

DEVELOPING BONE DISEASE CLINICAL PERFORMANCE MEASURES FOR PATIENTS WITH KIDNEY FAILURE

Final Report

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ESRD Special Project

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Final Report

Bone Disease and Mineral Metabolism Clinical Performance Measures (CPMs) for Patients With Kidney Failure

Background for the End Stage Renal Disease Clinical Performance Measures

The Centers for Medicare & Medicaid Services (CMS) contracts with the End Stage Renal Disease (ESRD) Network Organizations to stimulate and facilitate improvements in the quality of care that patients with ESRD receive throughout the United States. In 1994, CMS established the ESRD Health Care Quality Improvement Program (HCQIP), and in an effort to identify and understand trends in ESRD care, CMS established the ESRD Core Indicators Project. This project involved collecting quality indicator data for anemia management, dialysis adequacy, nutrition, and blood pressure control on a 5% national sample of patients.

In 1998, following the publication of the National Kidney Foundation Dialysis Outcomes Quality Initiative (NKF-DOQI) guidelines, CMS contracted with Qualis Health (formerly PRO-West) to develop a set of clinical performance measures (CPMs) for dialysis adequacy, anemia management and vascular access.^{1,2,3} These CPMs were based on selected NKF-K/DOQI clinical practice guidelines (CPGs) and were developed as a method to measure and report the quality of care provided to beneficiaries of ESRD services under the Medicare program. These performance measures were merged with the ESRD Core Indicators Project in March 1999. The combined

projects, now known as the ESRD Clinical Performance Measures Project, have provided insight into the quality of care received by ESRD patients in the United States. A report of the ESRD CPM Project results is published annually and is available on the CMS website at www.cms.hhs.gov/esrd/1.asp.

Description of Project to Develop Additional Measures

Renal bone disease is a complication of ESRD that has an important impact on the morbidity and mortality of chronic kidney disease (CKD) patients.⁴ In 2003, NKF - K/DOQI published CPGs for Bone Metabolism and Disease in Patients with Chronic Kidney Disease.⁵ To further expand understanding of this important parameter of care, CMS issued a Statement of Work to develop clinical performance measures to assess and track the management of renal bone disease and mineral metabolism for patients receiving dialysis therapy.

In the summer of 2004, CMS contracted with the Renal Network of the Upper Midwest (Network 11) to develop bone disease and mineral metabolism CPMs for patients with chronic kidney failure receiving dialysis. (Project Team members are listed in Appendix A.) The Statement of Work required Network 11 to develop and recommend a set of CPMs to assess and track bone disease management at the dialysis facility level.

The measures were to be based on the 2003 K/DOQI CPGs for Bone Metabolism and Disease in Patients with Chronic Kidney Disease and were to specifically address adult CKD Stage 5 patients receiving dialysis therapy.

The specific tasks identified in the Statement of Work included:

- Solicit input from the renal community to prioritize the K/DOQI Clinical Practice Guidelines for Bone Metabolism and Chronic Kidney Disease.
- Convene a Technical Expert Panel (TEP) to assist in prioritizing the guidelines and developing CPMs. The TEP membership was to include members from the NKF-K/DOQI bone disease workgroup, other clinical or technical experts, and a consumer representative. TEP members are listed in Appendix B.
- Coordinate an ESRD Stakeholders meeting at which time the proposed CPMs were to be available for stakeholder comment.
- Submit a set of CPMs, based on the 2003 NKF-K/DOQI Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease, for adult CKD Stage 5 patients receiving dialysis therapy that can be used for facility-level quality improvement and for public reporting at the dialysis facility level.
- Recommend a method to pilot test the data collection process.

Prioritizing the Guidelines

Network 11 collaborated with its consultants, Qualis Health and Nephrology Pharmacy Associates (NPA),

to design an input document to solicit opinions from the renal community to prioritize the Bone Metabolism and Disease CPGs according to their appropriateness for conversion to performance measures. This input document was available to all members of the renal community in paper format and as an on-line document on the Network 11 web site, www.esrdnet11.org.

The availability of this input document was publicized at the 2004 Annual Meeting of the American Society of Nephrology, through appropriate professional organizations (i.e., American Nephrology Nurses Association, American Association of Kidney Patients, National Kidney Foundation, Council on Renal Nutrition, etc.), and to all ESRD Network offices for dissemination to their respective Medical Review Boards. Respondents were asked to rate each of the K/DOQI guidelines for the following attributes:

- Clinical importance;
- Strength of evidence;
- Feasibility of measurement; and
- Suitability of the guideline for facility level measurement

Measures were rated based on a 5-point Likert scale (5 = strongly agree; 1 = strongly disagree). Certain guidelines that were not applicable to CKD stage 5 patients were excluded from this process. Ninety-seven renal professionals responded during the comment period of September 1 through October 31, 2004. The input document and results of the prioritization by the renal community can be found in Appendix C.

Technical Expert Panel

A Technical Expert Panel (TEP) was assembled to assist Network 11 in the development of the CPMs. The TEP included members of the K/DOQI bone guideline development workgroup, experts in the field of bone disease and mineral metabolism, people with experience in clinical performance measures, and a consumer of ESRD services. The TEP met three times and provided additional input and information electronically. The in-person meetings were held in Baltimore, MD.

