End Stage Renal Disease (ESRD)
Quality Measure Development and Maintenance
Mineral and Bone Disorder Clinical Technical Expert Panel Summary Report
Prepared by: Arbor Research Collaborative for Health and The University of Michigan Kidney Epidemiology and Cost Center
Conducted April 16-17, 2013 in Baltimore, MD
Sent to CMS on June 28, 2013

Contract No. 500-2008-00022I, Task Order No. HHSM-500-T0001

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Technical Expert Panel Summary

The Centers for Medicare & Medicaid Services (CMS) has contracted with Arbor Research Collaborative for Health (Arbor Research) and the University of Michigan Kidney Epidemiology and Cost Center (UM-KECC) to develop End-Stage Renal Disease (ESRD) Quality Measures (QMs) for the following four measure areas:

- Mineral and Bone Disorder
- Hemodialysis Adequacy
- Preventive Care (Pneumococcal, Hepatitis B, and Influenza Vaccinations)
- Dialysis Adequacy for Pediatric Patients (Peritoneal Dialysis Adequacy [PD])

The purpose of the project is to develop measurements that can be used to provide quality care to Medicare beneficiaries.

Technical Expert Panel Objectives

The objectives of these ESRD C-TEPs were described in the charter that was approved by the C-TEPs. The C-TEPs were charged with providing expertise and input to Arbor Research on the development and implementation of measures that will be used to assess and improve the quality of care for Americans with ESRD. The C-TEPs were to provide guidance and assist in the development and specification of new quality measures in specific clinical areas. In addition, the C-TEP members were to consider potential measures using the framework of CMS and the National Quality Forum (NQF). The four evaluation criteria are: *importance*, *scientific acceptability*, *feasibility, and usability*.

Technical Expert Panel Meeting

The Preventive Care, Mineral and Bone Disorder, and Hemodialysis Adequacy TEP met in Baltimore, MD on April 16-17, 2013. The Pediatric Peritoneal Dialysis Adequacy TEP met via conference call on April 11 and April 17, 2013.

The TEPs were comprised of individuals with the following areas of expertise and perspectives:

- Topic Knowledge: ESRD
- Performance Measurement
- Quality Improvement
- Consumer Perspective
- Purchaser Perspective
- Health Care Disparities

The following individuals participated in this TEP:

Name	Title	Organization	Measure Area	Conflict of Interest Disclosure
Patty Danielson, RN BC	Nurse Manager, Behavioral Health	Adventist Medical Center	Mineral and Bone Disorder	None
Kathy Schiro Harvey, MS RD CSR	Nutrition Manager	Puget Sound Kidney Centers	Mineral and Bone Disorder	None
Tamara Isakova, MD	Assistant Professor of Medicine	University of Miami Miller School of Medicine	Mineral and Bone Disorder	None
Mary Leonard, MD MSCE	Professor of Pediatrics and Epidemiology	The Children's Hospital of Philadelphia Research Institute	Mineral and Bone Disorder	Member of Amgen Prolia Scientific Methodological Advisory Committee
Julia Lewis, MD	Professor of Medicine	Vanderbilt University Medical Center	Mineral and Bone Disorder	Current PI for a Keryx-sponsored study; past grants/contracts with industry (self and spouse); investment with Nephrogenix through Vanderbilt
Hartmut Malluche, MD FACP	Professor and Chief, Division of Nephrology, Bone and Mineral Metabolism Department of Internal Medicine	University of Kentucky Medical Center	Mineral and Bone Disorder	Past or current research support from Celgen, Novartis, Vifor
Robin Mauer, FNP MSN	Nurse Practitioner	Washington University School of Medicine	Mineral and Bone Disorder	None
Klemens Meyer, MD	Professor of Medicine	Tufts University Medical Center	Mineral and Bone Disorder	Past grants from Covidien, Parexel ; salary support from DCI

Sharon Moe, MD FASN	Director, Division of Nephrology	Indiana University School of Medicine	Mineral and Bone Disorder	Research support from Genzyme; consultant to Genzyme, Sanofi, Amgen; Litholink, Kai pharma; past research support from Amgen

1. Background

1.1 Overview of measure areas to be discussed

This report summarizes discussions of the in-person CMS ESRD Technical Expert Panel (TEP) meeting held in Baltimore, MD, April 16-17. Prior to the TEP in-person meeting, TEP members reviewed the published clinical evidence (post-2011), clinical guidelines, and existing measures in the areas of mineral and bone disorder such as phosphorus, calcium, parathyroid hormone (PTH), vitamin D, fractures, and falls. In all of these areas, the TEP was charged with evaluating the relative importance of each of these topics in the ESRD population, assessing the evidence supporting potential quality measures in each area, and assessing the feasibility of implementing such measures. Specific topics discussed at the in-person meeting included PTH, dietary counseling, vitamin D, calcium and phosphorus, and areas of specific interest to CMS including serum vs. plasma measurements, corrected vs. uncorrected serum calcium measurements, and bone histology/bone fractures.

