

Measure Information Form

General Characteristics

Measure ID:	<i>(Auto-generated, when entered into QMIS by the Measures Manager)</i>
Measure Name:	Measurement of Serum Calcium Concentration
Measure Description:	Percentage of all adult (≥ 18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum calcium measured at least once within month.

CMS contact:

Thomas Dudley, MS, RN

Consumer Care Need

- Living With Illness

Quality Domain

- Effectiveness

Type of Measure

- Outcome
 - clinical outcome
 - quality of life

Body System

Hematologic (other)

Kidney/urinary tract

ESRD

Variable Characteristics

Measure Care Setting

- Dialysis Facility

Unit of Measurement

- Facility

Consensus Endorsement Status

- NQF (National Quality Forum)

Technical Specifications

Target Population

Age**Lower limit**

- 18

Lower Span

-Years

Gender

- Both Males and Females

Continuous Enrollment

NA

Anchor Date

NA

Effective Date

- 4/1/08- Please see Phase III ESRD Clinical Performance Measures (link below):

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRDPhaseIIICPM04012008Final.pdf>

Effective date basis

NA

Payer Source

- Medicare

Measure result reported as

- Positive

Current Alignment with CMS

NA

CHI Compliant

- Yes

Method of Data collection

- Electronic supplemented by medical record review

Numerator statement

Number of adult (≥ 18 years of age) dialysis patients included in denominator with serum calcium measured at least once within month

Data source

- Administrative and medical record data
- Retrospective electronic/paper data collection
- Instrument data collection form

Numerator Time Window

NA

Denominator statement

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

Data source

- Administrative and medical record data
- Retrospective electronic/paper data collection
- Instrument data collection form

Denominator Time Window

NA

Exclusion Criteria

Transient dialysis patients (in unit < 30 days), pediatric patients and kidney transplant recipients with a functioning graft.

Data source

- Administrative and medical record data
- Retrospective electronic/paper data collection
- Instrument data collection form

Exclusion Criteria Time Window

NA

History**Measure Status**

- Implemented/approved by CMS

CMS Active Implementation Date

- 2/1/09

Measure Developer

- CMS
Contractor: Arbor Research/UM-KECC

Intellectual property status

- Public Domain

Measure Source

- New

CMS Final Approval Date

- 4/1/08

CMS Implementation Use

- ESRD Disease Management
- ESRD Network Program
- Other
Quality Improvement and Public Reporting

Attachments

The **Measure Justification** is a required attachment

Depending on the measure contract (development/maintenance/reevaluation) and, if the measure is risk adjusted, some of the listed Measures Management System forms may be required

- Comprehensive Measure Reevaluation

Other attachments

NA

Comments:

Measure Justification

Measure ID	(Auto-generated when entered into QMIS)
Measure Name	Measurement of Serum Calcium Concentration
Completed by Initial & Date	CMS Measures Contractor; October 2, 2008
CMS Active Implementation Date	February 1, 2009
Date of Last Review	November 15, 2007

Section I: Importance/Relevance

Epidemiological relevance, Financial relevance, Policy relevance:

Epidemiological relevance:

In healthy individuals, the kidney occupies an integral, multi-faceted role in the maintenance of calcium-phosphorus homeostasis. It follows that abnormalities of calcium-phosphorus regulation are exceedingly common in patients with advanced chronic kidney disease, which, indeed, most data indicate that only 25-35% of dialysis patients are able to maintain calcium in the suggested target range of 8.4-9.5 mg/dL (KDOQI 2003). Numerous studies have demonstrated the impact of prolonged calcium-phosphorus dysregulation on patient morbidity and mortality (KDOQI 2003), which can lead to progressive bone weakness, bone pain and increased susceptibility to fractures, and severe arteriosclerosis that can precipitate strokes, heart attacks, and other adverse cardiac events. Unfortunately, overt symptoms can often remain unmanifested in many but the most extreme disordered states of calcium-phosphorus regulation, which is why routine blood tests are necessary to detect and monitor abnormal states of calcium and phosphorus balance in this especially vulnerable population.

Financial relevance:

In 2003, total Medicare costs for the ESRD program were \$18.1 billion, an increase of 7.2 percent over costs in 2002.

Policy relevance:

Articles referenced by KDOQI pertaining to the period prior to 2003 indicated that only 25-35% of dialysis patients were able to maintain calcium in the suggested target range of 8.4-9.5 mg/dL (KDOQI 2003). More recently, several studies evaluating the impact of KDOQI guidelines (post-2003) on the attainment of calcium concentrations consistently demonstrated that, while there have been some improvements in the proportion of patients meeting the KDOQI target range, typically fewer than one half of patients are able to be maintained within the recommended range, suggesting ample opportunity for improvement.

To our knowledge, disparity in care (with respect to measurement of serum calcium) is an issue that has neither been systematically explored nor developed. It is unlikely to play a major role since calcium and phosphorus measurements are typically included in the routine blood screening covered by Medicare.