- November 17-18, 2004
- February 16-17, 2005
- April 15, 2005

A Project Timeline and TEP meeting minutes are included in Appendices D-E. During the TEP meetings, results were presented from Network 11's quality improvement activities on bone disease and mineral metabolism. TEP members were encouraged to note improvements made by Network 11 dialysis facilities toward meeting the four goals described by the NKF-K/DOQI process. See Appendix F.

To provide input and assistance to Network 11, the TEP used the process of CPM development that was published by Sugarman, et al in October 2003.¹ A high priority was placed on developing CPMs that would positively impact important clinical outcomes. The same areas that had been used by NKF-K/DOQI to prioritize the guidelines (i.e., clinical importance; potential for improvement; ability to be measured accurately and reliably; and feasibility for collection,

analysis, and reporting purposes) were consistently used as guiding principles as measures were considered for recommendation.

The TEP recommended that the CPMs be facility-based, inclusive of all prevalent patients, amenable to electronic data gathering and reporting, and eventually available on a monthly or quarterly basis to facilities and oversight agencies. Current systems may allow for only annual reporting of these parameters, but the TEP strongly recommended that CMS and the ESRD Networks develop and use resources to make this information available on a monthly or quarterly basis.

Development of Measures

The Statement of Work specifically directed Network 11 to use the 2003 K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease as the evidence basis for suggested CPMs.⁵ For this reason, an exhaustive review of all medical literature to identify new evidence for the proposed CPMs was not performed. The TEP members were asked to review the pertinent medical literature published between January 1, 2001 and December 31, 2004. The references cited within the proposed CPMs are not meant to be a complete bibliography of all pertinent publications. The literature review includes two publications that provide more in-depth information regarding PTH assays.

At its first meeting, the TEP reviewed each of the K/DOQI Clinical Practice

Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease that were applicable to adult CKD Stage 5 patients receiving dialysis therapy. All

TEP members recommended that the guidelines in the following table be excluded from further consideration for the development of CPMs.

Excluded Guidelines and Rationale

GUIDELINE NAME	GUIDE-LINE NUMBER	RATIONALE
Dialysate Calcium Concentrations	9	This is a patient management decision rather than performance measure. These data would be extremely difficult to interpret without in-depth knowledge of the patient's medical problems, bone mineral status, full medication profile, and many other pieces of information that guide the nephrologist in choosing the dialysate calcium concentration.
β₂-Microglobulin Amyloidosis	10	There is no reliable, easily performed method to identify this condition, and there is no currently available therapy to stop disease progression or consistently provide symptomatic relief.
Aluminum Overload and Toxicity in CKD and Treatment of Aluminum Toxicity	11 12	Aluminum toxicity is an extremely serious, debilitating, and even potentially fatal disorder in dialysis patients. At the current time, however, the use of aluminum-containing phosphate binders and aluminum contamination of dialysis water are rare occurrences. The current incidence and prevalence of aluminum toxicity in dialysis patients are extremely low. Reporting of this data would be unlikely to benefit large numbers of patients, and numerous resources at the facility, CMS, and Network levels would be consumed in gathering such data. The TEP agreed that facilities should adhere to the current AAMI guidelines for dialysis water treatment and monitoring, and that facilities should continue to monitor serum aluminum concentrations at the frequency that is currently recommended by the K/DOQI guidelines (every 3 months) and allowed by current reimbursement schedules.
Parathyroidectomy in Patients with CKD	14	The difficulty in obtaining accurate and reliable surgical information in an efficient manner made it not feasible for facility level data collection. It was the consensus opinion of the TEP that the MRB, by monitoring the concentrations of PTH for patients within a facility, would have sufficient information to assess the issue of PTH control for that facility. Little additional information would be gained by monitoring the incidence or prevalence of parathyroid surgery.
Metabolic Acidosis	15	Controversies still exist regarding the optimal level of total CO ₂ . There are difficulties in obtaining accurate, reliable measurements of CO ₂ specifically due to the fact that many facilities submit blood samples via mail services to central labs, and there are certain methodological difficulties that might impact these measurements.

Each of the remaining K/DOQI guidelines that were applicable to adult stage 5 CKD patients receiving dialysis therapy was then categorized into one of two areas – lab measurement or facility management. A preliminary set of 6 CPMs regarding laboratory measurements (Measurement CPMs) and 16 CPMs regarding facility management of bone disease and mineral metabolism (Management CPMs) was drafted at the conclusion of the first TEP meeting. See Appendix G for this set of preliminary CPMs.

At its second meeting, the TEP reviewed each of these 22 draft CPMs with regard to its potential as an effective CPM. The TEP members agreed that the 16 proposed management CPMs did not meet criteria for feasibility, ease of interpretation, and accurate and reliable measurement. These proposed management CPMs included (but were not necessarily limited to) areas such as:

- Facility provision of prescriptions for oral medications;
- Nutritional instruction by dietitians;
- Investigation of psychosocial factors affecting bone disease and mineral metabolism;
- The presence of patient educational programs;
- Patient adherence to dietary and medication recommendations;
- Patient adherence to the dialysis prescription; and
- Effectiveness of educational tools.

