related to small sample size. We have applied this restriction to all the reliability and validity testing reported here.

5.1.4 Characteristics of Units of the Eligible Population

A total of 447,576 patients who belonged to the facilities with 10 or more patients were included in this analysis. Among these patients, the average age was 63, 41.4% were female, 56.3% were white, 34.7% were black, 20.5% were Hispanic, and 46.0% had diabetes as primary cause of ESRD.

5.2.1 Level(s) of Reliability Testing Conducted

Accountable entity level (i.e., measure score) (e.g., signal-to-noise analysis)

5.2.2 Method(s) of Reliability Testing

We used January 2022 – December 2022 data to calculate the inter-unit reliability (IUR) for the overall 12 months to assess the reliability of this measure. One of the PQM-recommended approach for determining measure reliability is a one-way analysis of variance (ANOVA), in which the between and within facility variation in the measure is determined. The inter-unit reliability (IUR) measures the proportion of the measure variability that is attributable to the between-facility variance. The yearly based IUR was estimated using a bootstrap approach, which uses a resampling scheme to estimate the within facility variation that cannot be directly estimated by ANOVA. We note that the method for calculating the IUR was developed for measures that are approximately normally distributed across facilities. Since this measure is not normally distributed, the IUR value should be interpreted with some caution.

5.2.3 Reliability Testing Results

The overall IUR was 0.767 across 12 reporting months, which is high and suggests 77% of variation in the measure is attributed to between facility variation and approximately 23% to within facility variation.

5.2.4 Interpretation of Reliability Results

The overall IUR for the sample dataset was 0.77. The IUR’s per deciles of patients ranged from 0.48 to 0.88. The overall IUR of 0.77 indicates 77% of variation in the overall measure can be attributed to between facility variations. This is considered to be a high degree of reliability.

Table 2. Accountable Entity Level Reliability Testing Results by Denominator, Target Population Size

Accountable Entity-Level Reliability Testing Results

	Overall	Minimum	Decile_1	Decile_2	Decile_3	Decile_4	Decile_5	Decile_6	Decile_7	Decile_8	Decile_9	Decile_10	Maximum
Reliability	0.767	0.356	0.476	0.590	0.652	0.694	0.728	0.757	0.783	0.810	0.839	0.883	0.951
Mean Performance Score	23.1%	0%	7.8%	13.4%	16%	18.4%	20.6%	22.9%	25.4%	28.3%	32.1%	45.8%	100%
N of Entities	7497	15	745	775	739	696	795	723	763	754	757	750	28
N of Persons / Encounters / Episodes	3,758,302	2,265	91,207	159,305	203,405	233,587	318,102	338,400	418,557	495,687	611,919	888,133	7,833

5.3.1 Level(s) of Validity Testing Conducted

Accountable entity level (i.e., measure score) (e.g., criterion validity)

5.3.3 Method(s) of Validity Testing

We used January 2022 – December 2022 EQRS clinical data to assess facility level performance scores. 7,497 facilities with 10 or more patients were used for validity testing, which includes 447,576 patients.

We assessed validity using Poisson regression models to identify the predictive strength of facility level performance scores for the measure, on mortality and days hospitalized, using the 2022 SMR and SHR related data. We anticipate a positive correlation with the SMR and SHR, and a dose-response with increasing rate ratios from lowest quintile of hyperphosphatemia to highest quintile of hyperphosphatemia.

5.3.4 Validity Testing Results

Progression Regression with SMR & SHR

Mortality:

Quintile 1, Performance Score: 10.4, Pr >ChiS q: <0.0001, Rate Ratio (95%CI): 1.0 (Reference)

Quintile 2, Performance Score: 17.2, Pr >ChiS q: <0.0468, Rate Ratio (95%CI): 1.03 (95% CI: 1, 1.05)

Quintile 3, Performance Score: 21.7, Pr >ChiS q: <0.0001, Rate Ratio (95%CI): 1.06 (95% CI: 1.04, 1.09)

Quintile 4, Performance Score: 26.8, Pr >ChiS q: <0.0001, Rate Ratio (95%CI): 1.09 (95% CI: 1.06, 1.11)

Quintile 5, Performance Score: 38.9, Pr >ChiS q: <0.0001, Rate Ratio (95%CI): 1.18 (95% CI: 1.16, 1.21)

Hospitalization:

Quintile 1, Performance Score: 10.4, Pr >ChiS q: <0.0001, Rate Ratio (95%CI): 1.0 (Reference)

Quintile 2, Performance Score: 17.2, Pr >ChiS q: <0.0001, Rate Ratio (95%CI): 1.04 (95% CI: 1.04, 1.05)

Quintile 3, Performance Score: 21.7, Pr >ChiS q: <0.0001, Rate Ratio (95%CI): 1.03 (95% CI: 1.03, 1.04)

Quintile 4, Performance Score: 26.8, Pr >ChiS q: <0.0001, Rate Ratio (95%CI): 1.07 (95% CI: 1.06, 1.07)

Quintile 5, Performance Score: 38.9, Pr >ChiS q: <0.0001, Rate Ratio (95%CI): 1.13 (95% CI: 1.12, 1.13)

5.3.5 Interpretation of Validity Results

The results of the Poisson regression suggests that facilities with a higher percentage of patient-months with chronic hyperphosphatemia experience a higher mortality rate and higher hospitalization rate relative to facilities with a lower percentage of patients with chronic hyperphosphatemia. Using quintiles defined by mean facility performance score, we find that facilities in the 5th quintile have mortality that is 18% higher when compared to facilities in the 1st quintile group. Similarly, facilities in the 5th quintile have hospitalization that is 13% higher when compared to facilities in the 1st quintile group. The direction of the relationship is as expected.

5.3.2 Type of Accountable Entity Level Validity Testing Conducted (derived)

Empirical validity testing at the accountable entity-level (e.g., criterion validity, construct validity, known groups analysis)

5.4.1 Methods Used to Address Risk Factors

No risk adjustment or stratification

6.1.1 Current Status

Not in use

6.1.2 Current or Planned Use(s)

Public Reporting, Payment Program

6.2.1 Actions of Measured Entities to Improve Performance

Actions that dialysis facilities can take to improve long-term phosphorus control include nutritional counseling to help patients choose low phosphorus foods as part of their nutrition plan, prescription of phosphorus binding agents, and potentially adjustment of dialysis prescription to maximize phosphorus clearance. These interventions can be challenging, but coordinated effort

by the interdisciplinary team can overcome obstacles such as prescription coverage for medications, improved adherence with a nutrition plan, and optimal dialysis.

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