2. Corrected versus Uncorrected Serum Calcium in the Hypercalcemia Measure

2.1 Discussion

As requested by CMS, the TEP discussed whether or not they thought it would be acceptable for facilities to report corrected calcium specifically for the NQF endorsed hypercalcemia measure (NQF ID #1454). It was noted that there are 3 options: 1) leave the measure with uncorrected calcium, as it was developed by the 2010 TEP and endorsed by the NQF 2) change the measure to use corrected calcium, or 3) to allow either uncorrected or corrected calcium to be used for calculation of the hypercalcemia measure. In agreement with the 2010 TEP, it was felt that corrected calcium obtained using formulas typically applied in clinical practice may not reflect ionized calcium levels (which are biologically active) better than uncorrected. Some TEP members expressed concerns for the various formulas that are used, since evidence suggests that in ESRD patients they may be inaccurate in estimating ionized calcium concentrations, the gold standard. One TEP member had concerns that the use of various formulas may cause unintended consequences in terms of additional burden related to data collection.

CROWNWeb patient level data from May to November 2012 was used to construct boxplots showing the distribution of corrected vs. uncorrected calcium for May 2012 as well as the percentage of patients in different calcium ranges (<8.4, 8.4-9.5, 9.6-10.2, and >10.2) when using corrected and uncorrected calcium . It was noted by Arbor that the CROWNWeb data and analyses were limited to patients for whom calcium data had been submitted as it was not a required data field. The TEP was shown boxplots of corrected vs. uncorrected serum calcium values at the patient-level where there was roughly a 1% decrease in mean serum calcium values when using uncorrected values instead of corrected values. Based on this distribution, TEP estimated the percentage of patients who are classified as hypercalcemic (i.e. having serum calcium > 10.2 mg/dl) when using corrected and uncorrected calcium. While the difference in the % of patients classified as hypercalcemic using corrected and uncorrected calcium is numerically small, one TEP member questioned whether it could be clinically significant l. There was

some concern that using corrected calcium could over-estimate the number of patients with hypercalcemia in a small number of patients with low albumin. The TEP agreed that some of these issues are technical issues such as which albumin assay was used to obtain corrected calcium rather than issues related to the measure definition itself.

2.2 Recommendations

Despite some of the technical issues described above, all TEP members unanimously recommended to leave the measure unchanged and to retain the current specification for uncorrected calcium. This is the current version of the measure as endorsed by NQF (#1454).

3. Serum versus Plasma Measurements of Phosphorus and Calcium

3.1 Discussion

The TEP was asked by CMS to consider a request submitted to CMS and the NQF regarding the use of plasma versus serum in measurement of phosphorous and calcium, respectively. Specifically, CMS received a letter from the Kidney Care Partners, a renal stakeholder organization, requesting a review of the current NQF endorsed phosphorus measure (#0225) to accept measurement of either serum or plasma phosphorous. This would allow facilities that routinely measure phosphorus on plasma not to be penalized under the current phosphorus reporting measure under the Quality Incentive Program (QIP). CMS felt that it was a reasonable request and deferred a decision on this issue to the MBD TEP.

Published literature assessing the difference in phosphorus levels measures using plasma versus serum indicates that the difference may actually be not negligible (Carothers, 1976). As far as the TEP members could determine, unpublished data provided by Spectra laboratory were conducted on normal volunteers and therefore may not be applicable to the HD population. The TEP had a lot of discussion regarding the preclinical processing issues (e.g. sample handling at the dialysis facility; shipping conditions etc.) that may result in lower phosphorus levels if drawn on plasma and whether or not the tubes were spun or properly handled. A TEP member explained that one study showed that the shipping of tubes, letting them sit for long periods, and not following other pre laboratory technical processing can affect levels of many analyses, including phosphorus. One TEP member agreed and pointed out that the collection, shipping and processing of blood draws bears review because of issues with repeat labs, more blood loss and other factors compromising the integrity of the lab specimen. However, it was felt that this discussion is beyond the expertise and scope of this TEP.

TEP members agreed that they should focus on whether or not to accept measurement of plasma phosphorus. Are there reasons to believe that measurement on plasma would alter the care of the patient (assuming that everything was processed correctly)? It was pointed out that plasma phosphate concentrations are about 10% lower than serum phosphate levels. However considering the current measure does not specify a target range this would not be an immediate issue but may in the future if a specified range would need to be defined. There was caution to accept labs that use a different assay and getting a different laboratory measurement when there is already quite a bit of biological variability based on diet and the time of the day the sample was drawn. Thus, the addition of an additional

potential confounder to the physician's interpretation of the results is premature without additional studies comparing 'real world' collection of samples from a dialysis unit that would evaluate not only the analytic differences but also whether this does indeed improve sample handling and processing mistakes at the level of the dialysis unit.

The TEP discussed the need for another lab-specific TEP that would include CLIA (Clinical Laboratory Improvement Amendments) and/or CAP (College of American Pathology) experts that would understand the laboratory values and focus on the laboratory tests and procedures that are necessary. CMS stressed that it was important to move forward with clinical quality measures because these can affect care at the dialysis facility, while measures of laboratory processes do not directly affect care processes delivered at the dialysis facility. TEP members agreed on this point. It was noted by one TEP member that some labs will only take samples processed correctly, while others will process specimens, even if they could have been compromised at the source or in transit (cracked tubes, limited amount of blood, etc.). Such a panel could agree on minimum standards for the determination of an acceptable sample at a laboratory.