Although current systems do not support effective CPMs in these management areas, each is very important in attaining the goals contained in the final set of

recommended CPMs. Network 11 and the TEP recognize that the dialysis facility itself and regional Network Medical Review Boards (MRBs) are in better positions to assess each of these individual factors in a dialysis facility that is not achieving desired performance with the recommended CPMs. Local knowledge of the patient population, and other subtle factors, are best left to the dialysis facility and regional Network MRBs. This analysis could help to better define areas for improvement in facilities that are not reaching the desired level of performance. It was the broad consensus of the TEP that current data gathering and analysis tools lack sufficient sophistication to allow for meaningful interpretation of the elements contained in the Management CPMs. At this time, these factors were not felt to be amenable to national oversight and that strict CPMs in this area might actually thwart innovative methods to attain the desired measurements in the area of bone disease and mineral metabolism. The spirit of these discussions has been incorporated in the comments section for each of the six recommended CPMs (see Appendix H).

At the end of the second TEP meeting, a set of six recommended CPMs was developed for subsequent presentation at a meeting of ESRD stakeholders. (See Appendix H).

ESRD Stakeholders Meeting and Final TEP Meeting

On April 14, 2005, CMS convened a meeting of ESRD stakeholders. The CPMs and background information were presented, and those in attendance were

given the opportunity to provide input at the meeting. Comments received at the meeting were reviewed and considered, as the proposed CPMs were refined at the third and final meeting of the TEP on April 15, 2005. Additional comments were received from the renal community until May 15, 2005. These additional comments were reviewed by Network 11 and distributed electronically to the TEP members for review. As appropriate, comments were incorporated into the proposed CPM

Recommended CPMs

Based on input from the renal community, comments from the ESRD Stakeholders, and assistance from the Technical Expert Panel, Network 11 recommends that the following Clinical Performance Measures be adopted by CMS into the National ESRD CPM Data Collection Project. For complete CPMs

with references and comments, please see Appendix H.

The setting, inclusion criteria, and exclusion criteria are the same for each of the following six CPMs, and are specifically identified in Appendix H.

- Setting and inclusion criteria: outpatient, stage 5, chronic kidney disease, adult patients on dialysis (both hemodialysis and peritoneal dialysis).
- Exclusions: transient dialysis patients, pediatric dialysis patients, and kidney transplant recipients with a functioning graft.

Patient sample, data collection methods, data validation, and data analysis are subject to those used for the overall ESRD CPM Project.

Bone Disease and Mineral Metabolism CPM #1

CLINICAL PERFORMANCE MEASURE NAME AND NUMBER

Bone Disease and Mineral Metabolism CPM #1: Measurement of serum phosphorus concentration

QUALITY STATEMENT

Serum phosphorus should be measured at least monthly in patients with CKD stage 5 currently receiving renal replacement therapy with hemodialysis (HD) or peritoneal dialysis (PD).

NKF-K/DOQI CLINICAL PRACTICE GUIDELINE NAME AND NUMBER

Evaluation of Calcium and Phosphorus Metabolism (Guideline 1.1)

EVIDENCE BASIS

- Measurement - evidence based
- Frequency - opinion based

GUIDELINE RANKING (RENAL COMMUNITY INPUT DOCUMENT)

- | | |
|--|--------|
| • Clinical importance | 97.44% |
| • Strength of evidence | 86.73% |
| • Feasibility of measurement | 87.93% |
| • Suitability for facility level measurement | 89.78% |

DATA COLLECTION, REPORTING, AND PURPOSE

- 5% national sample: public reporting of trends and regional differences
- 100% data collection: facility-specific public reporting on Dialysis Facility Compare web site and facility-specific and Network quality improvement purposes

MEDICAL REVIEW CRITERIA

Percent of patients with phosphorus measured at least monthly

NUMERATOR

Number of adult dialysis patients included in the denominator with serum phosphorus concentration measured at least once within the month

DENOMINATOR

All adult dialysis patients included in the sample for analysis

DATA SOURCE

Abstracted from facility records or received electronically

APPLICABLE SETTING

In-center HD, home HD, in-center PD, and home PD patients

DATA ELEMENT AND SPECIFICS OF DATA COLLECTION

- First serum phosphorus laboratory value of the calendar month
- For HD patients, the blood for testing should be drawn prior to the patient initiating a dialysis treatment
- For PD patients, the blood for testing should be drawn at or immediately prior to the monthly clinic visit

EXCLUSIONS

Transient patients, pediatric patients, kidney transplant patients with a functioning graft

Bone Disease and Mineral Metabolism CPM #2

CLINICAL PERFORMANCE MEASURE NAME AND NUMBER

Bone Disease and Mineral Metabolism CPM #2: Evaluation of serum phosphorus concentration

QUALITY STATEMENT

Serum phosphorus concentration should be maintained between 3.5 – 5.5 mg/dL in patients with CKD Stage 5 currently receiving renal replacement therapy with HD or PD.

