

Measure Information Form

General Characteristics

| | |
|-----------------------------|--|
| Measure ID: | <i>(Auto-generated, when entered into QMIS by the Measures Manager)</i> |
| Measure Name: | ESRD- HD Adequacy CPM III: Minimum Delivered Hemodialysis Dose for ESRD hemodialysis patients undergoing dialytic treatment for a period of 90 days or greater. |
| Measure Description: | Percentage of all adult (≥ 18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly, and have a residual renal function (if measured in the last three months) less than 2 ml/min/1.73m ² , whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2 during the reporting period. |

CMS contact:

Thomas Dudley, MS, RN

Consumer Care Need

- Living With Illness

Quality Domain

- Effectiveness

Type of Measure

- Outcome

Body System:

Kidney/urinary tract
ESRD

Variable Characteristics

Measure Care Setting

- Ambulatory Care
- Dialysis Facility

Unit of Measurement

- Facility
- Other (*please indicate*):
Stratified by ESRD Network

Consensus Endorsement Status

- NQF (National Quality Forum)

Consensus Endorsement Process Status

- Endorsed
- Endorsed Status Date**
November 15, 2007

Technical Specifications

Target Population

Age

Lower limit

- 18

Lower Span

-Years

Gender

- Both Males and Females

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 patients in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a $spKt/V \geq 1.2$.

Data source (*select all appropriate items and delete the rest; provide instructions and/or codes if needed*)

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

Numerator Time Window

Three month time period. Data collected for this ESRD CPM is for the three month time period (Oct-Dec) for the in-center hemodialysis patients. However, facilities implementing this measure may choose any time period.

Denominator statement

All adult (≥ 18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly and have a residual renal function (if measured in the last three months) less than 2 ml/min/1.73m².

Data source

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

Denominator Time Window

Three months

Exclusion Criteria

Patients on HD less than 90 days.

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

Measure Developer

- CMS
Contractor: Arbor Research/UM-KECC

Intellectual property status

- Public Domain

Measure Source

- New

New Measure, adapted from CPM III Minimum Delivered Hemodialysis Dose for ESRD hemodialysis patients undergoing dialytic treatment for a period of 6 months or greater.

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:

- Risk Adjustment
- Ad Hoc Measure Reevaluation
- Measure Maintenance Reevaluation
- Comprehensive Measure Reevaluation

Other attachments

Comments:

Measure Justification

| | |
|--------------------------------|--|
| Measure ID | (Auto-generated when entered into QMIS) |
| Measure Name | ESRD- HD Adequacy CPM III: Minimum Delivered Hemodialysis Dose for ESRD hemodialysis patients undergoing dialytic treatment for a period of 90 days or greater. |
| 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

At the end of 2003 there were 298,101 patients treated with hemodialysis in the US, which accounts for 92% of all dialysis patients. During that year 93,276 patients started ESRD therapy with hemodialysis (USRDS 2005 ADR).

At the end of 2004 there were 321,539 patients being dialyzed of which 104,056 were new (incident) ESRD patients.

Financial relevance

At the end of 2003, total Medicare costs for the ESRD program were \$18.1 billion, an increase of 7.2 percent over costs in 2002. A portion of this increase is due to a 4% increase in the number of hemodialysis patients in from 2002 to 2003. The majority of this cost is for hemodialysis patients accounting for nearly 63,000 per person per year for Medicare (USRDS 2005 ADR)

At the end of 2004, total Medicare costs for the ESRD program were \$20 billion. This represents approximately 8% of the total Medicare annual budget.

Policy relevance

In 1998, CMS developed ESRD Clinical Performance Measures (CPMs) based on the National Kidney Foundation's Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines, in response to the Balanced Budget Act of 1997. Sixteen CPMs were developed to measure and report the quality of dialysis services provided under Medicare, three of them in the areas of adequacy of hemodialysis and others dealing with peritoneal dialysis, anemia management, and vascular access management. Section 4558 (b) of the Balanced Budget Act (BBA) requires CMS to develop and implement by January 1, 2000, a method to measure and report the quality of renal dialysis services provided under the Medicare program. To implement this legislation, CMS decided to fund the development of CPMs based on the National Kidney Foundation's Dialysis Outcome Quality Initiative (DOQI) Clinical Practice Guidelines. KDOQI Guidelines have been updated for hemodialysis adequacy.

