DEVELOPING BONE DISEASE CLINICAL PERFORMANCE MEASURES FOR PATIENTS WITH KIDNEY FAILURE

Final Report
July 1, 2004 – June 30, 2005

ESRD Special Project

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Executive Summary
Bone Disease and Mineral Metabolism Clinical Performance Measures for Patients with Kidney Failure

Background

Clinical performance measures (CPMs) for patients with Chronic Kidney Disease (CKD) Stage 5 receiving renal replacement therapy by means of hemodialysis or peritoneal dialysis were first developed by Qualis Health in 1998. The End Stage Renal Disease (ESRD) CPMs addressed the four clinical areas of the original clinical practice guidelines published by the National Kidney Foundation (NKF) Dialysis Outcomes Quality Initiative (DOQI): anemia management, hemodialysis adequacy, peritoneal dialysis adequacy, and vascular access. The Centers for Medicare & Medicaid Services (CMS) merged the ESRD CPMs with the on-going ESRD Core Indicators Project to form the National ESRD CPM Data Collection Project. The first data for this project were collected in 1999 for the 4th quarter 1998.

In June 2004, CMS contracted with the Renal Network of the Upper Midwest, Inc. (Network 11) to further expand the ESRD CPM project by developing a new set of CPMs for bone disease and mineral metabolism. These CPMs were to be based on the NKF-K/DOQI guidelines for Bone Metabolism and Disease in Chronic Kidney Disease published in 2003. The contract cycle began on July 1, 2004 with the final recommendations and report being due to CMS on June 30, 2005. The contract included four major components.

- Obtain input from the renal community to prioritize the NKF-K/DOQI Bone Metabolism and Disease CPGs.
- Convene a Technical Expert Panel (TEP) to assist in the development of CPMs.
- Coordinate an ESRD Stakeholders Meeting to present the CPMs to the renal community and obtain additional input.
- Recommend Bone Metabolism and Disease CPMs, and recommend a method to pilot the data collection.

I. Prioritize the NKF-K/DOQI Guidelines – Obtaining Input from the Renal Community

A system was developed to rank the guidelines according to the following domains:

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

Only those guidelines that applied to CKD Stage 5 patients on dialysis were included in the tool. The ranking tool was available on-line as well as in paper format. Over 90 individuals completed the input document from September 1, 2004 – October 30, 2004. The responses were reviewed by the Technical Expert Panel at its first meeting. Of the 32 guidelines included in the ranking tool, 22 were considered appropriate for conversion to CPMs.

II. Convene a Technical Expert Panel (TEP)

Network 11 convened a Technical Expert Panel (TEP) to assist with the process of CPM development. The TEP reviewed each of the 22 guidelines based on the same criteria used in the input document (i.e., clinical importance, strength of evidence, feasibility of measurement, and suitability for facility-level measurement). The guidelines were divided into measurement and management guidelines for review purposes. Of the 22 guidelines reviewed by the TEP, six guidelines were recommended for conversion to CPMs.

III. Coordinate a Stakeholders Meeting

On April 14, 2005, CMS convened a meeting of ESRD stakeholders. The recommended CPMs were presented to those in attendance, and feedback was received. As a result of the meeting, additional comments were received for consideration through May 15, 2005. The input received at the meeting and following the meeting was reviewed by the TEP and included in the CPMs as appropriate.

IV. Recommend Bone Disease and Mineral Metabolism CPMs and a Method to Pilot the Measures

The TEP met for a 3rd and final meeting to review the stakeholder input and to finalize recommendations. Stakeholder comments were incorporated, as appropriate, into a set of six CPMs. Network 11 reviewed these CPMs and now submits them to CMS. The final recommended CPMs are as follows.

CPM #1	Measurement of serum phosphorus concentration
CPM #2	Evaluation of serum phosphorus concentration
CPM #3	Measurement of serum calcium concentration
CPM #4	Evaluation of serum calcium concentration
CPM #5	Measurement of parathyroid hormone concentration
CPM #6	Evaluation of parathyroid hormone concentration

The data to be collected for the bone disease and mineral metabolism CPMs will be laboratory data. CMS has collected data for the ESRD CPM Project since 1999 using a data collection tool developed by Qualis Health as part of their original ESRD CPM development project. Network 11 recommends to CMS that the bone disease and mineral metabolism CPMs be incorporated into the current ESRD CPM form. An example of that form has been submitted to CMS and has been reviewed by the CPM QI Committee. Network 11 also recommends that the sampling strategy and all inclusion and exclusion criteria be the same as the current ESRD CPM Project.

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. CMS

decided to pilot test the data collection of these measures during the annual ESRD CPM data collection effort in 2006.

Factors to Consider

Throughout this project, certain issues surfaced that warrant special consideration.

1. The purpose of this special project, as specified in the Statement of Work, was to develop CPMs to be used for quality improvement and public reporting. The ESRD CPM Project, as is currently conducted, measures a 5% national sample. This 5% sample provides an annual snapshot of clinical outcomes. This strategy has proven to be very helpful for measuring trends and identifying regional variations, but it is not amenable for facility-specific reporting. As electronic data collection makes it feasible to collect data on 100% of patients, this will allow Networks to have facility-specific data that will enhance quality improvement projects and public reporting using Dialysis Facility Compare.
2. The CPMs were to be developed using the K/DOQI Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease. Several major clinical developments have occurred since these guidelines were published in 2003. As additional information becomes available, it may be necessary to revise these guidelines sooner than would ordinarily be done.
3. The Statement of Work specified that the CPMs address adult, CKD Stage 5 patients on dialysis. Network 11 recommends that, as more evidence-based research becomes available, the CPMs be expanded to include pediatric patients and transplant patients, as these are two groups at substantial risk for alterations in bone disease and mineral metabolism.

Summary

Renal bone disease plays 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.