NKF-K/DOQI CLINICAL PRACTICE GUIDELINE NAME AND NUMBER

Evaluation of Serum Phosphorus Levels (Guideline 3.2)

EVIDENCE BASIS

Evidence based

GUIDELINE RANKING (RENAL COMMUNITY INPUT DOCUMENT)

- Clinical importance: 100%
 - Strength of evidence: 90.69%
 - Feasibility of measurement: 93.25%
 - Suitability for facility level measurement: 87.83%
-

DATA COLLECTION, REPORTING, AND PURPOSE

- 5% national sample: public reporting of trends and regional differences
 - 100% data collection: facility-specific public reporting on Dialysis Facility Compare web site and facility-specific and Network quality improvement purposes
-

MEDICAL REVIEW CRITERIA

Percent of patients with serum phosphorus concentration 3.5 – 5.5 mg/dL

NUMERATOR

Number of adult dialysis patients included in denominator with serum phosphorus concentration of 3.5 – 5.5 mg/dL (inclusive range)

DENOMINATOR

All adult dialysis patients included in the sample for analysis

DATA SOURCE

Abstracted from the facility medical record or received electronically

DATA ELEMENTS AND SPECIFICS OF DATA COLLECTION

- First serum phosphorus laboratory value of the calendar month
 - For HD patients, the blood for testing should be drawn prior to the patient initiating a dialysis treatment
 - For PD patients, the blood for testing should be drawn at or immediately prior to the monthly clinic visit
-

APPLICABLE SETTING

In-center HD, home HD, in-center PD, and home PD patients

EXCLUSIONS

Transient patients, pediatric patients, and kidney transplant patients with a functioning graft

Bone Disease and Mineral Metabolism CPM #3

CLINICAL PERFORMANCE MEASURE NAME AND NUMBER

Bone Disease and Mineral Metabolism CPM #3: Measurement of serum calcium concentration

QUALITY STATEMENT

Serum calcium concentration should be measured at least monthly in patients with CKD Stage 5 currently receiving renal replacement therapy with HD or PD.

NKF-K/DOQI CLINICAL PRACTICE GUIDELINE NAME AND NUMBER

Evaluation of Calcium/Phosphorus Metabolism (Guideline 1.1)

EVIDENCE BASIS

- Measurement – evidence based
 - Frequency – opinion based
-

GUIDELINE RANKING (RENAL COMMUNITY INPUT DOCUMENT)

- Clinical importance: 97.44%
 - Strength of evidence: 86.73%
 - Feasibility of measurement: 87.93%
 - Suitability for facility level measurement: 89.78%
-

DATA COLLECTION, REPORTING, AND PURPOSE

- 5% national sample: public reporting of trends and regional differences
 - 100% data collection: facility-specific public reporting on Dialysis Facility Compare web site and facility-specific and Network quality improvement purposes
-

MEDICAL REVIEW CRITERIA

Percent of patients with serum calcium measured at least monthly

NUMERATOR

Number of adult dialysis patients included in denominator with serum calcium concentration measured at least once within the month

DENOMINATOR

All adult dialysis patients included in the sample for analysis

DATA SOURCE

Abstracted from the facility record or received electronically

DATA ELEMENTS AND SPECIFICS OF DATA COLLECTION

- First serum calcium laboratory value of the calendar month
 - For HD patients, the blood for testing should be drawn prior to the patient initiating a dialysis treatment
 - For PD patients, the blood for testing should be drawn at or immediately prior to the monthly clinic visit
 - For both HD and PD patients, serum albumin concentration should be measured on the same day and same time that the serum calcium is measured
 - Data collection should also include the reference range for serum calcium measurement used by the laboratory serving the dialysis facility
-

APPLICABLE SETTING

In-center HD, home HD, in-center PD, and home PD patients

EXCLUSIONS

Transient patients, pediatric patients, kidney transplant patients with functioning graft

Bone Disease and Mineral Metabolism CPM #4

CLINICAL PERFORMANCE MEASURE NAME AND NUMBER

Bone Disease and Mineral Metabolism CPM #4: Evaluation of Serum Calcium Concentration

QUALITY STATEMENT

Concentrations of total corrected serum calcium should be maintained less than or equal to the upper limit of normal in patients with CKD Stage 5 currently receiving renal replacement therapy with HD or PD.

NKF-K/DOQI CLINICAL PRACTICE GUIDELINES, NAMES, AND NUMBERS

Serum Calcium and Calcium Phosphorus Product (Guidelines 6.2, 6.3c, 6.6a, 6.6b)

EVIDENCE BASIS

- 6.2 - opinion based
 - 6.3c - opinion based
 - 6.6a - opinion based
 - 6.6b - opinion based
-

GUIDELINE RANKING (RENAL COMMUNITY INPUT DOCUMENT)

	<u>6.2</u>	<u>6.3c*</u>	<u>6.6a*</u>	<u>6.6b*</u>
• Clinical importance:	87.59%	N/A	N/A	N/A
• Strength of evidence:	59.03%	N/A	N/A	N/A
• Feasibility of measurement:	93.32%	N/A	N/A	N/A
• Suitability for facility level measurement:	80.93%	N/A	N/A	N/A

MEDICAL REVIEW CRITERIA

Percent of patients with appropriately adjusted serum calcium concentration of ≤ 9.5 mg/dL**

NUMERATOR

- A. Number of adult dialysis patients included in the denominator with appropriately adjusted serum calcium concentration ≤ 9.5 mg/dL**
 - B. Number of adult dialysis patients included in the denominator with appropriately adjusted serum calcium concentration ≤ 10.2 mg/dL**
 - C. Number of adult dialysis patients included in the denominator with appropriately adjusted serum calcium concentration \leq the upper limit of normal for total serum calcium in the laboratory used by the facility**
-

DENOMINATOR

All adult dialysis patients included in the sample for analysis

DATA SOURCE

Abstracted from the facility record or received electronically

DATA ELEMENTS AND SPECIFICS OF DATA COLLECTION

- First serum calcium laboratory value of the calendar month
- First serum albumin laboratory value of the calendar month
- For HD patients, the blood for testing should be drawn prior to the patient initiating a dialysis treatment
- For PD patients, the blood for testing should be drawn at or immediately prior to the monthly clinic visit
- For both HD and PD patients, serum albumin concentration should be measured at the same day and time that the serum calcium is measured
- Data collection should also include the reference range for serum calcium measurement used by the specific laboratory serving the dialysis facility
- Data collection should also include the specific assay method for measuring serum albumin concentration, i.e. Bromocresol Green or Bromocresol Purple
- The K/DOQI methodology for serum calcium correction should be applied to the serum calcium concentration if the serum albumin concentration measured on the same day is below the lower limit of normal.
- The correction methodology recommended by K/DOQI is the following formula:
Corrected total serum calcium = total serum calcium (mg/dL) + 0.8 × [4 - serum albumin (g/dL)] (from Guideline 6: Serum Calcium and Calcium-Phosphorus Product – rationale)

APPLICABLE SETTING

In-center HD, home HD, in-center PD, and home PD patients

EXCLUSIONS

Transient patients, pediatric patients, kidney transplant patients with a functioning graft

* Guidelines 6.3c, 6.6a, and 6.6b not rated as part of the renal community input document.

** If the serum albumin concentration is within or above the normal reference range for the assay used by the facility, then the actual value for the total serum calcium, without application of the formula for corrected serum calcium, will be used for purposes of analysis. But, if the serum albumin concentration is below the lower limit of the normal reference range for the assay used by the facility, then the formula for calcium correction should be used by the facility and for the purposes of this analysis.

Bone Disease and Mineral Metabolism CPM #5

CLINICAL PERFORMANCE MEASURE NAME AND NUMBER

Bone Disease and Mineral Metabolism CPM #5: Measurement of Serum Parathyroid Hormone (PTH) Concentration

QUALITY STATEMENT

Serum parathyroid hormone (PTH) concentration should be measured at least every 3 months in patients with CKD Stage 5 currently receiving renal replacement therapy with HD or PD.

NKF-K/DOQI CLINICAL PRACTICE GUIDELINE NAME AND NUMBER

Evaluation of Calcium/Phosphorus Metabolism (Guideline 1.1)

EVIDENCE BASIS

- Measurement - evidence based
 - Frequency - opinion based
-

GUIDELINE RANKING (RENAL COMMUNITY INPUT DOCUMENT)

- Clinical importance: 93.95%
 - Strength of evidence: 79.08%
 - Feasibility of measurement: 90.49%
 - Suitability for facility level measurement: 82.60%
-

DATA COLLECTION, REPORTING, AND PURPOSE

- 5% national sample: public reporting of trends and regional differences
 - 100% data collection: facility-specific public reporting on Dialysis Facility Compare web site and facility-specific and Network quality improvement purposes
-

MEDICAL REVIEW CRITERIA

Percent of patients with PTH concentration measured quarterly (every 3 months)

NUMERATOR

Number of adult dialysis patients included in the denominator with serum PTH measured at least once within 3 months

DENOMINATOR

All adult dialysis patients included in the sample for analysis

DATA SOURCE

Abstracted from facility records or received electronically

DATA ELEMENTS AND SPECIFICS OF DATA COLLECTION

- First serum parathyroid hormone laboratory value of the calendar month
 - For HD patients, the blood for testing should be drawn prior to the patient initiating a dialysis treatment
 - For PD patients, the blood for testing should be drawn at or immediately prior to the monthly clinic visit
 - Type of PTH assay used for measurement should be collected along with the laboratory values. In addition, the normal laboratory reference range for that assay should be collected.
 - Care must be taken to assure that correct sampling technique is used when collecting samples and preparing samples for transport to the testing laboratory.
-

APPLICABLE SETTING

In-center HD, home HD, in-center PD, and home PD patients

EXCLUSIONS

Transient patients, pediatric patients, and kidney transplant patients with a functioning graft.

Bone Disease and Mineral Metabolism CPM #6

CLINICAL PERFORMANCE MEASURE NAME AND NUMBER

Bone Disease and Mineral Metabolism CPM #6: Evaluation of Serum Parathyroid Hormone (PTH) Concentration

QUALITY STATEMENT

Serum Intact PTH concentrations should be maintained between 150 – 300 pg/mL in patients with CKD Stage 5 currently receiving renal replacement therapy with HD or PD*.

NKF-K/DOQI CLINICAL PRACTICE GUIDELINE NAME AND NUMBER

Evaluation of Calcium and Phosphorus Metabolism (Guideline 1.4)

EVIDENCE BASIS

Evidence based

GUIDELINE RANKING (RENAL COMMUNITY INPUT DOCUMENT)

- Clinical importance: 93.02%
 - Strength of evidence: 71.71%
 - Feasibility of measurement: 89.66%
 - Suitability for facility level measurement: 81.94%
-

DATA COLLECTION, REPORTING, AND PURPOSE

- 5% national sample: public reporting of trends and regional differences
 - 100% data collection: facility-specific public reporting on Dialysis Facility Compare web site and facility-specific and Network quality improvement purposes
-

MEDICAL REVIEW CRITERIA

- Percent of patients with intact PTH concentration 150 – 300 pg/mL (num A/den)
 - Percent of patients with intact PTH concentration < 150 pg/mL (num B/den)
 - Percent of patients with intact PTH concentration > 300 pg/mL (num C/den)
-

NUMERATOR

- A. Number of adult dialysis patients included in denominator with intact PTH concentration 150 – 300 pg/mL (inclusive range)
 - B. Number of adult dialysis patients included in denominator with intact PTH concentration < 150 pg/mL
 - C. Number of adult dialysis patients included in denominator with intact PTH concentration > 300 pg/mL
-

DENOMINATOR

All adult dialysis patients included in the sample for analysis

DATA SOURCE

Abstracted from the facility record or received electronically

DATA ELEMENTS AND SPECIFICS OF DATA COLLECTION

- First serum parathyroid hormone laboratory value of the calendar month
 - For HD patients, the blood for testing should be drawn prior to the patient initiating a dialysis treatment
 - For PD patients, the blood for testing should be drawn at or immediately prior to the monthly clinic visit
 - Type of PTH assay used for measurement should be collected along with the laboratory value. In addition, the normal laboratory reference range for that assay should be collected.
 - Care must be taken to assure that correct sampling technique is used when collecting samples and preparing samples for transportation.
-

APPLICABLE SETTING

In-center HD, home HD, in-center PD, and home PD patients

EXCLUSIONS

Transient patients, pediatric patients, and kidney transplant patients with a functioning graft

* For a detailed discussion of PTH measurement methods, see pages 16-17 (*Selected Observations, Caveats, and Limitations of the Project – CPM #6*) of the final report and the comments section of CPM #6 in Appendix H. These two sections provide a comparison of the commonly used methods of PTH measurement.

Selected Observations, Caveats, and Limitations of the Project

CPM #2: Evaluation of serum phosphorus concentration.

Attaining the desired goals for serum phosphorus presents a challenge to dialysis clinicians. Because patient adherence to dietary and medication regimen plays a central role in attaining desired serum phosphorus outcomes, patients must be deeply involved in quality improvement programs. Patient-related barriers such as education, financial limitations, psychosocial factors, and adherence to recommended medication and dialysis programs will need to be closely assessed. National and local organizations for both nephrology care providers and dialysis patients should develop assessment and improvement tools for this important clinical area. In the meantime, dialysis facility staff should be encouraged to use those tools that are already available. Providers must also be aware that hyperphosphatemia may be a proxy for other issues that are affecting patient behavior (e.g., learning disabilities, financial limitations, depression, etc.).

CPM #4: Evaluation of serum calcium concentration.

There are unique difficulties in defining the optimum serum calcium concentration. The K/DOQI guidelines state three desirable concentrations of serum calcium:

- The normal range for the laboratory of a specific dialysis facility;
- Serum calcium less than 10.2 mg/dL; and

- A desired upper limit for serum calcium of 9.5 mg/dL.

Dialysis facilities and local Network MRBs should be aware of these issues when assessing the performance of an individual dialysis facility. The main intent of the K/DOQI guidelines was to avoid hypercalcemia that might be pharmacologically driven by the administration of calcium salts, vitamin D sterols, or the use of high concentrations of dialysate calcium. The K/DOQI guidelines recommend the use of a specific equation for the correction of serum calcium when serum albumin is lower than normal (K/DOQI Guideline 6, Serum Calcium and Calcium-Phosphorus Product; Background and Strength of Evidence). That equation is:

Total corrected serum calcium = Total serum calcium (mg/dL) + 0.8 × [4 - serum albumin (g/dL)].⁵

In some cases, however, clinicians have begun to adjust serum calcium even in the presence of a normal albumin concentration. This practice has led to adjustments of serum calcium when both calcium and albumin concentrations are within the normal range. The TEP recommends that this practice should be discouraged. If both albumin and calcium concentrations are normal, the values should be regarded as being normal; and therefore the calcium would require no correction (K/DOQI Guideline 6, Serum Calcium and Calcium-Phosphorus Product, Background and Strength of Evidence).⁵ It is of concern that a normal serum calcium value might be adjusted downwards if the serum albumin concentration was at the upper limit of normal. This might prompt facilities to develop protocols for the

administration of calcium salts or vitamin D in situations where these medications would not ordinarily be recommended.

CPM #6: Evaluation of parathyroid hormone concentrations.

The original K/DOQI guidelines were developed based on studies using PTH assays that measured serum intact PTH concentrations. Clinical practice has changed since the development of these guidelines, and most dialysis patients in the USA have PTH measurements determined by methodologies that measure the whole molecule 1-84 PTH. These newer assays for whole molecule 1-84 PTH give values that are approximately 50 percent of the older assays for serum intact PTH concentrations. By inference, the desired range for these assays should be approximately 50% of those measured with intact PTH assays.⁶ K/DOQI states that the desired range for intact PTH is 150-300 pg/mL. By inference, the equivalent range for the desired concentrations of whole molecule 1-84 PTH appears to be approximately 75-150 pg/mL. There are several different assays currently in use that measure whole molecule 1-84 PTH. There are no large evidence- or outcome-based studies regarding the most desirable range for the concentrations of the newer 1-84 PTH assays in CKD patients receiving dialysis therapy. For further discussion of this issue, see the comments listed in Appendix H, CPM #6.