3.2 Recommendations

All TEP members voted and unanimously recommended to keep the measure unchanged – facilities would need to report phosphorus levels measured on serum. The TEP also recommended that this would apply to the measurement of calcium. Specifically, the NQF endorsed hypercalcemia measure (#1454) specifically state measurement of serum calcium, and a previous process measure for calcium (#0261) that was retired by NQF in 2011.

The TEP members also recommended that a lab-specific TEP be convened that included experts in CLIA and CAP for the purpose of defining measures for laboratory tests and procedures that may affect laboratory values.

4. Bone Biopsies

4.1 Discussion

CMS asked the TEP to consider whether there may be a role for bone histology as a quality indicator for the care of dialysis patients.

While most TEP members agreed that bone biopsies are the gold standard to analyze abnormalities in bone histology, they also pointed out that there is no evidence that routine adoption of bone biopsies would result in improved patient outcomes, including quality of life. There is no evidence base of trial data utilizing this technique to guide specific interventions. Moreover, bone biopsies are relatively invasive procedures, are not routinely performed across the country and while in general complication rates are low most patients would not welcome such procedures.

One TEP member felt strongly that bone histology provides important information, especially in selected patients (e.g. those with unexplained bone fractures) and it should be considered the gold standard to guide therapeutic strategies; furthermore, bone biopsies would be cost effective in the long run if

appropriate therapies are chosen based on biopsy results. All TEP members felt that bone biopsies should be considered on a case by case basis and performed as clinically indicated. It was felt that since the indication differs largely on clinical presentation in each patient, it would be nearly impossible to create a quality indicator that applies to the majority of dialysis patients.

The majority of the TEP agreed that based on the available evidence it would not be feasible to create an appropriate quality indicator related to bone histology. While bone biopsies may be needed for a specific patient that is not the case for the vast majority of dialysis patients. One TEP member, however, disagreed and believed it to be feasible; clinicians would need to be trained in performing and interpreting results of bone biopsies, and would have the most appropriate information to decide what the appropriate treatment should be.

4.2 Recommendations

The majority of the TEP members (eight out of nine) recommended that a quality measure for bone biopsies not be developed at this time due to insufficient evidence.

5. Review of Current Mineral and Bone Disorder Measures

5.1 Discussion of existing MBD measures

5.1.1Proportion of patients with hypercalcemia (NQF ID #1454)

None of the TEP members had any issues with the 10.2 threshold but one TEP member expressed concerns with the potential for missing values a calcium measurement – particularly if the patient was a new patient at the unit at the end of the month. The current exclusions to the measures are children, transient patients, and transplant patients with a functioning graft (the hypercalcemia measure also restricts to patients who have been on dialysis for >90 days). A TEP member pointed out that patients who were in the hospital may be an issue. Ideally if a patient is hospitalized labs should be re-drawn when they come back to the dialysis facility and re-start dialyzing; however, it is often the case that monthly labs that were not drawn at the time the patient was in the hospital are not drawn while the patient is discharged from the hospital and back on dialysis.

The TEP also discussed the current exclusions that exist for the hypercalcemia measure (pediatric patients as well as transient patients). One TEP member explained that while different thresholds may be appropriate for pediatric patients, the frequency of measurement should be the same noting that some things should be measured more often but at a minimum should be measured monthly.

There was some general discussion among TEP members about the possibility of restricting the measure to patients that dialyze at least 2 or 3 times in the month. It was pointed out that this is an exclusion that is generally applied to all QIP measures and is not exclusion for the NQF endorsed “Proportion of patients with hypercalcemia” measure. There was concern over some patients that never show up and transient patients (for example patients that go to Florida for several months). One TEP member explained that there is a difference between transient patients that would not be included in the denominator (and would be included in another facility’s denominator after a month of treatment) and

patients that belong to a facility and never show up. Some more discussion regarding the number of months/treatments that a patient should have to be included in the denominator continued.

In reviewing the hypercalcemia measure there was a brief discussion of the age of a pediatric patient (the current hypercalcemia measure uses patients less than or equal to 18 years old). One TEP member mentioned that some consider patients less than the age of 21 to be pediatric. It was decided to leave the exclusion as is (< 18 years).

The TEP attempted to maintain consistency among the measures and wanted to change the hypercalcemia measure to say percentage of patients rather than proportion of patients. There was a discussion because this measure is a little different than the other measures that are process measures in which a three month rolling average is used, that the wording "proportion of patients" should remain as is. There was also a brief discussion of the consistency among the different measures in using the 90 day criterion for patients in a facility in the denominator. It was decided that because the hypercalcemia measure is a 3 month rolling average that it makes sense for a patient to have to be in the facility for 90 days and therefore the TEP decided to not change the language or specifications to the hypercalcemia measure.

5.1.2 Measurement of Serum Phosphorus Concentration (NQF ID #0255)

The TEP was informed that among facilities reporting mineral metabolism data for the months of May-November 2012, the current reporting frequency of phosphorus is high (>99% patients having at least one observation per month). CMS also explained that the measure should make it feasible for facilities to reach 100% but that this issue has surfaced in many other TEPs and that there is not usually a 100% standard for the QIP (the threshold is not set).

In an effort to maintain consistency among the measures, the TEP discussed adding an exclusion for patients who were not on dialysis for at least 90 days. The TEP agreed that unlike the "Proportion of patients with hypercalcemia" measure, there was not the same need to have this exclusion. The TEP did not want the patient to wait 90 days before having a measurement completed for serum phosphorus.