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 Hemodialysis Adequacy: Update 2006.
Title of Book or Journal: American Journal of Kidney Disease
Publication Date: July 2006
Journal Volume and Number: 48 (1 Suppl 1)
Pages: S17
Web link: http://www.kidney.org/Professionals/kdoqi/guideline_upHD_PD_VA/index.htm
Level of Evidence and Rating Scheme: A

Literature citation for supporting evidence/study

Author Last Name/Organization: Eknoyan G
Author First Name:
Title of Chapter or Article: :Effect of dialysis dose and membrane flux in maintenance hemodialysis-sis
Title of Book or Journal: New England Journal of Medicine
Publication Date: 2002
Journal Volume and Number:347
Pages: :2010-2019
Web link: www.nejm.org
Level of Evidence and Rating Scheme: A

Author Last Name/Organization: Greene T
Author First Name:
Title of Chapter or Article: Association of achieved dialysis dose with mortality in the Hemodialysis Study: An example of dose-targeting bias
Title of Book or Journal: Journal of the American Society of Nephrology
Publication Date: 2005
Journal Volume and Number: 16
Pages: 3371-3380
Web link: www.jasn.org
Level of Evidence and Rating Scheme: B

Author Last Name/Organization: Rocco MV
Author First Name:
Title of Chapter or Article: The effect of dialysis dose and membrane flux on nutritional parameters in Hemodialysis patients: Results of the HEMO Study
Title of Book or Journal: Kidney International
Publication Date: 2004

Journal Volume and Number: 65
Pages: 2321-2334
Web link: <http://www.nature.com/ki/index.html>
Level of Evidence and Rating Scheme: A

Author Last Name/Organization: Unruh M
Author First Name:
Title of Chapter or Article: Effects of Hemodialysis dose and membrane flux on health-related quality of life in the HEMO Study.
Title of Book or Journal: Kidney International
Publication Date: 2004
Journal Volume and Number: 66
Pages: 355-366
Web link: <http://www.nature.com/ki/index.html>
Level of Evidence and Rating Scheme: A

Other aspects of scientific soundness:

Reliability, Validity, and Adequacy of risk adjustment:

Please see below link for the Reliability Report

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

Appendix B

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

Appendix D - *“Relationship Between CPM’s and Outcomes Among Patients Receiving Long-Term Hemodialysis*

Appendix E – *“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.*

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>

Appendix C

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: | Hemodialysis Adequacy |
| Measure Name: | Minimum delivered hemodialysis dose for ESRD hemodialysis patients undergoing dialytic treatment for a period of 90 days or greater |
| Measure Description: | Percentage of all adult (≥ 18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly, and have a residual renal function (if measured in the last three months) less than 2 ml/min/1.73m ² , whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V ≥ 1.2 during the reporting period. |
| CMS GTL/PO: | Thomas Dudley, MS, RN |

Version Changes

Summarize what has changed in this version?

CROWN Web will begin to collect information on the residual renal function for patients starting in February 2009. This version of the measure will incorporate only patients with insufficient residual renal function (less than 2 ml/min/1.73m²) in the adequacy measure.

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).

This is a new measure which has not be used before. Therefore, current performance data are not available.

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

The workgroup recommended and the committee agreed that home Hemodialysis patients should be included in measures of dialysis adequacy; that six months was too long of an exclusion period; and that for combined outcome/process measures, the outcome component must be scored and reported and plan of care further specified. The workgroup recommended and the committee agreed that a plan for inadequate hemodialysis should address at least the dialysis prescription, vascular access, and justification of a lower Kt/V based on residual renal function. The committee also discussed that if a measure contained a process component for a plan of care for patients who do not achieve the outcome value, exclusions were not needed. Measures were recommended only on the condition that the measures were revised to address these issues.

In the case of the CMS facility outcome measure, CMS agreed with changing the exclusion period to <90 days, but noted that patients with residual renal function >2 should be excluded. The six-month exclusion period was used as a proxy to exclude patients with residual renal function. CMS thought that was necessary because the distribution of patients on dialysis for 90 days to 6 months varied widely across facilities. The current data collection system does not capture residual renal function. CMS submitted a revised measure and also requested that the current measure be approved until residual renal function could be collected in the CROWN system beginning in 2009. The Steering Committee agreed to recommend both the current and revised facility outcome measures, as well as the two process measures for monthly adequacy assessments.

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."

List of Publications is as follows:

1. Fernandez EA, Valtuille R, Presedo JM, Willshaw P., Comparison of different methods for hemodialysis evaluation by means of ROC curves: from artificial intelligence to current methods. *Clinical Nephrology*. 2005 Sep; 64(3):205-13.
2. Stuart L. Goldstein, Andrew Brem, Bradley A. Warady, Barbara Fivush, Diane Frankenfield, Comparison of single-pool and equilibrated Kt/V values for pediatric hemodialysis prescription management: analysis from the Centers for Medicare & Medicaid Services Clinical Performance Measures Project, *Pediatric Nephrology* (2006) 21: 1161–1166
3. Tanja Hojs-Fabjan and Radovan Hojs, Polyneuropathy in hemodialysis patients: The most sensitive electrophysiological parameters and dialysis adequacy *Wien Klin Wochenschr* (2006) 118 [Suppl 2]: 29–34
4. Korohoda P, Pietrzyk JA, Miklaszewska M, Komorowska M, Rumian R, Drozd D, Krawentek L, Zachwieja K., Does daily hemodialysis influence urea kinetic modeling (UKM) coefficients?--Preliminary report], *Przegl Lek*. 2006; 63 Suppl 3:194-7.
5. John K. Leypoldt, Bertrand L. Jaber and Deborah L. Zimmerman, Predicting Treatment Dose for Novel Therapies Using Urea Standard Kt/V, *Seminars in Dialysis-Vol 17, No 2 (March–April) 2004 pp. 142–145*