The TEP members strongly support the ongoing efforts to analyze and standardize all of the various PTH assays.

The desirable range for whole molecule 1-84 PTH concentrations in CKD Stage 5 patients may need to be altered as newer evidence becomes available to the renal community. In addition, the introduction of calcimimetic agents (that were not available during the development of the K/DOQI guidelines) may result in changes to the desirable concentrations of serum PTH because older studies were performed in a time during which only vitamin D sterols were used to suppress serum PTH concentration. It is not known if the widespread availability and co-administration of calcimimetic agents and vitamin D sterols might alter the relationships between bone histology, patient outcomes, and desirable levels of whole molecule 1-84 PTH in dialysis patients.

Serum PTH concentrations are very dynamic. Dialysis facilities and Network MRBs should monitor trends in PTH, rather than a single PTH value, especially for patients having serum intact PTH concentrations in the ranges of 100-150 pg/mL and 300-400 pg/mL (approximate equivalent whole molecule 1-84 PTH ranges of 50-75 pg/mL, and 150-200 pg/mL). Even though the recommended CPM does not include routine collection of any information about drug use within a facility, if the facility or the Network MRB notes that the number of patients outside the desired range for PTH is elevated, then more information regarding the drug use can be investigated to see if this pattern is due to factors intrinsic to the patients or related to pharmacologic agents. The recommended CPM regarding evaluation of parathyroid hormone was designed to

carefully identify and distinguish patients with pharmacologically driven low concentrations of serum PTH from those patients who have spontaneously low serum concentrations of PTH. This distinction is quite important because many conditions that are associated with low serum concentrations of PTH (e.g., diabetic patients and elderly, small, white women) are conditions that cannot be altered by the dialysis facility. In addition, there are no currently available treatments that can reliably increase the serum concentrations of PTH into desired ranges for such patients.

Current reimbursement policy, which allows for only annual or semiannual determinations of PTH without extensive medical documentation, is in conflict with the guidelines that have been issued by experts in this field. Such guidelines call for determination of serum PTH concentration every 3 months in Stage 5 CKD patients receiving dialysis therapy. It would thus appear that reimbursement policy, rather than the guidelines, are driving medical practice and making it difficult for ESRD professionals to follow such guidelines. Serum parathyroid hormone concentrations should be measured as frequently as necessary to accurately identify, treat, and monitor this important medical condition. It is strongly recommended that CMS work to correct the inconsistencies between reimbursement policy (see Appendix I) and expert guidelines with regard to the desired frequency for monitoring serum concentration of parathyroid hormone.

Calcium-phosphorus product.

The TEP recommended that, in spite of evidence that the calcium-phosphorus product has been shown to be a risk factor for morbidity and mortality, it should not be the subject of a CPM. The previously derived evidence regarding calcium-phosphorus product was obtained in eras when there was more widespread use of calcium-containing phosphate binders, higher concentrations of dialysate calcium, and the absence of calcimimetic agents. With the availability of calcimimetic agents, more non-calcium containing phosphorus binders, and the emphasis on attaining lower concentrations of serum calcium, there could emerge a trend for decreases in the average concentrations of serum calcium. There is concern that these practice changes might affect the validity of calcium-phosphorus product as a risk factor for morbidity and mortality. In addition, undue emphasis on the calcium-phosphorus product might obscure significant hyperphosphatemia, which appears to be a more important risk factor for morbidity and mortality.⁷ For example, a patient with a serum phosphorus concentration of 6.5 mg/dL and a corrected serum calcium concentration of 8.4 mg/dL would have a desirable calcium-phosphorus product (< 55 mg²/dL²), but an undesirable concentration of serum phosphorus.

There have been increasing anecdotal reports of dialysis facilities attempting to simultaneously attain two of four or three of the four main foci of the K/DOQI guidelines (phosphorus, calcium, PTH, and calcium-phosphorus product). Facilities have begun to report quality

outcomes in a format that determines how many patients meet two or more of the four main measures noted above. Continued reporting in this manner, and inclusion of the calcium-phosphorus product as one of these metrics, might allow potential for misuse of this indicator while obscuring problems in attaining desired levels of serum phosphorus and PTH— which might be more important than the calcium-phosphorus product.

Sampling Strategies and Data Collection

In 1999, Qualis Health published the final report, “Developing Clinical Performance Measures for the Care of Patients with End Stage Renal Disease.”^{1,2,3} This report identified strategies for data collection, data processing, and data analysis. These strategies have been adopted by CMS and have been used since 1999 for the ESRD CPM Project. Network 11 recommends that data collection, processing, and analysis of the bone disease and mineral metabolism CPMs be incorporated into this currently used strategy.

Patients included in this data collection will be a 5% national random sample, stratified by Network, of adult (≥ 18 years old) in-center hemodialysis and home peritoneal dialysis patients who are alive and dialyzing on December 31 of the data collection year. While home hemodialysis patients are not included in the national CPM data collection project, Network 11 recommends that those patients be included in the collection of bone disease and mineral metabolism CPMs. Transient patients (dialyzed for less than 30 days at a specific facility)

should be excluded from the analysis, as are pediatric patients and kidney transplant patients with a functioning graft.

In the same project, Qualis Health also developed and recommended a data collection tool. This data collection tool has been used by CMS for the ESRD CPM project since 1999. Network 11 recommends that the bone disease and mineral metabolism clinical indicators be integrated into this data collection system. A proposed data collection form is included as Appendix J. File specifications for this data collection project are found in Appendix K.

CMS is currently working with Computer Sciences Corporation (CSC) and the Large Dialysis Organizations (LDOs) to use electronic means to collect lab values and other clinical indicators needed for the ESRD CPM project. Network 11 supports this initiative and recommends that CMS continue to move towards electronic collection of CPM data elements. Network 11 is confident that the data elements required for the recommended CPMs are amenable to electronic collection. Although independent facilities complete a paper data collection form or a spreadsheet at the present time, Network 11 recommends that CMS and CSC continue to collaborate in an effort to reduce the burden of data collection for these independent dialysis facilities.

Purpose of the Data Collection

The Statement of Work for this project required that Network 11 develop and recommend CPMs that could be used for quality improvement and public

reporting. Currently, data for the national ESRD CPM Project are collected annually for the 4th quarter of each calendar year. The results of this process are reported to the public by means of the ESRD CPM Project Annual Report. As currently proposed, data elements for the bone disease and mineral metabolism CPMs would be collected and reported in the same manner. Data collected as a small national sample should be used to publicly report trends and regional differences. Reporting of a 5% national sample is not adequate, however, for facility-specific public reporting such as the Dialysis Facility Compare web site.

It is recommended that in the future, CPMs for bone disease and mineral metabolism should be collected and reported back to facilities on a quarterly basis, using a 3-month rolling average methodology. This methodology, similar to that used for erythropoietin reimbursement, would assist facilities to identify trends and minimize the dynamic effect of PTH measurement. However, with currently available data collection methods, monthly data collection poses an undue burden on independent dialysis facilities. At such time as facility-specific data are collected from all facilities, they should be made available to dialysis facilities, Network MRBs for quality improvement purposes, and for public reporting on the Dialysis Facility Compare web site.

Pilot Data Collection

The CPMs that are recommended in this final report require the collection of laboratory values and information related

to laboratory methodology. A plan to pilot test the clinical indicators for these CPMs was developed and submitted to CMS in December 2004. The proposal included collection of clinical indicators using both electronic data transfer and hard copy. For a number of reasons, CMS decided to pilot test the data collection of these measures during the annual ESRD CPM data collection effective in 2006, which collects data from the 4th quarter 2005. Draft file specifications for the individual clinical indicators have been submitted to CMS for inclusion in the national CPM data collection for the 4th quarter of 2005, to be collected in 2006. See Appendix J. This information will be obtained electronically from Large Dialysis Organizations and manually from independent facilities – a practice that is already being used. As the results for these bone disease and mineral metabolism CPMs become available, it is possible that CMS, dialysis facilities, and local Network MRBs may require additional time to become more familiar with this previously unavailable data so that it can be appropriately used for quality improvement.

Summary

Bone disease and mineral metabolism play an important role in the morbidity and mortality of CKD Stage 5 patients on dialysis. It has historically been misunderstood, under recognized, and under treated. The development of these CPMs is the first step towards collecting and analyzing the data that will help to identify where quality improvement efforts can best be directed. The current

ESRD CPM Project has shown that the care provided for dialysis patients can be improved. The inclusion of clinical performance measures for bone disease

and mineral metabolism into the current set of indicators will enhance our ability to monitor and improve care for those patients receiving dialysis therapy.

¹ Frederick PR, Maxey NL, Clauser SB, Sugarman JR. Developing facility-specific measures for public reporting.. *HealthCare Financing Review* 2002, 23:4, pp 37-50.

² Sugarman JR, Frederick PR, Frankenfield DL, et al. Developing clinical performance measures based on the dialysis outcomes quality initiative clinical practice guidelines: Process, outcomes, and implications. *Am J Kidney Dis* 2003; 42:806-812.

³ Sugarman JR. ESRD special project: Developing clinical performance measures for the care of patients with end stage renal disease. Final Report, January 1999.

⁴ Block GA, Klaasen PS, et al. Mineral metabolism, mortality, and morbidity in maintenance hemodialysis. *J Am Soc Nephrol* 2004; 15:2208-2218.

⁵ National Kidney Foundation. K/DOQI clinical practice guidelines for bone and mineral metabolism and disease in chronic kidney disease. *Am J Kidney Dis* 2003; 42 (suppl 3):S1-S202.

⁶ Martin KJ, Akhtar I, Gonzales EA. Parathyroid hormone: New assays, new receptors. *Semin Nephrol* 2004; 24:3-4 (Review)

⁷ Young EW, Akiba T, Albert JM. Magnitude and impact of abnormal mineral metabolism in hemodialysis patients in the dialysis outcomes and practice patterns study (DOPPS). *Am J Kidney Dis* 2004; 44 (suppl 2):S34-S38.