5.1.3 Measurement of Serum Calcium Concentration (NQF ID #0261, previously endorsed by NQF – retired in 2011)

The TEP felt that it was just as important to measure serum calcium in pediatric patients at least once a month and decided to remove the pediatric exclusion criteria from the process measure (measuring serum calcium at least once a month). In contrast, in regards to the hypercalcemia measure, it was felt by the TEP that pediatric patients wouldn't necessarily have 10.2 as an appropriate threshold for hypercalcemia and would suggest leaving the exclusion in the hypercalcemia measure (as noted above).

The TEP discussed the current exclusion for transplant patients with a functioning graft. It was explained that these are patients that have delayed graph viability so need dialysis until the transplant kicks in. A TEP member said that somebody should check the labs anyway for these patients and these patients shouldn't be excluded.

In an effort to maintain consistency among the measures, the TEP discussed adding an exclusion for patients who were not on dialysis for at least 90 days. The TEP agreed that unlike the "Proportion of patients with hypercalcemia" measure, there was not the same need to have this exclusion. The TEP did not want the patient to wait 90 days before having a measurement completed for serum calcium.

5.2 Recommendations

5.2.1 Proposed revisions to the serum calcium and serum phosphorus process measures

The TEP recommended two changes to the current process measures for serum calcium and serum phosphorus:

1. The TEP recommended that pediatric patients (< 18 years) be included in the denominator for the process measures of monthly measurement of serum calcium and serum phosphorus.

2. The TEP also recommended that transplant recipients with a non-functioning graft should be included in the denominator and that the current exclusion of these patients in the two process measures should be taken out.

5.2.1.1 Measurement of serum phosphorus

Percentage of all peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum phosphorus measured at least once within a month.

Numerator: Number of dialysis patients included in denominator with serum phosphorus measured at least once within a month

Denominator: All peritoneal dialysis and hemodialysis patients included in the sample for analysis.

Exclusions: Transient dialysis patients (in unit < 30 days)

5.2.1.2 Measurement of uncorrected serum calcium

Note: The previously NQF endorsed measurement of serum calcium measure was retired in 2011. The TEP recommended this measure be submitted to NQF for endorsement and reinstated for uncorrected serum calcium.

Measure description: Percentage of all peritoneal dialysis and hemodialysis patients included in the sample for analysis with uncorrected serum calcium measured at least once within a month.

Numerator: Number of dialysis patients included in denominator with uncorrected serum calcium measured at least once within a month

Denominator: All peritoneal dialysis and hemodialysis patients included in the sample for analysis.

5.2.2 Proposed revisions to the hypercalcemia measure

As the existing hypercalcemia uses a 3-month rolling average, while the measurement of serum phosphorous and measurement of serum calcium measures specify measurement at least once within

the month. The TEP recommended to revise the current hypercalcemia measure so that monthly calcium measurements would be required as part of the measure specification.

6. Parathyroid Hormone

6.1 Literature Review and scientific importance

There was also a lengthy discussion of the strength of evidence regarding PTH as a risk factor for adverse outcomes, in light of recent randomized trials including EVOLVE (EVOLVE Trial Investigators, 2012) and the ADVANCE study (Raggi 2011) . The TEP was divided on the strength of the evidence but concluded that they are the current strongest bodies of evidence that exist since the 2010 TEP convened.

It was recognized that the previously cited problem with assay variability could be overcome if the unit utilizes the same assay each time. Furthermore, given the normal physiologic oscillations in PTH, measurement should be more often if variability is to be minimized. Other TEP members agreed that the combination of laboratory values (PTH with calcium and phosphorus) may be more predictive of mortality, but since each lab value changes individually, it would be very difficult to make a recommendation based on a combination. .

A few TEP members suggested that phosphorus would be measured at the same time as PTH and mentioned that phosphorus and calcium both contribute to PTH secretion regulation.

6.2 Review of existing measures

The TEP reviewed some of the existing measures (percent of patients on a phosphate binder with iPTH measured within the last 3 months; percent of patients with iPTH greater than 100 pg/mL (or greater than 1.5 times the upper limit of normal for each assay used) and/or phosphorus greater than 4.5 mg/dL and are prescribed a low phosphorus diet for 1 month; percent of patients with one measurement of iPTH) and considered the final decisions of the 2010 TEP which was to not recommend a PTH process measure.

6.3 Recommendations

6.3.1 Proposed measure

Measurement of plasma PTH concentration

Measure description: Percentage of all peritoneal dialysis and hemodialysis patients included in the sample for analysis with plasma PTH measured, together with documentation of the specific PTH assay utilized*, at least once within a 3 month period

Numerator: Peritoneal dialysis and hemodialysis patients included in the sample for analysis with plasma PTH measured, together with documentation of the specific PTH assay utilized, at least once within a 3 month period

Denominator: All peritoneal dialysis and hemodialysis patients included in the sample for analysis

Exclusions: Transient patients (in unit < 30 days)

**This includes type of assay (intact, whole), and assay kit manufacturer*

Measure Criteria:

Importance

- Elevations in PTH are associated with increased morbidity and mortality.
- Therapies in dialysis patients that affect PTH are commonly used and hence, PTH should be monitored.
- Evidence in the EVOLVE and ADVANCE studies (that were published in 2011-2012, and hence not available for the 2010 TEP) demonstrate efficacy of strategies to lower PTH in a priori planned secondary analyses adding to the strength of evidence.

Scientific acceptability

- Prior concerns about assay variability are attenuated by the requirement to report the specific type of assay (e.g., intact, whole, other) and kit manufacturer utilized

Feasibility

- PTH is routinely measured in dialysis facilities

Usability

- Nephrologists routinely measure and interpret PTH levels
- With measurement and assay reporting, clinicians can interpret trends in PTH as per KDIGO recommendations

6.3.1.1 Discussion of numerator and denominator

Initial discussions considered the time period in which PTH should be measured. It was noted that a study showed that with more frequent PTH measurement the value of PTH was lower but there was also a significant increase in calcimimetics and vitamin D analogues (Greenberg 2011). One TEP member noted that increasing the measurements to monthly may make it more of a burden on facilities. CROWNWeb data analyses were examined for PTH including the proportion of patients with various PTH measurements in a 1 month period, 2 month period, 3 month, as well as a 4 month period. It was noted however, that because PTH is not a required data element in CROWNWeb that the results should be interpreted with caution. The rest of the TEP agreed that measuring PTH every 3 months would be sufficient and that it would be more of a burden and expensive to measure PTH monthly. There were, however, concerns about the possibility of increasing drug prescriptions and medication usage and the side effects that may result from this if the frequency of measurement was increased given a single paper that noted this. Conversely, in the studies that demonstrate efficacy of various treatments (calcitriol and its analogs, calcimimetics), that PTH was measured more frequently. A vote was conducted, with one TEP member voting for monthly measurements, and the other TEP members voting for at least 1 measurement in a 3 month period (quarterly). The TEP also decided to remain consistent with the exclusions that were stated in the process measures for calcium and phosphorus in which only transient patients (in the facility for <30 days) would be excluded but pediatric patients (< 18 years) would not be.

There was additional discussion of the definition and distinction between the mandatory versus voluntary fields in CROWNWeb particularly in terms of the feasibility of making PTH a mandatory field, and the feasibility of knowing what assay was used. One TEP member was concerned about the possibility that some facilities may not know what assay is being used. Another TEP member pointed out that it would be preferable for the unit to have an pre-populated field for a facility so that the facility would have one assay and only the patient's PTH level would have to be inserted but that if the facility changed assays (changed laboratories) then that pre-populated field could be changed. TEP members agreed that this would be the most ideal situation in asking a facility to report the assay used for PTH measurements.

6.3.1.2 Importance

A first draft of the importance text was drafted with language input from all TEP members.

Importance: *Elevations in PTH are associated with increased morbidity and mortality. Commonly used therapies in dialysis patients are prescribed to affect PTH and hence PTH should be monitored. Recent evidence in the EVOLVE and ADVANCE studies demonstrate efficacy of strategies to lower PTH in a priori secondary analyses.*

There was a long discussion among TEP members regarding the EVOLVE specifications and the ADVANCE study specifications since these two are the main studies that provide the evidence that treatments aimed at lowering PTH have outcomes of importance (coronary artery calcification and mortality/cardiovascular morbidity). It was concluded that they are the best RTCs available to support the importance of this parameter and although the primary end points of both studies were negative, the importance of the pre-specified secondary end points provides the strongest evidence to back up the importance of the measure. The TEP felt that the evidence provided by these studies was substantial enough to proceed with a measure.

6.3.1.3 Scientific acceptability

A first draft of the scientific acceptability text was drafted with language input from all TEP members.

Scientific Acceptability: *Prior concerns about assay variability are attenuated by required reporting of assay utilized such that trends in PTH can be monitored.*

There was a discussion of assay reporting for PTH given the earlier conversation of the variability that can affect the PTH measurement. There was some concern whether facilities should stick with the same assay or be allowed to change. PTH measures previously proposed by other measure developers were rejected because the scientific acceptability could not be determined. The EVOLVE and ADVANCE studies as well as several other studies were discussed briefly to ensure that scientific acceptability was more robust. One TEP member noted that most physicians should know the type of assay used based on the normative range for PTH given. Not all TEP members thought this would be the case. One TEP member was not sure if there was a linear relationship between higher or lower PTH values between different PTH assays. A TEP member hypothesized that NQF did not endorse the last a PTH measure proposed in 2010 by an organization other than CMS because of the concern over the assay variability which can be accounted for if the dialysis facilities report changes in the assay used and otherwise use

the same assay. The KDIGO guidelines suggested a range based on the normal value for the assay used. Furthermore, the EVOLVE and ADVANCE studies did not exist for the last TEP and therefore there is now more scientific acceptability.

6.3.1.4 Feasibility and usability

A first draft of the feasibility and usability text was drafted with language input from all TEP members.

Feasibility: *Routinely done in facilities.*

Usability: *Nephrologist routinely measure and interpret PTH levels. With measurement and assay reporting clinicians can interpret trends in PTH as per KDIGO recommendations.*

There was overall discussion of the language to use for these two points but there were also no objections by any TEP members regarding the content.

7. Dietary Counseling

7.1 Literature Review and Scientific Importance

One TEP member noted a paper (Shi 2013) that showed if the dietician spends more time with a patient, then the phosphorus levels tended to be more in a normal range but that the effect tapered off after 6 months. Another TEP member noted that dialysis facilities needed to have a dietician on staff but it wasn't clear if there was a requirement to see all patients. There was a discussion among all TEP members of the target patient population, which is to only counsel patients in need (high phosphorus levels versus all patients). A TEP member expressed concerns that this could turn into just E&M (Evaluation and Management) coding as an unintended consequence. There were also concerns that it is possible that a dietician may spend a lot of time with a patient and still may not be able to get the phosphorus levels down to an acceptable range. TEP members agreed at this point that the proposed measure would be a process measure, and therefore would not specify the duration of the interaction.

One TEP member thought that the measure would be more likely to be endorsed if it was specific to patients with high phosphorus. A TEP member responded by saying that there is not strong enough evidence to determine a threshold for high phosphorus; it was also mentioned that a 3 month rolling average should be considered if that was the path that was to be taken. Other TEP members agreed that the measure would become too complicated and that instead the measure should apply to every patient, that is, every patient would receive counseling. There were differing opinions about the frequency for providing counseling to patients. These varied from monthly to once a year. However there was consensus about educating patients to be able to recognize and avoid foods containing phosphorus as an additive as well as foods that are lower in phosphorus for the purpose of getting phosphorus lowered and maintaining it through diet. One TEP member thought that counseling should be once every month, while another thought it could be every 3 months. A TEP member pointed out two studies provide strong evidence that counseling a patient can be effective in lowering phosphorus – one intervention showed a significant difference of 0.6 (Sullivan 2009) lower phosphorus checked 3 months later while another intervention yielded a threshold of 5.5 (Mayne 2012). It was thought that

these studies were strong enough to possibly get the measure NQF endorsed. One TEP member noted that behavioral intervention of dietary counseling is very time intensive and requires consistency. The TEP discussed a similar sodium measure, "Dietary Sodium Reduction", that was not NQF endorsed during the 2010 cycle because of the failure to meet importance criteria.

One TEP member expressed concern about making additional rules in a facility that distracts people from doing all of the other patient-care activities that they were already doing so it is important that this measure doesn't distract from things like addressing other issues like albumin levels.

A TEP member stated that there is no mandate to counsel patients but the standard of care is to counsel patients and reevaluate every 3 months or if the patient has changed modalities. Overall, the TEP decided that if everyone agreed on the importance of the measure, such measure should be submitted. One TEP member mentioned that the language of the measure needed to be specific in that the dietary counseling was done and documented instead of just coming up with a plan. There was a belief that many patients may not get the actual counseling but instead the provider would document there is a plan. As discussions moved toward drafting measure specifications one TEP member stressed that the concept was that there are all kinds of dieticians but renal dieticians are specifically trained to deal with renal appropriate diets including phosphate control. The dietician would be able to counsel the patient on foods that are naturally high in phosphorus as well as foods that have phosphate as an additive.

7.2 Review of existing measures

The TEP discussed a comparable dietary counseling measure, "Dietary Sodium Reduction", specific to sodium intake. This measure was not NQF endorsed because of the importance criteria in that there was lack of evidence that dietary advice has an effect on sodium and that it is not clear what the consequences of high sodium are.

7.3 Recommendations

7.3.1 Proposed measure

Measure description: Percentage of all hemodialysis and peritoneal dialysis patients included in the sample for analysis with dietary counseling of the patient and/or caregiver on appropriate phosphorus sources and content as part of an overall healthy nutrition plan at least once within each six-month period

Numerator: Number of hemodialysis and peritoneal dialysis patients included in the denominator with dietary counseling, as described above, conducted at least once within six-months

Denominator: All hemodialysis and peritoneal dialysis patients included in the sample for analysis

Exclusions: Transient patients (in unit < 30 days), patients exclusively on non-oral food sources (i.e., total parenteral or enteral nutrition)

Measure Criteria:

Importance

- Hyperphosphatemia and severe hypophosphatemia are associated with increased morbidity and mortality.
- Dietary counseling as an intervention has been shown to reduce phosphorus levels in hyperphosphatemic patients.
- Recent studies have shown that reducing foods high in phosphate additives may result in reduction of serum phosphorus.
- Expert counseling, typically from a renal dietician, will limit potential adverse effects of unmonitored diets.

Scientific acceptability

- Renal dieticians are trained to individualize plans of care for improving phosphorus control.

Feasibility

- Dieticians are readily available in dialysis units and are adequately trained to implement the proposed measure.

Usability

- The above dietary counseling intervention is readily documentable.

7.3.1.1 Discussion of numerator and denominator

The discussion of the frequency of counseling patients was based on the current standard of care in which a patient is counseled at least once a year. It was decided that monthly was too much burden on the facility and if the TEP felt that every 3 months was necessary then they would need to restrict to just patients with hyperphosphatemia which means a threshold for high phosphorus would need to be established. The TEP did not feel comfortable establishing a threshold for high phosphorous and therefore every 6 months seemed appropriate. The TEP also decided that it should be for all patients including pediatric patients in which an appropriate caregiver should also be included. The only exclusion would be transient patients in the facility <30 days. The TEP also discussed the issue of patients with low serum phosphorus and whether increasing dietary phosphorus intake may impact patient outcomes.

The TEP was informed that based on the CMS Conditions for Coverage, patients are required to have a plan of care done within the first 30 days in a facility and then at 3 months and every year after that. They were asked to determine whether the dietary intervention proposed measure was specific enough to modify current practices that are already required. One TEP member countered with the fact that the same argument holds with phosphorus in which it is measured once a month anyway but there is still a requirement to measure it. It was stressed that it was a matter of seeing evidence that it is happening. Another TEP member expressed that this proposed measure is different because they are proposing every 6 months, as opposed to other dietary requirements outlined possibly in NKF in which the minimum may be every 12 months after the first 3 months of dialysis

One TEP member brought up a point about possibly excluding patients who are hearing or visually impaired as these would be barriers to receive and use verbal or written forms of counseling. Others agreed that these patients would still need dietary counseling but that it would have to be through another caregiver of the patient or through a translator. A TEP member brought up the point that patients with total parenteral nutrition or enteral nutrition could be excluded because these patients are already under extensive dietary intervention and the physician would change the prescription for the nutrition if there was an issue. The rest of the TEP agreed with this exclusion.

7.3.1.2 Importance

A first draft of the importance text was drafted by one TEP member. This text was then reviewed, edited, and discussed by the group.

Importance: *Hyperphosphatemia and severe low phosphorus levels are associated with increased morbidity and mortality. Dietary counseling has been shown to lower elevated levels.*

Discussions regarding importance are included in the summary in Section 7.1 Literature Review and Scientific Importance.

7.3.1.3 Scientific acceptability

A first draft of the scientific acceptability text was drafted by one TEP member. This text was then reviewed, edited, and discussed by the group.

Scientific Acceptability: *Dieticians offer the ability to individualize plan of care for improving MBD management*

Discussions regarding scientific acceptability are included in the summary in Section 7.1 Literature Review and Scientific Importance.

7.3.1.4 Feasibility and usability

A first draft of the feasibility and usability text was drafted by one TEP member. This text was then reviewed, edited, and discussed by the group.

Feasibility: *Dieticians are readily available in dialysis units and are adequately trained to deliver this intervention.*

Usability: *Results will limit adverse effects of patient's self-implemented diets (ex: low protein)*

Discussions regarding feasibility and usability are included in the summary in Section 7.1 Literature Review and Scientific Importance.

8. Vitamin D

8.1 Discussion

One TEP member brought up that the TEP had not discussed the subject of Vitamin D at this point. Another TEP member responded by saying the subject of Vitamin D in the general population is controversial and it would be more controversial in dialysis patients, given that the role of vitamin D in mineral metabolism in patients with ESRD may be even more complex . One TEP member added that the levels are all low and that they don't know the appropriate levels nor do we know the morbidity or mortality associated with levels. It was quickly agreed that there is not strong evidence to support a measure for Vitamin D at this time in ESRD patients.

8.2 Recommendation

The majority of the TEP agreed that there is not enough evidence to develop a Vitamin D measure.

9. Recommendations for Studies to improve the level of evidence in MBD, Funding, Policy, and CROWNWeb

9.1 Discussion

Since the TEP agreed that it is not possible to propose additional measures due to lack of evidence, CMS requested the TEP to come up with a list of studies that would provide the evidence needed. The TEP repeatedly raised the issue of the overall lack of evidence that was available due to the lack of randomized clinical trials that exist in order to inform recommendations for proposed measures, and meet the criterion of scientific acceptability. One TEP member said that if there had been a large randomized clinical trial that compared placebo and binders then the TEP would probably have felt that they would have sufficient evidence for a measure specifying either a phosphorus level or a treatment regimen; however, she acknowledged that it would not be funded due to concerns over the ethical concerns of a true placebo in an ESRD patients. However, a study that compared the achievement of two different levels of phosphorus would be ethical (for example randomized to phosphorus of 7 versus 4 mg/dl). However, a phosphate binder versus placebo study in CKD patients with hard end points was needed. The TEP discussed a pilot 9 month study in pre-dialysis CKD patients (Block2012) that showed no benefit on coronary calcification or bone density. . The TEP also determined that it would be useful to have studies that had hard outcomes such as cardiovascular events, fractures, mortality, hospitalizations etc. Randomized controlled trials that target different goals of phosphorus or PTH levels with hard outcomes would be the most ideal. Due to the lack of funding for studies in the field of MBD within the dialysis population, the TEP came up with a list of recommendations to CMS regarding ways to fund these studies. A few TEP members thought that CMS can direct and wholly or partially fund LDOs to try to conduct some of these studies for the sake of information.

Based on information provided by representatives from the CROWNWeb project team, the TEP members had a short discussion about the proposed measures. Some TEP members thought that the data entry for each patient would be too much of a burden to require lab values for all three of the

values (calcium, phosphorus, and PTH). There was some discussion that it might be easier for the facility to just input the percentage of patients instead of values for each patient. It was explained to the TEP that from a data standpoint it is much more accurate to input the patient's individual laboratory values.