6. Sridhar Nagaraja Rao, Hurst, Carolyn, Hayes, Patrick, Tandem Dialyzers With Two Monitors to Meet Target KT/V, Dialysis & Kinetics ASAIO Journal 2005
7. Robert A. Wolfe, Tempie E. Hulbert-Shearon, Valarie B. Ashby, Sangeetha Mahadevan, and Friedrich K. Port, Improvements in Dialysis Patient Mortality Are Associated With Improvements in Urea Reduction Ratio and Hematocrit, 1999 to 2002, American Journal of Kidney Diseases, Vol 45, No 1 (January), 2005: pp 127–135

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Level of Evidence and Rating Scheme: A

Literature citation for supporting evidence/study

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Author First Name:
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Title of Book or Journal: New England Journal of Medicine
Publication Date: 2002

Journal Volume and Number:347
Pages: :2010-2019
Web link: www.nejm.org
Level of Evidence and Rating Scheme: A

Author Last Name/Organization: Greene T
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Web link: www.jasn.org
Level of Evidence and Rating Scheme: B

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Author First Name:
Title of Chapter or Article: The effect of dialysis dose and membrane flux on nutritional parameters in Hemodialysis patients: Results of the HEMO Study
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Publication Date: 2004
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Web link: <http://www.nature.com/ki/index.html>
Level of Evidence and Rating Scheme: A

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Title of Book or Journal: Kidney International
Publication Date: 2004
Journal Volume and Number: 66
Pages: 355-366
Web link: <http://www.nature.com/ki/index.html>
Level of Evidence and Rating Scheme: A

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.

<http://www.cms.hhs.gov/CPMProject/Downloads/ESRDTEPFinalReport05212008.pdf>

C-TEP recommendations

Current CPM III

Minimum Delivered HD Dose

The patient's (for those patients on hemodialysis six months or longer and dialyzing three times per week) delivered dose calculated from data points on the data collection form (monthly measurement averaged over the three-month period) of hemodialysis is $spKt/V \geq 1.2$ using the Daugirdas formula.

Numerator:

Number of patients in denominator whose average delivered dose of HD (calculated from data points on the data collection form) was a $spKt/V \geq 1.2$ during the study period

Denominator:

All adult (>18 years old) HD patients in the sample for analysis who have been on HD for six months or more and dialyzing three times per week

Proposed Revised CPM III:

The patient's (for those patients on hemodialysis *31 days or longer* and dialyzing three times per week) delivered dose calculated from data points on the data collection form (monthly measurement averaged over the three-month period) of hemodialysis is $\text{spKt/V} \geq 1.2$ using UKM or the Daugirdas II formula

Numerator:

Number of patients in denominator whose average delivered dose of HD (calculated from data points on the data collection form using the UKM or Daugirdas II formula) was a $\text{spKt/V} \geq 1.2$ during the study period

Denominator:

All HD patients in the sample for analysis who have been on HD for 31 days or more and dialyzing three times per week

Exclusions:

Patients on HD less than 31 days

Recommended Revisions to the Current CPMs

CPM III: Minimum Delivered HD Dose

- The minimum delivered dose of dialysis should be calculated for all patients in the sample, and not limited to only adult patients
- This measure should include patients on hemodialysis *31 days or longer*
- The frequency of dialysis per week should be recorded for all patients
- The minimum delivered dose should only be calculated using either the UKM or Daugirdas II formula

D-TEP recommendations

CPM III: Minimum delivered hemodialysis dose.

Current CPM III: For those patients on hemodialysis six months or longer and dialyzing three times per week, delivered dose calculated from data points on the data collection form (monthly measurement averaged over the three-month period) of hemodialysis is $\text{spKt/V} \geq 1.2$ using the Daugirdas formula.

Proposed CPM III Revision: For those patients on hemodialysis *31 days or longer* and dialyzing three times per week, delivered dose calculated from data points on the data collection form (monthly measurement averaged over the three-month period) of hemodialysis is $\text{spKt/V} \geq 1.2$ using UKM or the Daugirdas II formula.

Comments:

Currently, the measure is calculated from the first lab value of the month, averaged over a three-month period. If one month's value is outside the range, then the average of the remaining two months is utilized. There was some concern about facilities possibly "cherry picking" their lab values and what facilities should do if the last lab draw presents invalid data.

For this measure, the D-TEP consensus was that the last lab test of the calendar month should be utilized rather than the first lab test of the calendar month.

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 type="checkbox"/> Retain | | |
| | | | Effective Date of Action |
| | <input type="checkbox"/> Revise (as described above) | | 2/09, pending CROWNWeb |
| | <input checked="" type="checkbox"/> Replace | | |
| | <input type="checkbox"/> Rotate | | |
| | <input type="checkbox"/> Retire | | |
| Rationale for recommendation | CROWN Web will begin to collect information on the residual renal function for patients starting in February 2009. This version of the measure will incorporate only patients with insufficient residual renal function (less than 2 ml/min/1.73m ²) in the adequacy measure. | | |
| 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: |