Section 2: Scientific Soundness

Explicit evidence base:

Complete one literature citation for each guideline or study on which the measure is based, stating level of evidence and rating scheme used. A suggested format is below; another format may be used.

Literature citation for clinical guideline

Author Last Name/Organization: National Kidney Foundation (NKF)

Author First Name:

Title of Chapter or Article: NKF-K/DOQI Clinical Practice Guidelines for Bone Metabolism and Disease in Chronic Kidney Disease

Title of Book or Journal: American Journal of Kidney Disease

Publication Date: October 2003

Journal Volume and Number: 42 (Suppl 3)

Pages: S17

Web link: http://www.kidney.org/professionals/kdoqi/guidelines_bone/index.htm

Level of Evidence and Rating Scheme:

Clinical Practice Guidelines

- [Guideline 1.](#) Evaluation of Calcium and Phosphorus Metabolism
- [Guideline 2.](#) Assessment of Bone Disease Associated With CKD
- [Guideline 3.](#) Evaluation of Serum Phosphorus Levels
- [Guideline 4.](#) Restriction of Dietary Phosphorus in Patients With CKD
- [Guideline 5.](#) Use of Phosphate Binders in CKD
- [Guideline 6.](#) Serum Calcium and Calcium-Phosphorus Product

Literature citation for supporting evidence/study

Please see 'Appendix G: Literature citation for supporting evidence/study'

Other aspects of scientific soundness:

Reliability, Validity, and Adequacy of risk adjustment:

Given the ready availability of basic demographic data, this frequency measurement can be characterized by high levels of repeatability, stability, and consistency. Numerator and denominator specifications are stably defined; inclusion/exclusion criteria are consistently defined. The data collected are reliable and valid and therefore reflect actual practice patterns. These data are suitable for use in describing quality of patient care and guaranteeing providers are monitoring an important component of patient care.

Please see below link for the Reliability Report

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRD2006ReliabilityReport.pdf>

Please see the following reports on the validity of the CPM data:

Appendix D - MV Rocco, MD, DL Frankenfield, DrPH, SD Hopson, MSPH, et al. "Relationship between Clinical Performance Measures and Outcomes among Patients Receiving Long-Term Hemodialysis." *Ann Intern Med* 2006;145:512-519.

Appendix E - DL Frankenfield, DrPH, ME Brier, PhD, MR Bedinger, BA, et al. "Comparison of Urea Reduction Ratio and Hematocrit Data Reported in Different Data Systems: Results From the Centers for Medicare & Medicaid Services and The Renal Network Inc." *Am J of Kidney Dis*, Vol 41, No 2 (February), 2003: pp 433-441.

Adequacy of risk adjustment

Risk adjustment is not applicable for this measure.

Section 3: Usability/Actionability

Provides actionable decision support, Message is clear to recipient, Operational relevance

Please see below link for the Annual Report.

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRD2006AnnualReport.pdf>

Section 4: Feasibility

Specifications are well-defined, Reasonable burden of data collection, Minimum distortion

Administrative and Medical Record data is used.

There are no potential barriers to retrieving data necessary for the measure, and there are no data availability issues.

Approximate time for data collection,

FOR ALL MEASURES TOTAL IN THE ESRD DIALYSIS FACILITY MEASURES SET: Approximately 30 minutes for data abstraction, less if the patient's medical record has not been sent to offsite storage. This is the time estimate if all of the data elements are manually abstracted. However, for those facilities that are owned by Large Dialysis Organizations (LDO's), a majority of the data elements are submitted electronically from the LDO's corporate database to CMS. Only a few if any elements are abstracted manually by facility staff, so their time for data abstraction is reduced considerably.

CMS is in the process of implementing a web-based data collection system called **CROWNWeb** for the measures; however, at this time CMS has not assessed the cost and administrative burden of using CROWNWeb by dialysis facilities. CROWNWeb is scheduled to be implemented early 2009.

Comprehensive Reevaluation

<i>Measure ID</i>	(Auto-generated when entered into QMIS)
Measure Set:	Mineral Metabolism
Measure Name (<i>should be brief, concise</i>):	Measurement of Serum Calcium Concentration
Measure Description:	Percentage of all adult (≥ 18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum calcium measured at least once within month.
CMS GTL/PO:	Thomas Dudley, MS, RN

Version Changes

Summarize what has changed in this version?

No major changes in this version.

Date of review (NQF approval date(s))

November 15, 2007

I. Summary of Current Performance Data Analysis on Each Measure—(measure data as submitted to NQF).

Attach charts, graphs, or tables, as directed by CMS, that summarize the performance of the measure since it was initially used by CMS (ideally) or at least since it was last evaluated (either at measure inception or previous comprehensive evaluation).