One TEP member recommended that there is a difference in what we need from CROWNWeb and what we want from CROWNWeb. This TEP member said that the TEP is really only asking for a yes/no that phosphorus, calcium and PTH were done in the specified time frames for each measure whereas this could serve as rich resource for determining future measures. Another TEP member questioned why they would ask for the name of the assay if the TEP only wanted CW to report a yes/no for each of these measures instead of a value. A TEP member thought that it was important to know the assay so that it remained consistent. Other TEP members believed that it was easier to submit a value than to check a Yes/No box in CW and that most LDOs may have this process automated. The TEP discussed the burden of the data collection on the facility.

Due to the lack of definitive consensus on the required data elements for CROWNWeb, the TEP ultimately decided that it was best to leave the proposed measures as currently defined but suggested that the TEP have the opportunity to look at the data elements as they appear in CW and provide feedback prior to a change.

9.2 Recommendations for Studies that would Improve the Level of Evidence

The TEP's final recommendations for additional studies that they would like to see:

- Randomized controlled clinical trials in patients undergoing dialysis that target different goals of phosphorus or PTH levels with hard outcomes (mortality, fractures, hospitalizations, cardiovascular events) in ESRD patients
- Non-dialysis CKD patients - phosphorus binders vs. placebo for hard outcomes.
- Develop better dietary instructions appropriate for various levels of health literacy (i.e., reduced math and reading literacy)
- Incidence and prevalence of fractures, falls and frailty in dialysis patients needs further study
- Bone density, bone biomarkers, bone biopsies and other novel measures of bone health in dialysis patients

9.3 Recommendations for Funding

The TEP recognized that the key obstacle for any of the proposed studies is the lack of dedicated funding. Therefore, they specified the following funding recommendations for CMS consideration:

- CMS could partially or wholly fund studies that may improve care and result in health care cost savings in the field of MBD
- CMS could encourage the NIH/AHRQ to fund research in the field of MBD
- CMS could encourage LDOs to conduct national pragmatic trials in the field of MBD

9.4 Recommendations for Policy

The TEP also came up with a policy recommendation slide for limitations that arose within several discussions earlier and would be ideal in order to make future recommendations

- We encourage CMS to collaborate with the FDA as a major limitation to dietary phosphate control is a lack of quantitative food labeling for phosphate
- Furthermore phosphate additive are on the GRAS (generally regarded as safe) list and should be reevaluated.

9.5 Recommendations for CROWNWeb

CROWNWeb Related Request:

- The TEP should be consulted during the development of the implementation plan for collection of data by CMS for adopted quality measures

10. Conclusion and Summary Recommendations

The TEP addressed topic areas of interest to CMS, namely serum vs. plasma measurements for phosphorous and calcium, corrected vs. uncorrected serum calcium measurements, and bone histology/bone fractures. The TEP also recommended two new measures during their discussions at the in-person meeting.

- Measurement of Plasma PTH Concentration
- Percentage of Patients with Dietary Counseling

The TEP also suggested revisions to the existing measures:

- Measurement of serum phosphorus
- Measurement of uncorrected serum calcium (to be revised and then resubmitted to NQF, as this measure is currently retired; NQF #0216)

The TEP discussed the current hypercalcemia measure and recommended to not make any changes.

10.1 Recommendations for a future TEP

The TEP members recommended that a lab-specific TEP be convened that included experts in CLIA and CAP for the purpose of defining measures for laboratory tests and procedures that may affect laboratory values.

Due to the low level of evidence in the published literature on mineral and bone disorder, the TEP provided several recommendations for areas where further study and funding are needed as well as policy recommendations that would to aid in making future measure recommendations:

10.2 Recommendations for studies

- Randomized controlled clinical trials ESRD patients undergoing dialysis examining various levels of phosphorus or PTH levels and outcomes such as mortality, fractures, hospitalizations, and cardiovascular events
- Examining hard outcomes in Non-dialysis CKD patients on phosphorus binders vs. placebo
- Health literacy levels and dietary instructions
- Further study into the incidence and prevalence of fractures, falls
- Novel measures of bone health in dialysis patients

10.3 Recommendations for funding

- CMS could partially or wholly fund studies that may improve care and result in health care cost savings in the field of MBD
- CMS could encourage the NIH/AHRQ to fund research in the field of MBD
- CMS could encourage LDOs to conduct national pragmatic trials in the field of MBD

10.4 Recommendations for policy

- Collaboration between CMS and the FDA on quantitative food labeling
- Reevaluation of phosphate additives on the GRAS (generally regarded as safe) list

11. Summary of Measure Recommendations

Measure Name	**Measure Description**	**Type of Measure**
Measurement of Uncorrected Serum Calcium	Percentage of all peritoneal dialysis and hemodialysis patients included in the sample for analysis with uncorrected serum calcium measured at least once within a month	Process
Measurement of Serum Phosphorus	Percentage of all peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum phosphorus measured at least once within a month	Process
Measurement of Plasma PTH Concentration	Percentage of all peritoneal dialysis and hemodialysis patients included in the sample for analysis with plasma PTH measured, together with documentation of the specific PTH assay utilized*, at least once within a 3 month period	Process

Percentage of Patients with Dietary Counseling	Percentage of all hemodialysis and peritoneal dialysis patients included in the sample for analysis with dietary counseling of the patient and/or caregiver on appropriate phosphorus sources and content as part of an overall healthy nutrition plan at least once within each six-month periods	Process

12. References

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