Please see the 2006 ESRD CPM Annual Report (link below)

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRD2006AnnualReport.pdf>

II. Summary of Analysis of the Comments and Questions Received Going into the TEP and during the NQF comment period:

- A. Importance
- B. Scientific Acceptability
- C. Feasibility
- D. Usability

Please see the 2006 ESRD CPM Annual Report (link below)

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRD2006AnnualReport.pdf>

III. Environmental scan to identify relevant scientific or other information published since the last time the measure was evaluated.

Document all relevant publications found, with a clear indication of:

- A. The type of information
- B. The level of evidence

- C. The relevant Web address (if the article is accessible via the Web)
- D. A brief synopsis of the information and its relevance to the Comprehensive Reevaluation
 - Example #1 (for new guidelines): “ACC HF guidelines now consider ARBs to be equivalent to ACEIs.”
 - Example #2 (for a study on antibiotics): “Study shows increase in inappropriate use of antibiotics in ER patients since measure was implemented.”

Please see attached Measure Justification Form (Section 2: Scientific Soundness) and Appendix G “Literature citation for supporting evidence/study.”

IV. A technical expert panel was convened: Yes No

If yes, date(s) of the meeting(s):

Clinical-TEP: September 18-19, 2006

Data-TEP: October 11-12, 2006

Briefly summarize the TEP recommendations here.

C-TEP recommendations:

Measurement of Serum Calcium Concentration

Quality Statement

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

Numerator:

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

Denominator:

All adult peritoneal dialysis and in-center hemodialysis patients included in the sample for analysis

Exclusion Criteria:

Transient dialysis patients, home hemodialysis patients, pediatric patients and kidney transplant recipients with a functioning graft

Data Elements and Specifics of Data Collection

- First serum calcium laboratory value of the calendar month
- For HD patients, the blood testing should be drawn prior to the patient initiating a dialysis treatment

Discussion Highlights

The TEP recognized the “opinion-based” level of evidence in support of the NKF–KDOQI CPGs for measurement of serum concentration of calcium. Notwithstanding, the TEP drew attention to many studies observing that abnormalities of serum calcium concentration are common in this population and that failure to monitor and correct such abnormalities are strongly associated with morbidity and mortality. In light of the mandate to improve rehabilitation, mortality, and quality of care for ESRD patients in the U.S., the TEP felt strongly that monitoring is a crucial component of efforts supporting these goals for this highly vulnerable population and, consequently, that these factors necessitate an explicit measure that serves to monitor and sustain routine surveillance processes for calcium.

D-TEP recommendations:

Mineral Metabolism

The measure was being pilot-tested at the time of TEP and is detailed below.

Current CPM III: Serum calcium should be measured at least monthly in patients with CKD Stage 5 currently receiving renal replacement therapy with hemodialysis or peritoneal dialysis.

Comments:

The panel agreed that this CPMs for mineral metabolism was straightforward and there was no further discussion on these.

V. If any of the codes used in the technical specifications have changed since the last measure update or comprehensive reevaluation, specify the change(s) with an explanation of its impact on the measure.

NA

VI. If material¹ changes to the measure have occurred — i.e., wording, data elements, time periods, abstraction instructions, etc. — document them here. If material changes were made to the measure, was the measure tested?

Yes No

If yes, indicate the results of the testing.

¹ A **material change** is one that changes the intended meaning of the measure or the strength of the measure in terms of measure evaluation criteria. NQF's process for an ad hoc expedited review will be triggered at any point when the measure developer make material changes to the measure construct (including the numerator, denominator, and exclusions) or measure logic. The timing of the ad hoc review will depend on whether there is an accompanying safety concern. If changes to the measure are deemed appropriate:

- Would a change in the measure result in statistical discontinuity from the current measurement baseline?
- Would a change in the measure significantly impact current processes and the burden for data collection, analysis, and reporting?
- Would the proposed change unintentionally result in the modification of a current clinical or administrative practice?

Measure Contractor Recommended Disposition			
Measure contractor recommended disposition of the measure	<input checked="" type="checkbox"/> Retain		
			Effective Date of Action
	<input type="checkbox"/> Revise (as described above)		2/09, pending CROWNWeb
	<input type="checkbox"/> Replace		
	<input type="checkbox"/> Rotate		
	<input type="checkbox"/> Retire		
Rationale for recommendation			
Effective date basis	<input type="checkbox"/> Discharges	<input type="checkbox"/> Admissions	<input type="checkbox"/> Service Date <input type="checkbox"/> Other:
Recommended by	Name: Date:		

CMS Role	
CMS decision for measure disposition	<input type="checkbox"/> Retain
	Effective Date of Action
	<input type="checkbox"/> Revise
	<input type="checkbox"/> Replace
<input type="checkbox"/> Approved as recommended.	<input type="checkbox"/> Rotate
	<input type="checkbox"/> Retire
Comments about decision	
Approved by	Name: Date: